

## **\$704m penalty for drug maker Improper efforts to build demand**

By Ross Kerber and Charlie Savage, Globe Staff | October 18, 2005

Swiss drugmaker [Serono SA](#) has agreed to pay \$704 million to settle criminal and civil charges that it illegally promoted its AIDS drug, prosecutors said yesterday, in one of the biggest sums collected in the government's growing scrutiny of pharmaceutical firms.

The company's Serono Labs unit of Rockland agreed to plead guilty to charges it conspired to market Serostim by supplying doctors diagnostic software that was not fully approved by the Food and Drug Administration. The software, prosecutors said, led to an increase in demand for the drug prescribed to treat wasting in AIDS patients.

The company also agreed to plead guilty to offering doctors all-expense-paid trips to a medical conference in Cannes, France, in return for writing prescriptions of Serostim, an arrangement that US Attorney General Alberto R. Gonzales blasted as "The 'Cannes Kickback' campaign."

In all, prosecutors said, nearly 85 percent of the prescriptions written for Serono's growth hormone Serostim weren't necessary. Some excess demand came from bodybuilders who, like AIDS patients, wanted to gain weight and bulk up.

Serono violated federal laws that prohibit companies from making false claims about their products and from offering bribes to win government business such as drugs sales whose costs are covered by the federal Medicare program.

Last spring Serono publicly released the outline of the deal it had reached with state and federal prosecutors. The company has already taken a \$725 million charge to cover the costs. It said its larger business of selling treatments for infertility and multiple sclerosis wouldn't be affected because they are sold by other divisions.

"We are pleased to put the matter behind us," said Thomas G. Gunning, the company's general counsel. "The activities described in the settlement were confined to one unit in our US operations and cover a very brief period in our history."

Like many other cases against drug companies, the charges stem from complaints first brought to the government's attention by company employees. Under federal antifraud rules that provide incentives for employees to report company violations, five former employees, including one in Massachusetts and one in Connecticut, and a clinic operator will split \$75 million from the settlement.

Serono will pay a \$136.9 million criminal fine and \$567 million to settle civil liabilities, of which \$305 million will go to federal agencies that were billed for unnecessary prescriptions, and about \$262 million to state Medicare programs. Prosecutors said the terms were equal to the amount of revenue and profit the company made from Serostim since it came onto the market in 1996.

Some conservative and business groups have been critical of the large payments to individuals allowed under whistleblower cases. Yet the Justice Department, which like the FDA has been under pressure to rein in questionable drug marketing practices, trumpeted the agreement.

"The pharmaceutical industry will not be allowed to benefit from the criminal misconduct such as that in which Serono engaged, putting patients' best interests second to profit," said Michael J. Sullivan, US attorney for Massachusetts, at a press conference in Washington yesterday morning.

*... Garcia's attorney, **Robert Thomas of Boston**, described him as pleased with the settlement. "He filed this case at great personal risk to himself and his career, and is enormously gratified to see that his actions have helped make the industry's practices better."*

*He expects to receive more than \$10 million in the settlement. Thomas said.*

Attorneys general from other states were also involved in the investigation, including Thomas F. Reilly of Massachusetts, who recovered \$1.1 million for the state's Medicare program.

The settlement could have been much worse for Serono, whose shares fell just 2 percent in trading in New York yesterday. The agreement bars the Serono Labs unit in Rockland from doing business with all federal healthcare programs for five years. But other Serono units that sell drugs like Rebif for MS won't be affected, and Gunning said control of Serostim itself has been transferred to Serono Inc., a different unit also of Rockland. Supplies of the drug will not be affected; the company noted that the FDA re-affirmed the efficacy of the treatment in 2003.

Explaining why prosecutors didn't seek to restrict more of the company's sales, Mary Beth Carmody, assistant US attorney who helped handle the case, said "public health was one of the key concerns here."

The company also did not acknowledge several broader contentions by the government, such as the idea the company marketed Serostim for a condition for which it wasn't approved, lipodystrophy, often characterized by weight loss in the limbs.

Federal prosecutors spelled out some details of the case against Serono last spring when they filed criminal charges against four individual executives they held responsible as well. All four have denied wrongdoing. Still, the documents filed as part of yesterday's plea agreement provide the greatest detail yet about the investigation that has dogged Serono for years. Serostim was first approved to help AIDS patients fight the life-endangering weight loss that characterized the disease. But late in the decade the rise of cocktails of protease inhibitors made Serostim less important in AIDS treatment.

According to the government, Serono began in 1997 to "redefine AIDS wasting" in a way that would boost Serostim sales. One method was to train its sales representatives to tell doctors that "body cell mass" was a key metabolic measurement.

Serono then worked with another company, RJL Sciences Inc., which made machines commonly used to measure body fat and body mass, to help diagnose patients in need of the drug. But the software for the machines never got certain FDA approvals, a violation of federal medical device rules. In April, RJL and its president, Rudolph J. Liedtke, pled guilty to conspiracy charges and are awaiting sentencing.

The second set of charges relates to trips in 1999 to a French medical conference that Serono offered doctors in return for prescribing set amounts of Serostim. Court filings don't identify any Massachusetts doctors who received the trips. Prosecutors wouldn't elaborate beyond the filings.

Some of these sales practices raised red flags internally, and court filings yesterday named five former employees who first alerted the government about the wrongdoing. They include former sales representatives Christine Driscoll of Massachusetts and Frank Garcia, 41, of Connecticut, and three people from Maryland including Kimberly Jackson, a former Serono regional director.

The AIDS Healthcare Foundation, a California-based health clinic operator, also filed a complaint with the government and will receive a share of the payout through the former employees.

Garcia's attorney, Robert Thomas of Boston, described him as pleased with the settlement. "He filed this case at great personal risk to himself and his career, and is enormously gratified to see that his actions have helped make the industry's practices better."

He expects to receive more than \$10 million in the settlement, Thomas said.

Ross Kerber can be reached at [kerber@globe.com](mailto:kerber@globe.com); Charlie Savage at [csavage@globe.com](mailto:csavage@globe.com). ■