

GOVERNMENT OF THE DISTRICT OF COLUMBIA
Office of the Inspector General



Inspector General

SERONO, S.A.

The National Association of Medicaid Fraud Control Units (“NAMFCU”) and District of Columbia Office of the Inspector General announced on December 15, 2005 that the Medicaid programs of 42 states and the District of Columbia recovered and distributed almost \$262 million dollars as a result of a settlement with Serono, S.A., a Swiss Corporation. Serono S.A. is the manufacturer of Serostim, a drug approved to treat HIV wasting, an AIDS-related syndrome. The company operates in the United States through its affiliates Serono Inc. and Serono Laboratories, Inc., both of which have their principal place of business in Rockland, Massachusetts. According to Inspector General Charles J. Willoughby, the settlement is the result of investigation conducted by the Medicaid Fraud Control Unit, one of four divisions of his office. The Director of the D.C. Medicaid Fraud Control Unit, Susan Bieber Kennedy, reported that Attorney Stuart Silverman and Auditor Clark Geiger worked on the investigation and data collection and analysis.

As part of the settlement, the District of Columbia’s Medicaid program will receive a total of \$ 2,003,507.76 to address Serono’s conduct in marketing Serostim. State Medicaid programs paid claims for the drug between 1997 and 2004 that were not eligible for reimbursement because they were generated by the use of unapproved testing devices, were for unapproved uses or were induced by kickbacks.

Serono, S.A. together with its U.S. subsidiaries and related entities agreed to pay a total of \$704 million dollars to resolve criminal charges and civil liabilities in connection with these illegal schemes to promote, market and sell Serostim. The sum consists of a \$136.9 million criminal fine and \$567 million, including the \$262 million state recovery, for total federal/state Medicaid damages.

Serono Laboratories agree to plead guilty to the following:

- Promoting Serostim for uses not approved by the FDA, including lipodystrophy and body cell mass wasting.
- Using unapproved software in connection with tests to determine patients’ need for Serostim. The states alleged the software was intended to result in greater utilization of the drug.
- Paying illegal kickbacks to pharmacists and physicians in an effort to increase sales of Serostim. The kickbacks included payments and travel expenses, including trips to Cannes, France.

As a result of its criminal conviction, Serono Laboratories will be excluded from all federal health care programs for at least five years. Serostim will remain eligible for reimbursement by state Medicaid programs.

Serostim is approved by the FDA to treat AIDS wasting syndrome, which is marked by the involuntary loss of significant body weight and chronic weakness; and other forms of cachexia, the wasting away of body fat and muscle because of disease. The drug is quite expensive, with a Medicaid reimbursement price of approximately \$6,000 per month. The suggest course of treatment is three months, but many patients have used Serostim much longer.

This global federal and state settlement is a result of federal False Claims Act qui tam actions filed in 2000 in Massachusetts, Connecticut, and Maryland by former Serono employees.

The civil settlements with Serono will also subject all its U.S. affiliates to a Corporate Integrity Agreement with the Office of Inspector General, U.S. Department of Health and Human Services to ensure future compliance with the law. Serono was also required to provide cooperation to the states in any related investigations they undertake.

NAMFCU, representing the Medicaid Fraud Control Units in 48 states and the District of Columbia worked closely with numerous federal agencies, including the United States Department of Justice, the U.S. Attorney's office in Boston, and the Office of Inspector General of the United States Department of Health and Human Services to reach this global settlement.

NAMFCU negotiating team members are the Directors of the Maryland and Missouri MFCUs, and Assistant Attorneys General from the Florida, Massachusetts, and New York MFCUs.

For further information, please contact Barbara L. Zelner, Counsel, NAMFCU (202) 326-6020 or Susan Kennedy, District of Columbia Medicaid Fraud Control Unit, (202) 727-8008.

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