

SERONO, S.A.
PRESS RELEASE

The National Association of Medicaid Fraud Control Units (NAMFCU) 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 that manufactures Serostim, a drug that is used to treat an AIDS-related syndrome. Serono Inc. and Serono Laboratories are U.S. affiliates of Serono, S.A. Both have their principal place of business in Rockland, Massachusetts.

State Medicaid programs reimbursed more than they should have when Serono knowingly submitted false and fraudulent claims for Serostim, between 1997 to 2004, 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.

Serono, S.A. together with its U.S. subsidiaries and related entities agreed to pay \$704 million dollars to resolve criminal charges and civil liabilities in connection with illegal schemes to promote market, and sell Serostim.

Serono Laboratories agreed to pay a \$136.9 million criminal fine and its affiliate companies will pay a total of \$567 million for civil liabilities.

Serono Labs agreed to plead guilty to the following:

- Promoting Serostim for uses not approved by the FDA, including for lipodystrophy and body cell mass wasting.
- Using unapproved software as part of tests to determine if patients were appropriate candidates to use Serostim. The states alleged the software resulted in more patients being prescribed the drug than what was appropriate.
- Engaging in illegal kickbacks to pharmacists and physicians in an effort to increase prescriptions. The kickbacks included payments and trips, including trips to Cannes, France.

As a result of its criminal conviction, Serono will be excluded from all federal healthcare programs for at least five years.

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, a wasting away of body fat and muscle caused by disease. Serostim prescriptions are quite expensive, with a Medicaid reimbursement price of approximately \$6,000 per month. The suggested course of treatment is three months, but many recipients use Serostim for much longer.

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This global federal and state settlement is a result of a federal False Claims Act (FCA) qui tam action filed in Massachusetts in 2000 by a former Serono Labs employee.

The civil settlements with Serono Labs and its U.S. subsidiary, Serono Holding and all of its U.S. affiliates will be subject 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 also will 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, 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, Missouri MFCUs, and Assistant Attorneys General from the Florida, Massachusetts and New York MFCUs.

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