ILLINOIS ATTORNEY GENERAL LISA MADIGAN



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ATTORNEY GENERAL MADIGAN: MERCK SETTLEMENT NETS \$18.5 MILLION FOR ILLINOIS MEDICAID PROGRAM

Chicago - Illinois Attorney General Lisa Madigan today announced that the State of Illinois will receive \$18.5 million as part of two separate global settlements totaling \$649 million with Merck & Co., Inc., and involving 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 to state Medicaid programs under the Federal Medicaid Drug Rebate statute. The settlements also resolve claims filed by whistleblowers in the United States District Court for the Eastern District of Pennsylvania in *United States ex rel. H. Dean Steinke v. Merck & Co., Inc.*, No. 00-6158 (E.D. PA), in the United States District Court for the District of Nevada in *State of Nevada ex rel. H. Dean Steinke v. Merck & Co., Inc.*, No. CV-N-05-322 (D. Nev.), and in the Eastern District of Louisiana in *United States ex rel. William St. John LaCorte, M.D. v. Merck & Co.*, Inc., No. 99-3807 (E.D. LA).

Attorney General Madigan's Medicaid Fraud Bureau, working with representatives for the attorneys general of Nevada, Delaware and Massachusetts, led the negotiations, on behalf of the National Association of Medicaid Fraud Control Units, which represented all the states and the District of Columbia.

"We have consistently taken action to demonstrate that we will not tolerate pharmaceutical companies' efforts to avoid following the law and paying rebates," said Attorney General Madigan. "When drug companies do this, they prevent our Medicaid programs from receiving needed resources and, ultimately, harm the patients who benefit from these programs."

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. Under the law, the manufacturers are required to file "best price" information with the federal Centers for Medicare and Medicaid Services (CMS). This information is then used to calculate rebates to be paid by manufacturers to the state Medicaid programs. In general, as the "best price" gets lower, the rebate obligation increases.

Federal law requires that the "best price" reported by the manufacturers include any discounts that they offer. However, prices that are considered "merely nominal" are exempted from the reporting requirement. The states

have maintained that "merely nominal" means that the discounted price is not tied to any conditions, such as volume purchase requirements or market shares.

The question of what "merely nominal" means, and how those prices impact the rebates owed to the states, specifically came up when Merck tried to use the nominal price exceptions in two company discount programs. The SAVE program (Simvastatin Acute-care Value Enhancement program), involved the marketing of the drug Zocor, and the VIP program (Vioxx Incentive Program) involved Vioxx marketing. At the heart of each program was an agreement that Merck would sell the drugs to hospitals at a 92 percent discount from the catalog price, but only if the hospitals reached certain market shares for the drugs. Because the 92 percent 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.

In another discount program, known as Flex NP, and involving the marketing of Merck's drug Pepcid, 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 percent on Pepcid tablets, and lesser discounts on other types and formulations of Pepcid. The governments argued that 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 which requires that Merck will market, sell and promote its products in accordance with all federal health care program requirements.

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