

Pharmacies that sold AIDS drug by Serono may face US inquiry Policies of stores could have violated pricing regulations

By Ross Kerber, Globe Staff | October 19, 2005

Pharmacies that sold [Serono SA's](#) drug to treat AIDS may be next on prosecutors' target list, court filings suggest.

The pharmacies' practices are questioned in private lawsuits filed against Serono, Europe's largest biotechnology company, that led to a \$704 million legal settlement that prosecutors disclosed on Monday.

One of the private suits contends Serono provided Serostim to some unnamed parties, apparently pharmacies, at discounts of up to about 4 percent. The company then let these parties pocket the difference from the regular sales price, which could violate federal drug pricing rules.

The Justice Department would say only that it is continuing to investigate the marketing of Serostim. Assistant US Attorney Mary Beth Carmody added that "the allegations against Serono are resolved by the global settlement," meaning the company wouldn't face further action.

On Monday prosecutors said a company unit, Serono Labs of Rockland, has agreed to plead guilty to two criminal charges related to the illegal promotion of Serostim and pledged to abide by oversight of its operations. The deal won't affect its ability to supply the drug, the firm said, and it didn't acknowledge other contentions by the government, such as that it tried to market Serostim for unapproved uses or made improper arrangements with pharmacies.

Serostim is a growth hormone to treat the life-endangering weight loss that can accompany AIDS. Demand for the drug fell off shortly after it was approved in 1996 as the success of drug cocktails of protease inhibitors made Serostim less important in treatments. Prosecutors said that Serono offered doctors kickbacks and used unapproved diagnostic methods to boost demand, perhaps making as much as 85 percent of prescriptions unnecessary.

Prosecutors are involved in the case to protect the interests of federal and state programs, like Medicaid, that pay for drugs. The government's charges resulted from complaints from former Serono workers who filed lawsuits alleging wrongdoing by their employer. Three of those suits were unsealed as a result of Monday's action.

The papers show other allegations against Serono, especially in its interaction with unnamed pharmacies, that could lead to actions against those parties even though the suits were to be dismissed as part of the settlement. When assistant US Attorney General Peter Keisler introduced the settlement Monday, he said the case should serve as a warning to the healthcare industry "that American taxpayers should not pay for prescriptions induced by unproven medical tests and improper payments to doctors and pharmacies."

For instance, a lawsuit filed against Serono in January 2004 by the AIDS Healthcare Foundation, a California clinic operator, lists inappropriate sales practices it said Serono used to boost Serostim sales. One practice was to pay pharmacists up to \$300 each month per prescription in return for providing demographic information about patients and prescribing doctors.

Another complaint filed by two former Serono workers -- Christine Driscoll of Marshfield and Frank Garcia of Greenwich, Conn. -- names as defendants both Serono and parties whose names were blacked out before the document was unsealed. The black marks often indicate prosecutors' interest.

Their filing points heavily at some of Serono's sales partners, who they seem to be accusing of wrongdoing, though some specifics of their complaint were also blacked out. At one point Driscoll and Garcia write that Serono gave a 3.75 percent discount on Serostim to a party who still billed the government at full price. The discount was part of a system in which Serono was "providing preferential pricing to a select group of pharmacies," the complaint states.

Federal rules require medical firms to offer products to the government at the best possible price, and the discounts suggest that wasn't happening, said Patrick Burns, spokesman for Taxpayers Against Fraud, a Washington advocacy group. The legal filing, he said, suggests "the specialist pharmacies may have their own false-claims problems to deal with."

The suits don't name pharmacies involved. A spokesman for one of the country's largest pharmacies, [CVS Corp.](#) said the company has not been contacted by the Justice Department regarding sales of Serostim. A spokesman for another large pharmacy chain, Walgreens, did not return a message seeking comment.

A third filing in Maryland by three former Serono employees states that Serono often increased the dosage that patients were prescribed when orders were submitted to Serono's Massachusetts offices, increasing billing in turn. Another scam, they wrote, came in South Florida where company-approved pharmacies paid patients \$300 to be prescribed Serostim, money then paid by Medicaid.

These violations weren't mentioned by prosecutors previously in papers filed in connection with their settlement with Serono. One reason may be that their investigation failed to establish the truth of the claims. Alternatively, they may have occurred too long ago to bring legal actions.

A Serono spokeswoman referred to a statement by the company's general counsel Monday that the settlement concludes the investigation.

Ross Kerber can be reached at kerber@globe.com. ■