GOVERNMENT OF THE DISTRICT OF COLUMBIA
Office of the Inspector General

Inspector General

February 7, 2008

District of Columbia Settlement with Merck & Co., Inc.

Inspector General Charles J. Willoughby announced that the District of Columbia will receive $ 1,096,291 as part of two separate global settlements totaling $649 million with Merck & Co., Inc. The settlements involve 49 states, the District of Columbia and the federal government. Merck is the manufacturer of the drugs Zocor, Vioxx, and Pepcid. The agreements with Merck resolve allegations that the company failed to pay rebates due state Medicaid Programs under the Federal Medicaid Drug Rebate Act. The settlements also resolve claims filed by whistleblowers in the United States District Court for the Eastern District of Pennsylvania *United States ex rel. H. Dean Steinke v. Merck & Co., Inc.*, (U.S. Dist. Ct. No. 00-6158 [E.D. PA]), in the United States District Court of Nevada *State of Nevada ex rel. H. Dean Steinke v. Merck & Co., Inc.*, (U.S. Dist. Ct. No. CV-N-05-322 [D. Nev.]), and in the Eastern District of Louisiana *United States ex rel. William St. John LaCorte, M.D. v. Merck & Co., Inc.*, (U.S. Dist. Ct. No. 99-3807 [E.D. LA]).

Pharmaceutical manufacturers that supply products to Medicaid recipients are required by the federal Medicaid drug rebate law to give the Medicaid programs the benefit of the "best price" available for those products. The manufacturers are required to file "best price" information with the Centers for Medicare and Medicaid Services (CMS). This information is then used to calculate rebates to be paid by these manufacturers to the state Medicaid programs. In general, the lower the "best price", the higher the rebate obligation. The federal law requires the "best price" reported by the manufacturers to include discounts. However, prices that are considered "merely nominal" are exempted from the reporting requirement. The states have maintained that "merely nominal" means the discounted price is not tied to any conditions, such as volume purchase requirements or market shares.

The cases that were pending in Pennsylvania and Nevada involve the SAVE and VIP programs, which were two Merck discount programs wherein Merck tried to use the nominal price exceptions. The SAVE program (Simvastatin Acute-care Value Enhancement program), was for the marketing of the drug Zocor, and the VIP program (Vioxx Incentive Program) was for the drug Vioxx. At the heart of each program was an agreement that Merck would sell the drugs to hospitals at a 92% discount from the catalog price, but only if the hospitals reached certain market shares for the drugs. Because the 92% discounts were conditioned on the hospitals' volume purchases to reach certain market shares, the states contend that the resulting

discounted prices were not "merely nominal". Therefore, the states contend that Merck was required to report these discounted prices to CMS, and that their failure to do so resulted in less rebates paid to the state Medicaid programs.

The case in Louisiana involved Merck's drug, Pepcid, and another discount program, FLEX NP. Under this program, Merck sold various formulations of Pepcid to hospitals in bundled pricing arrangements. In exchange for the hospital meeting a certain market share or other purchase requirements, Merck gave hospitals an array of discounts of up to 92% on Pepcid tablets, and lesser discounts on other types and formulations of Pepcid. According to the government, the transactions under the FLEX NP Program constituted "bundled sales", which required Merck to adjust "best price" among the different formulations to reflect these discounts. The states contend that Merck failed to reflect these discounts in their "best price" reports, resulting in less rebates paid to the state Medicaid programs.

In addition to the monetary recovery, Merck has entered into a Corporate Integrity Agreement with the United States Department of Health and Human Services' Inspector General. The Corporate Integrity Agreement will include provisions to ensure that Merck will market, sell, and promote its products in accordance with all Federal health care program requirements. Merck did, however, begin voluntary compliance initiatives associated with their sales and marketing activities prior to learning of the government's investigation of the conduct associated with these settlements.

"This is a significant recovery not only for our Medicaid program but also for program recipients," Inspector General Willoughby said.

The National Association of Medicaid Fraud Control Units conducted the settlement negotiations on behalf of the states, with representatives of the Nevada, Illinois, Delaware and Massachusetts Medicaid Fraud Control Units leading the effort. Mr. Willoughby thanked DC Medicaid Fraud Control Unit Attorney Stuart Silverman and Auditor Clark Geiger for their fine work on these investigations.

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