



U.S. Department of Justice

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PRESS RELEASE

**SCHERING TO PAY \$435 MILLION FOR
THE IMPROPER MARKETING OF DRUGS AND
MEDICAID FRAUD**

Boston, MA... Delaware corporation **SCHERING-PLOUGH CORPORATION**, together with its subsidiary, **SCHERING SALES CORPORATION** have agreed to pay a total of \$435,000,000 to resolve criminal charges and civil liabilities in connection with illegal sales and marketing programs for its drugs Temodar for use in the treatment of brain tumors and metastases, and Intron A for use in treatment of superficial bladder cancer and hepatitis C. The resolution also pertains to Medicaid fraud involving Schering's drugs Claritin RediTabs, a non-sedating antihistamine, and K-Dur, used in treating stomach conditions.

United States Attorney for the District of Massachusetts Michael J. Sullivan, Department of Health and Human Services Regional Inspector General Joseph Moraski, United States Food and Drug Administration Special Agent in Charge Mark Dragonetti, Department of Defense Criminal Investigative Service Special Agent in Charge Edward Bradley, and Department of Veteran's Affairs Special Agent in Charge Jeffrey Hughes announced today that **SCHERING SALES CORPORATION** will pay a \$180,000,000 criminal fine and, together with **SCHERING-PLOUGH CORPORATION**, another \$255,000,000 to settle civil liabilities. Today's global resolution ensures that the federal Medicaid program and each of the State Medicaid agencies which paid for prescriptions of Claritin RediTabs and K-Dur will obtain the benefit of the best price offered by Schering to commercial purchasers of those drugs, and will ensure that Schering pays appropriate damages for improperly promoting its drugs for uses not approved by the FDA and from offering or paying kickbacks to physicians to prescribe those drugs.

"The Justice Department is committed to rooting out and prosecuting health care fraud," said Deputy Attorney General Paul J. McNulty. "It is vital to public health and safety that pharmaceutical companies are deterred from improperly marketing their drugs to doctors and patients to treat illnesses that these drugs are not approved to treat. This settlement sends a clear message to the pharmaceutical industry that the Justice Department will not tolerate these deceptive and illegal marketing practices."

“The American people, as both taxpayers and consumers, expect our health care system to be free from fraud and corruption,” stated U.S. Attorney Michael J. Sullivan. “The pharmaceutical industry has an obligation to ensure that all rules, regulations and laws are complied with. To do less erodes public confidence, compromises the patient physician relationship and adds costs to important government programs. We will not tolerate attempts to profit at the expense of the ill and needy in our society.”

To resolve the criminal charges, **SCHERING SALES CORPORATION** has agreed to plead guilty to a one count criminal conspiracy to make false statements to both the Food and Drug Administration regarding its improper drug promotional activity and to the Health Care Financing Administration regarding its best price for certain drugs, and to pay a \$180,000,000 criminal fine. As a result of its criminal conviction, **SCHERING SALES** will be excluded permanently from participation in all federal health care programs.

SCHERING PLOUGH CORPORATION also agreed to settle its civil False Claims Act liabilities and liabilities under the Food Drug and Cosmetic Act for a total of \$255,025,000. Specifically, **SCHERING** will pay \$159,502,000, plus interest, to the United States in civil damages for losses suffered by the Medicare program, the federal portion of the Medicaid program, the Veteran’s Administration, the Department of Defense and the Federal Employees Health Benefits program as a result of **SCHERING**’s improper drug promotion and marketing misconduct, and Medicaid rebate fraud. **SCHERING** will also pay a total of \$91,602,000, plus interest, to settle its civil liabilities to the fifty states and the District of Columbia for losses the state Medicaid programs suffered. In addition, **SCHERING** will refund \$3,921,090 to the Public Health Service (PHS) programs that also were entitled to a lower price on certain drugs.

The first object of the conspiracy to which **SCHERING SALES** will plead guilty charges that it conspired with others to give free Claritin Redi-Tabs to a major health maintenance organization to disguise a new lower price being offered to the HMO to obtain its business. Drug manufacturers are required to report their best price on drugs provided to certain commercial customers, including HMOs, to the Health Care Financing Administration (“HCFA”), and to pay quarterly rebates to the Medicaid program, the nation’s taxpayer funded health insurance program for the poor and disabled, to be sure the Medicaid program obtains the benefit of that low price. From April 1998 through 1999, **SCHERING SALES** reported a false best price to HCFA, which failed to include the new low price of Claritin Redi-Tabs provided to the HMO, to avoid paying millions of dollars in additional rebates to the Medicaid program.

“Investigation of prescription drug fraud is a priority of the Office of Inspector General (OIG) and resolution of this case stems from OIG’s strong relationship with our law-enforcement partners,” said Daniel R. Levinson, Inspector General of the U.S. Department of Health and Human Services. “In addition to enforcement, OIG strongly supports implementation of compliance measures by pharmaceutical companies that are designed to address all risk areas of their business - whether they be pricing, marketing or promotional practices. The expanded Corporate Integrity Agreement with Schering-Plough incorporates additional ways for OIG and the Company to monitor these issues and minimize the risk of off-label promotion.”

"The Centers for Medicare & Medicaid Services is committed to protect the Medicare program for beneficiaries and taxpayers, and with the implementation of the prescription drug benefit, it is even more important for the Government to fully investigate health care fraud relating to prescription drugs," said CMS Administrator Mark B. McClellan, M.D., Ph.D. "At the same time, drug manufacturers have a duty to implement strong compliance measures that will address all risk areas of their business including pricing, marketing or promotions. "

The second object of the conspiracy to which **SCHERING SALES** will plead guilty charges that it conspired with others to make false statements to the FDA in response to the FDA's inquiry regarding certain illegal promotional activities by the Company's sales representatives at a national medical conference for oncologists. Those false statements were designed to reassure the FDA that the promotional activities were isolated and not directed by home office, when in fact, the activities were widespread and part of the national marketing plan. In addition, the Company sought to falsely lull the FDA into believing that it had taken appropriate steps to reinforce the message with its sales representatives that such promotional activities were prohibited, when in fact, the Company knew and expected that those activities would continue.

"The FDA takes seriously its responsibilities to protect consumers from products that are promoted for unapproved uses," says Margaret Glavin, the FDA's Associate Commissioner for regulatory affairs. "Pharmaceutical manufacturers who mislead FDA place consumers at risk."

The civil settlement resolves allegations that **SCHERING-PLOUGH CORPORATION** and **SCHERING SALES** knowingly caused the submission of false and/or fraudulent claims for **SCHERING'S** drugs that were not eligible for reimbursement. These included the government's claims that (1) **SCHERING** misreported its best price to HCFA on Claritin ReidTabs to evade Medicaid rebate liability, (2) **SCHERING** misreported its best price on private-labeled K-Dur to HCFA to evade Medicaid rebate liability, (3) **SCHERING** overcharged the PHS entities because of its misreporting of best price to HCFA, (4) **SCHERING** induced physicians to start patients on Intron A for Hepatitis C by paying them remuneration through three marketing programs, (5) **SCHERING** induced physicians to use Temodar for certain patients with brain tumors and brain metastases and to use Intron A for certain patients with superficial bladder cancer through improper preceptorships, sham advisory boards, lavish entertainment, and improper placement of clinical trials; and (6) **SCHERING** knowingly promoted off label uses of Temodar for certain brain tumors and brain metastases and Intron A for superficial bladder cancer despite not having FDA approval.

SCHERING-PLOUGH CORPORATION will be subject to an amendment to its existing Corporate Integrity Agreement. That amendment requires Schering to continue extensive work that the Company has undertaken in the last two years to monitor and correct the shortcomings in Schering's drug sales, marketing and pricing activities. After the activities were uncovered by the government, **SCHERING-PLOUGH** cooperated with the investigation and actively worked on compliance issues through a significantly expanded compliance department.

The investigation was conducted by the Food and Drug Administration's Regional Office of Criminal Investigations in both Boston and Miami; the Department of Health and Human Services' Office of Inspector General, Office of Investigations; the Defense Criminal Investigative Service of the Department of Defense; and the United States Office of Veteran's Affairs' Office of the Inspector General.

Assistance in the investigation was also provided by Patrick Lupinetti, Director of the New York State Attorney General's Special Projects and Medicaid Fraud Control Unit and David Waterbury, Director of the Washington State Attorney's General's Medicaid Fraud Control Unit, who coordinated the National Medicaid Fraud Units. The criminal investigation and resolution were handled by Assistant U.S. Attorneys Susan Winkler, Chief of Sullivan's Health Care Fraud Unit, and Jeremy Sternberg. The civil investigation and settlement were handled by Assistant U.S. Attorneys Susan Winkler, Jennifer Boal, Chief of Sullivan's Civil Division, Gregg Shapiro, and Department of Justice Trial Attorney Andy Mao of the Fraud Section of the Civil Division. The Amendment to the Corporate Integrity Agreement was negotiated by Senior Counsel Mary Riordan in the Office of General Counsel in the Department of Health and Human Services, Office of Inspector General.

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