Schering To Admit Paying Kickback In Exchange For Preferred Treatment – Will Also Settle False Claims Liability

Pennsylvania Attorney General's Office, Oct 06, 2004

July 30, 2004 - PHILADELPHIA – Patrick L. Meehan, United States Attorney for the Eastern District of Pennsylvania and Jerry Pappert, Pennsylvania Attorney General, announced today that Schering Sales Corporation, a subsidiary of drug manufacturer Schering-Plough Corporation, has agreed to plead guilty to criminal charges and to pay a fine of $52.5 million. Schering-Plough Corporation has agreed to pay more than $290 million to resolve its civil liabilities in connection with its illegal and fraudulent pricing of its blockbuster drug, Claritin.

The global resolution includes the following components: (1) Schering Sales Corp., Schering-Plough Corporation's sales and marketing subsidiary, has agreed to plead guilty and pay a $52.5 million fine for violating the Anti-Kickback Act when it paid a kickback to a customer in exchange for preferred treatment for Claritin; (2) Schering-Plough Corporation has agreed to settle its False Claims Act liability and to pay the United States, the 50 state Medicaid programs, and the Public Health Entities $292,969,482 for losses suffered as a result of Schering's overcharges for Claritin by failing to report its true best price for the drug; (3) Schering-Plough Corporation will enter into a Corporate Integrity Agreement with the Department of Health and Human Services to correct its government pricing and Medicaid rebate reporting failures.

"Schering used terms like 'data fee' and 'value added' as camouflage for what was nothing more than an old-fashioned kickback," said Meehan. "This wasn't a mistake. It was a marketing strategy. The result was that programs created to provide healthcare to the poorest among us were actually paying more for drugs than those who have private health insurance. There is a point at which pursuit of market share crosses the line that separates competition and illegal conduct. This case serves as an example that the consequences of stepping over that line can be costly."

The Criminal Charges

The Information filed today charges that Schering Sales offered and paid a health maintenance organization ("HMO") a kickback of $1.8 million to induce the HMO to keep Claritin on its formulary (a list of drugs that the HMO covers for its beneficiaries).

As charged in the Information, in the late 1990s, Claritin, a prescription drug used to treat allergies, was Schering Sales' best-selling drug. It was substantially more expensive than its closest competitor, Allegra. When one of Schering Sales' best customers demanded a price reduction in Claritin because it cost the HMO millions of additional dollars a year to purchase Claritin rather than Allegra, Schering Sales refused to lower the price in part because it knew that by doing so it would have to lower the Claritin price for the Medicaid programs. Following the HMO's decision to take Claritin off its formulary (in essence, the death knell for Claritin sales to that customer), Schering Sales offered to make up the difference between the price of Claritin and Allegra by offering the HMO a $10 million package of added value, in lieu of an actual price reduction on Claritin.

As part of this "value added" package to induce the HMO to keep Claritin on its formulary, Schering Sales offered to pay an annual fee of 2% of the annual gross sales of Schering drugs to the HMO, approximately $2.4 million. Disguising the true nature of this fee, Schering Sales called it a "data fee" to give the appearance that the fee was a fair market value transaction rather than a hidden inducement to the HMO to keep Claritin on its formulary. The "data fee" was purportedly for an annual report, which was nothing more than a resubmission of quarterly reports the HMO had previously provided. Although Schering Sales never used the report, which contained the exact same information as the quarterly reports, Schering paid the HMO more than $1.8 million for this duplicate data.

The Civil Claims

Under the provisions of the Medicaid Rebate Statute, Schering was required to provide drugs to Medicaid at the best price that it charged its commercial customers. Similarly under the provisions of the Public Health Service drug pricing program, Schering was required to charge the PHS entities such as Aids drug programs and community health centers a discounted price, based in part on the Medicaid price.

Schering marketed a broad range of drugs including the Claritin family of antihistamines and used a broad range of strategies to gain access to managed care customers' formularies. However, when two of its biggest managed care customers threatened to remove Claritin from their formularies due to its high price, Schering offered various incentives to, in essence, indirectly lower the price of Claritin to those customers without providing Medicaid and PHS with the same lower price. Schering failed to include these additional payments, services, and discounts in the Claritin best price it reported to the Medicaid program and the PHS entities.

Schering provided managed care customer Cigna: (a) a data fee which is the subject of the criminal charge described above; (b) three million dollars' worth of deeply discounted Claritin redeaths; (c) health management services at far below fair market value; and (d) an interest free loan in the form of prepaid rebates.

For managed care customer PacifiCare, Schering provided (a) a risk share arrangement in which Schering covered a portion of the managed care customer's respiratory drug costs; (b) deep discounts on other Schering products; (c) payment and services for Internet development; and (d) an interest free loan in the form of prepaid rebates.
As a consequence of the unlawful price reporting activity, the Medicaid program and PHS entities paid far more for Claritin from 1998-2002 than these two managed care customers. To resolve these allegations, Schering-Plough has agreed to pay a total of $292,969,482 for losses to the Medicaid program and PHS entities.

"The state Attorneys General have joined the federal authorities in making these cases a priority in an effort to combat the high cost of prescription drugs for our citizens," said Attorney General Pappert, who represented the nation's Attorneys General and their Medicaid Fraud Control Units. "We will not allow drug companies to defraud our Medicaid programs and our taxpayers. This case should send a strong message that we will continue to monitor their activities and ensure they follow the law."

In addition, Schering-Plough has agreed to enter into a corporate integrity agreement with the Department of Health and Human Services that addresses Schering's sales, marketing and pricing of its drugs to government programs. This integrity agreement includes five years of independent audits to ensure Schering's compliance with all federally funded health care programs. As a result of its criminal plea, Schering Sales Corporation will be excluded from participation in all federal health care programs for at least five years.

"Drug companies should take notice that they need to be vigilant in verifying the prices they report for drugs," said Mark B. McClellan, M.D., Ph.D., Administrator for the Centers for Medicare and Medicaid Services. "We will be watching closely to assure the accuracy of the information reported on drug prices and to assure that all business practices are in compliance with federal rules and regulations."

"The Medicaid drug rebate program is a key control on expenditures for Medicaid-reimbursed drugs. As this settlement demonstrates, the government continues to scrutinize pharmaceutical manufacturers' compliance with program requirements," said Dara Corrigan, Acting Principal Deputy Inspector General. "We are also examining the relationships and transactions between pharmaceutical manufacturers and managed care organizations. Through the CIA, the OIG will monitor both of these aspects of Schering's operations on a going-forward basis."

This investigation began when Charles Alcorn, Beatrice Manning, and Raymond Pironti, Jr., ("the relators") three former employees of ITG, Inc. a subsidiary of Schering Plough, filed a suit on behalf of the United States government under the private whistleblower provision of the False Claims Act. As part of the civil resolution, the relators will receive $31,662,173.

Assistant United States Attorneys Marilyn May and Michael L. Levy handled the criminal case. Trisha Doyle of the U.S. Attorney's Office, Special Agent Patrick Coar, Department of Health and Human Services, and Postal Inspector Gregory Wauck, Postal Inspection Service, performed the investigation.

Assistant United States Attorneys Marilyn May and Margaret L. Hutchinson handled the civil case with the assistance of Andy Mao of the U. S Attorney's Office and Nicole Freda, Department of Health and Human Services performed the audit work.

The National Association of Medicaid Fraud Control Units represented the states. The Association's committee members include John Guthrie of the Ohio Attorney General's Office, Chris Abruzzo of the Pennsylvania Attorney General's Office, Ellyn Sternfield of the Oregon Attorney General's Office, and Pat Keenan of the Illinois Attorney General's Office. Senior Counsel Mary Riordan in the office of Counsel to the Inspector General for the Department of Health and Human Services negotiated the corporate integrity agreement. "Other filings today reveal that the HMO is Cigna."

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