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SERONO TO PAY $704 MILLION FOR THE ILLEGAL MARKETING OF AIDS DRUG

WASHINGTON, D.C. - Swiss corporation, Serono, S.A., together with its U.S. subsidiaries and related entities, has agreed to pay $704 million to resolve criminal charges and civil allegations in connection with illegal schemes to promote, market and sell its drug, Serostim, the Justice Department announced today. Serostim is used to treat AIDS wasting, a condition involving profound involuntary weight loss in AIDS patients. Under the settlement, Serono Laboratories has agreed to pay a $136.9 million criminal fine and its affiliate companies a total of $567 million to settle civil liabilities. Today's global resolution, the third largest health care fraud recovery by the U.S., also ensures that the Medicaid program and each of the state Medicaid agencies which paid for Serostim during the time frame of the investigation, 1996 through 2004, will recoup all monies paid based on Serono's illegal activity.

"Americans who need medical care depend on health care companies to have their medical devices and drugs thoroughly evaluated and approved before use," said Attorney General Alberto R. Gonzales. "Serono abused the system of testing and approval, and put its desire to sell more drugs above the interest of patients. Today's settlement will repay with interest the losses to federal and state Medicaid programs incurred by Serono's conduct, and would-be wrongdoers are on notice that we will not tolerate attempts to profit at the expense of the ill and needy in our society." Serono Labs has agreed to plead guilty to charges that the company conspired with medical device manufacturer RJL Sciences to market bioelectrial impedance analysis (BIA) computer software packages for use in calculating body cell mass and diagnosing AIDS wasting. The device has not been approved by the Food and Drug Administration for these uses. Serono Labs conspired with RJL to increase the market for the devices/software in order to increase the market for Serostim. Serono Labs employees also directly administered BIA tests to patients to induce doctors to prescribe Serostim and to get Medicaid agencies and other payers to reimburse for the drug. RJL and its president, Rudolph J. Liedtke, pleaded guilty to their roles in the conspiracy in April of this year and are awaiting sentencing. Additionally, Serono Labs agreed to plead guilty to offering physicians an all expense-paid trip to a medical conference in Cannes, France in return for the doctors writing up to 30 new prescriptions of Serotism, which cost $21,000 per course of treatment, for a total value of $630,000 per doctor. As a result of its criminal conviction, Serono Labs will be excluded from all federal health care programs for at least five years. Serono's U.S. subsidiary, Serono Holding and all U.S. affiliates will also be subject to a stringent Corporate Integrity Agreement for the next five years. "This plea agreement and settlement reflect an exemplary coordinated use all of the appropriate anti-fraud weapons available to us," said Assistant Attorney General Peter Keisler of the Department's Civil Division. "This settlement sends the unequivocal message to the health care industry that American taxpayers should not pay for prescriptions induced by unproven medical tests and improper payments to doctors and pharmacies." Under the federal civil settlement, Serono will pay $305 million plus interest to the U.S. for losses suffered by the federal portion of the Medicaid program, the Veteran's Administration, the Department of Defense and the Federal Employees Health Benefits program. Under separate civil settlement agreements with the states, the company will also pay nearly $262 million plus interest to state Medicaid programs. The civil settlement resolves allegations that Serono knowingly submitted false and fraudulent claims for Serostim that were not eligible for reimbursement because they were for the unnecessary and/or off label use of Serostim and because the claims were for prescriptions induced by kickbacks. The FDA granted accelerated approval for Serostim in 1996 solely for use in treating AIDS wasting, which at the time was one of the leading causes of death among AIDS patients. Serostim came on the market at the same time as protease inhibitor drugs, which when used in combination with one another as an “AIDS cocktail,” dramatically curtail the progress of the AIDS syndrome. As a result, the incidence and prevalence of AIDS wasting began to markedly decline and the demand for Serostim dropped significantly immediately following its launch. Serono Labs then began engaging in a marketing and sales campaign to redefine AIDS wasting and create a market for Serostim. “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 of the District of Massachusetts. “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. Without the assistance of concerned citizens illegal conduct on government programs would go undetected.” The investigation leading to today’s global resolution was initiated in 2000 in Massachusetts after a former Serono Labs employee filed a False Claims Act suit. Four other employees filed similar suits in Maryland and Connecticut. As a result of the settlement, the private individuals who filed the whistleblower suits will share in approximately $51.8 million. Under the whistleblower provisions of the False Claims Act, private parties can file an action on behalf of the United States and receive a portion of the proceeds of a settlement or judgment awarded against a defendant. The investigation was conducted by the Federal Bureau of Investigation; the Food and Drug Administration’s Office of Criminal Investigations; the Department of Health and Human Services’ Office of Inspector General, Office of Investigations; the Department of Labor’s Employee Benefits Security Administration, Boston Regional Office; and the U.S. Postal Service’s Office of Inspector General. Assistance in the investigation was also provided by the New York State Attorney General’s Special Projects and Medicaid Fraud Control Unit; the Medicaid Fraud Control Unit in Florida’s Attorney General’s Office; the Medicaid Fraud Section of the New Jersey Attorney General’s Office; and the California Department of Justice. The Corporate Integrity Agreement was negotiated by the Office of Inspector General at the Department of Health and Human Services.

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