Wasting Money: Serostim Users See Payback

April 5, 2007 By James Wortman

You may remember the cautionary tale of pharma excess in which hundreds, maybe thousands, of HIV positive Americans took the wasting drug Serostim to beef up their bodies—even though they didn't have FDA-defined wasting in the first place. Well, now it's payback time. Two years after the federal government fined Serostim-maker EMD Serono $704 million for marketing the drug to doctors too aggressively, the drug takers and insurance companies that paid for the injectable treatments are about to recoup some of their money. In a settlement expected to be finalized this summer, patients and so-called third-party payers will divide up a second payout of $24 million.

Victory is sweet for Serono's critics. "Serono had a 'hot' drug, priced it through the roof and then pushed it on people who didn't need it to make even more money," says AIDS activist Mark Milano. "I have little sympathy for Serono." Adds attorney Audrey Browne of District Council 37, the New York City public employee union that, along with the Prescription Action Litigation Project, filed the class action lawsuit behind the civil settlement. "We're happy to play a small part in getting a little piece of justice here. We have to stand up and fight these kinds of practices whenever we see them."

As the story goes, Serono gave doctors perks such as lavish trips to Europe—and had a remarkable impact on their prescribing habits: Eighty-five percent of patients taking Serostim between July 1, 1995, and December 31, 2006, were on it for reasons not OKed by the FDA (their wasting was measured by a muscle-fat ratio instead of the official standard: a 10% or greater loss of a person's ideal body weight). Serostim is an engineered version of human growth hormone, which promotes cell growth. A 12-week supply costs $21,000.

In 2005, the company pled guilty on federal criminal charges of unlawfully marketing Serostim. In addition to paying the $704 million fine, the company (which was recently bought by the German company Merck KgaA—no relation to the U.S.-based Merck—to form EMD Serono), adopted a "Corporate Integrity Agreement" that subjects it to government monitoring and internal audits.

Since then, Serono claims to have cleaned up its act (and is currently petitioning the FDA for approval of Serostim as a treatment for HIV adipose redistribution syndrome or HARS, a new umbrella term for the body fat changes caused by some HIV meds). "EMD Serono remains committed to meeting the needs of HIV patients with Serostim for HIV-related wasting," the company commented in February when the civil settlement won preliminary approval by the U.S.

District Court in Boston.

Browne says it's hard to gauge the impact the Serono case will have on the pervasive practice of kickbacks and other off-label doctor influencing that continues to plague the drug industry as a whole. FDA restrictions now limit pharma-doctor influence, but some of the rules and regulations are open to interpretation.

"Only time will tell," says Browne. "We're watching [the industry] and when we uncover evidence of wrongdoing, we're going to sue." Attorney David Maher, who worked on the Serono class action case on behalf of the law firm Harke & Clasby, says, "It's hard to be overly optimistic [about changing the way some pharmaceutical companies do business] due to the overwhelming amount of these cases that we come across."

Any analysis about the lessons of this case is further clouded by the fact that patients were in many cases complicit in Serostim's over-prescription because some were looking for drugs to help them bulk up and sought out doctors willing to prescribe them.

What about the Serono case's impact on the often fragile trust between drug makers and HIV positive drug takers? Taking Serostim when it wasn't necessary doesn't seem to have resulted in any medical harm to patients, but did it harm public confidence in the industry?

"I think it will have a bigger effect on doctors [than on pharma]," says Martin Delaney of Project Inform. "It will end the practice of sleazy doctors doing this kind of stuff." That said, he advises, "Every patient with HIV should be on guard, and take responsibility for educating themselves and learning the most that they can. I would hope that patients don't casually assume that their doctors have the best information or will instinctively act in the patient's best interest."

In June, objections and patient concerns raised by the Serono civil settlement will be aired before the court. Anyone wishing to file a claim or learn more about this litigation can visit www.serostimsettlement.com for details.

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