

## Serono agrees to pay \$704 million to settle fraud allegations

AP Associated Press

By Mark Sherman, Associated Press Writer | October 17, 2005

WASHINGTON --The Swiss manufacturer of the AIDS treatment drug Serostim agreed Monday to pay \$704 million and plead guilty to scheming to boost sagging sales by, among other things, offering kickbacks to doctors to write prescriptions.

As part of the plea, Serono Laboratories will be barred from participating in federal health programs for five years and will pay a criminal fine of \$136.9 million and civil penalties of \$567 million.

The amount is the third largest payment for health care fraud, Attorney General Alberto Gonzales said in announcing the plea agreement. "Serono put its desire to sell more Serostim above the interests of patients and the public," Gonzales said at a news conference at the Justice Department.

Thomas G. Gunning, Serono's vice president and general counsel in the United States, said, "This settlement concludes a four-year government investigation into commercial practices related to Serostim, and we are pleased to put the matter behind us. The activities described in the settlement were confined to one unit in our U.S. operations and cover a brief period in our history." The company's U.S. headquarters is in Rockland, Mass., a half hour south of Boston.

Serostim, which contains the human growth hormone Somatropin, was approved by the Food and Drug Administration in 1996 to treat AIDS wasting, an often-fatal condition involving severe weight loss.

At about the time the FDA approved the drug, protease inhibitor drugs came on the market. Those drugs, when used in combinations or "cocktails," sharply curtailed the AIDS virus in patients, making them less prone to AIDS wasting.

Serono offered doctors free trips to the south of France in return for agreeing to write up to 30 new prescriptions for Serostim, which cost \$21,000 for a 12-week treatment regimen, said Michael Sullivan, the U.S. Attorney in Boston.

The company also conspired to introduce a new test for AIDS wasting, despite not having FDA approval. The test diagnosed AIDS wasting even in the absence of weight loss, Sullivan said.

He estimated that 85 percent of Serostim prescriptions were unnecessary.

Five former Serono executives also have been indicted, he said.

Geneva-based Serono has eight biotechnology products on the market in the fields of reproductive health, neurology, dermatology and treatment of HIV-associated wasting and growth deficiencies.

The company earned \$494 million on sales of \$2.46 billion in 2004. Shares of its stock fell 1.2 percent to 833 Swiss francs (\$649) in trading Monday on the Zurich exchange.

The federal investigation grew out of whistleblower lawsuits filed by U.S. employees of Serono. Four people will split \$51 million as their share of the settlement, which is allowed under the federal False Claims Act, Sullivan said.

Monday's settlement is the latest in a series of whistleblower claims that have resulted in more than \$3 billion in payments from drug companies in recent years.

Last month, GlaxoSmithKline PLC said it will pay \$150 million to settle claims it overcharged the government for two anti-nausea drugs

Federal and state officials are looking into 150 price and marketing fraud cases involving more than 500 drugs, according to Peter Keisler, assistant attorney general in charge of the Justice Department's Civil Division.

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On the Net:

Taxpayers Against Fraud: <http://www.taf.org>

Serono Laboratories: <http://www.serono-usa.com/> ■