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Merck to Pay More than \$650 Million to Resolve Claims of Fraudulent Price Reporting and Kickbacks

WASHINGTON -- Merck & Company has agreed to pay more than \$650 million to resolve allegations that the pharmaceutical manufacturer failed to pay proper rebates to Medicaid and other government health care programs and paid illegal remuneration to health care providers to induce them to prescribe the company's products, the Justice Department announced today. The allegations were brought in two separate lawsuits filed by whistleblowers under the qui tam, or whistleblower, provisions of the False Claims Act.

"Not only is the combined recovery in these two cases one of the largest healthcare fraud settlements ever achieved by the Justice Department," said Attorney General Michael B. Mukasey, "it reflects our continuing effort to hold drug companies accountable for devising pricing schemes that deliberately seek to deny federal health care programs the same lower prices for drugs that are available to other commercial customers."

H. Dean Steinke, a former Merck employee, alleged in his suit filed in Philadelphia that Merck violated the Medicaid Rebate Statute in connection with its marketing of its drugs Zocor and Vioxx. (Zocor is a cholesterol lowering drug and Vioxx, pulled from the market by Merck in September of 2004, was used for the treatment of acute pain and in the treatment of arthritis.) Merck allegedly offered deep discounts for the two drugs if hospitals used large quantities of those drugs in place of competitors' brands.

The Medicaid Rebate Statute requires that drug manufacturers report their "best prices" and other cost information to the government in order to ensure that Medicaid obtains the benefit of the same discounts and price concessions that other purchasers enjoy. An exception to this rule allows manufacturers to exclude from the prices they report any discounted prices that are "nominal" in amount. Merck improperly termed as "nominal" the prices it offered to hospitals to boost their sales and excluded those discounts from the prices it reported to the government.

Steinke's suit further alleged that from 1997-2001, Merck had approximately fifteen different programs used by its sales representatives to induce physicians to use its many products. These programs primarily consisted of excess payments to physicians that were disguised as fees paid to them for "training," "consultation" or "market research." In fact, the government alleged that these fees were illegal kickbacks intended to induce the purchase of Merck products. Merck agreed today to pay \$399 million plus interest to settle the Medicaid Rebate as well as the kickback allegations.

In a separate suit filed by physician William St. John LaCorte in New Orleans, it's alleged that Merck had established a marketing scheme in which it provided substantially reduced prices for its Pepcid products once the hospitals agreed to primarily use the drug instead of a competitor's. (Pepcid is used to reduce stomach acid and to treat heartburn and acid reflux.) Merck allegedly offered these incentives to hospitals in order to obtain the benefit of spillover business when patients would continue to purchase Pepcid once he or she was discharged. Merck improperly termed as "nominal" the prices it offered to hospitals to boost the sales of Pepcid, excluded those discounts from the prices it reported to the government, and thus effectively denied the government the benefit of these lower prices. Merck agreed today to pay \$250 million plus interest to settle these allegations.

Under the two settlement agreements, the federal government will receive more than \$360 million, and forty-nine states and the District of Columbia over \$290 million. In addition, Mr. Steinke will receive \$44,690,000 from the federal share of the settlement amount and an additional \$23.5 million from the states. Similarly, Dr. LaCorte will receive a share of the proceeds from the federal and state settlement amounts under their respective qui tam statutes.

"Our health insurance programs rely upon the integrity of health providers, including pharmaceutical manufacturers, when they report to the government programs which reimburse their products and services with scarce funds," said Patrick L. Meehan, U.S. Attorney for the Eastern District of Pennsylvania, whose office led the investigation of the Steinke matter.

"Particularly in the wake of Hurricane Katrina, it is critical that precious government resources not be lost to fraud and

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abuse," said Jim Letten, the U.S. Attorney for the Eastern District of Louisiana, whose office led the investigation of the LaCorte matter. "This office is dedicated to prosecuting pricing fraud so that healthcare dollars go to help the most vulnerable of our citizens – the disabled and the poor."

"The Office of Inspector General has a strong record of pursuing violations in the Medicaid drug rebate program and is working closely with Federal and State law enforcement to hold accountable pharmaceutical companies engaged in illegal practices resulting in Medicaid fraud," said Daniel R. Levinson, Inspector General of the Department of Health and Human Services.

Today's settlement was the result of close cooperation between the Justice Department, state attorneys general and other law enforcement entities including Medicaid Fraud Control Units, and the Office of Inspector General of the Department of Health and Human Services.

As part of the resolution of these two cases, the Department of Health and Human Services Office of Inspector General (HHS-OIG) and Merck have entered into a five-year Corporate Integrity Agreement to ensure that such improper conduct does not occur in the future.

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