Serono’s long-awaited $704 million settlement with the U.S. has broad implications for pharma

The U.S. Justice Department last week announced the long-awaited $704 billion settlement with the Swiss-based Serono and its U.S. subsidiaries. Serono agreed to pay massive penalties to resolve criminal charges and civil allegations in connection with illegal schemes to promote, market, and sell the human growth hormone, Serostim. Under the settlement, Serono Labs agreed to pay a $136.9 million criminal fine and its affiliate companies will pay a total of $567 million to settle civil liabilities. The civil settlement is the largest pharmaceutical settlement in the history of the False Claims Act, and the third largest overall.

The underlying investigations were related to the company’s marketing practices of Serostim, says qui tam attorney Robert Thomas, Jr. of Boston, MA, who represented Frank Garcia, one of the whistleblowers and a former sales representative of Serono. The charges included marketing adulterated medical devices, “off label” promotion of Serostim, and kickbacks to physicians and pharmacies. ▶ Cont. on page 2

Rx Compliance Report announces Pharma Web Conference: Lessons of Serono’s $704 million settlement for Illegal Off-Label Promotion, Kickbacks, and Other Violations

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Rx Compliance Report has assembled an expert panel to examine the impact of the Serono investigation and settlement from the perspective of DOJ, the OIG, the qui tam bar, and private counsel. Topics include:

- The “off label” promotion of Serostim and kickbacks to physicians and pharmacies
- Examination of the OIG’s corporate integrity agreement
- The implications of the Serono settlement for pharma

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To register, contact Jim Miller at 800/292-0450 (ext. 1270) or jim_miller@medconference.net
The path to a record civil settlement from the view of the government’s top lawyer

On October 17, 2005, Attorney General Alberto Gonzales announced the government’s landmark resolution with Serono at the Department of Justice in Washington, DC. Gonzales was joined at the podium by U.S. Attorney Michael Sullivan of the District of Massachusetts. Also on hand were Assistant U.S. Attorney Michael Loucks, who supervised the case, and Mary Elizabeth Carmody, the lead prosecutor.

Here is a firsthand rundown of the investigation and settlement as viewed by Gonzales and Sullivan:

“We have all seen the horror of the AIDS virus and those living with this terrible syndrome,” said Gonzales. Serostim, he noted, was approved by the FDA in 1996 as a treatment for AIDS wasting, a condition that causes extreme weight loss, which was then one of the leading causes of death in AIDS patients. However, at the time that Serostim was approved as a treatment wasting, breakthroughs in pharmaceutical research, including the introduction of what are commonly known as AIDS cocktails, dramatically reduced the progress of the AIDS syndrome and the occurrence of AIDS wasting, he added. As a result, said Gonzales, the incidence and prevalence of AIDS wasting began to markedly decline and the demand for Serostim dropped significantly immediately following its launch.

“This dramatically reduced the market for Serostim,” said Gonzales. “When this happened, Serono put its desire to sell more Serostim above the interests of patients and the public,” he asserted. In short, he said, Serono abused the system of testing and approval.

According to DOJ, Serono Labs then began engaging in a marketing and sales campaign to redefine AIDS wasting and create a market for Serostim. “When the demand for the drug Serostim began to wane, Serono put a fraudulent marketing and promotion campaign into high gear,” said Gonzales. The company introduced unapproved computer software that helped increase the diagnosis of the AIDS wasting condition, he said, and thus artificially increased the market for Serostim.

Serono also offered financial incentives to doctors, said Gonzales, such as all-expense-paid trips to Cannes, France, in return for their prescribing a certain amount of the expensive drug. Such incentives are not only obviously illegal, he said, they are also dangerous because they interfere with how doctors exercise their medical judgments in deciding on the best treatments and care for their patients.

Serono Labs agreed to plead guilty to offering physicians all expense-paid trips to a medical conference in Cannes, France, as an inducement for the doctors’ writing up to 30 new prescriptions of Serostim. At $21,000 per course of treatment, these prescriptions represent a total value of $630,000 per doctor, said DOJ.

According to Gonzales, Serono profited more than $90 million from the illegal activity charged in the criminal information. “The Cannes kickback campaign alone [resulted in] more than $6 million in sales in just six days,” he said.

The settlement

Serono Labs agreed to plead guilty to two counts of criminal conspiracy to resolve civil liability in connection with several illegal schemes. Serono will pay more than $704 million in fines and damages. Serono agreed to the terms of a sweeping corporate integrity agreement (CIA).

Note: The HHS OIG released the CIA yesterday.

The record resolution will repay, with interest, the losses incurred by federal and state Medicaid programs as a result of Serono’s illegal conduct, he added. Because AIDS patients are disproportionately insured by state Medicaid agencies, said Gonzales, these programs issued reimbursements for hundreds of millions of dollars of ineligible and fraudulently obtained Serostim prescriptions. Under the resolution, he said, state Medicaid agencies across the country will recover what they paid as a result of Serono’s marketing illegal activity.

In short, the resolution recovers all losses suffered by federal and state health insurance
programs, said Sullivan. “This global approach to addressing health care fraud, particularly within the pharmaceutical industry, is an area in which the Department of Justice and HHS have been particularly active,” he said.

Under the federal civil settlement, Serono will pay $305 million plus interest to the U.S. for losses suffered by the federal portion of the Medicaid program, the Veteran’s Administration, the Department of Defense, and the Federal Employees Health Benefits program. Under separate civil settlement agreements with the states, the company will also pay nearly $262 million plus interest to state Medicaid programs. The civil settlement resolves allegations that Serono knowingly submitted false and fraudulent claims for Serostim 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.

“The vast rules, he noted. prohibited by the HIPAA patient confidentiality data” used in determining whether their drug should be prescribed. Today, such activities are expressly prohibited by the HIPAA patient confidentiality rules, he noted.

Sullivan said these actions amounted to a campaign to redefine AIDS wasting. “The vast majority – approximately 85 percent of the prescriptions written for Serostin – were unnecessary,” he said.

However, Serostin is a life-saving drug for the small number of AIDS patients who are truly suffering from AIDS wasting, he added.

RJL and its president, Rudolph Liedtke, pleaded guilty to their roles in the conspiracy in April of this year and are awaiting sentencing.

Impact of exclusion debated
As a result of its criminal conviction, Serono Labs will be excluded from all federal health care programs for at least five years. However, Serono’s U.S. subsidiary, Serono Holding, and all U.S. affiliates will be subject to the CIA, but not excluded.

“The activities described in the settlement were confined to one unit in our U.S. operations,” Serono said in a statement, “and cover a brief period in our history.” Notably, says qui tam Mark Kleiman, “when you look at who is being excluded from the program, it is not the U.S. operating division. It is people who do no sales in the U.S.

“The history of exclusions in large qui tam settlements has usually been to carve out a tiny entity where it won’t have any impact,” Kleiman maintains.

“Creating a market”
U.S. Attorney Michael Sullivan of the District of Massachusetts said that Serono’s “comprehensive effort to create market” for Serostim included several schemes. “Arguably, the most essential to Serono was its efforts to effectively redefine AIDS wasting,” he said. “Serono not only conspired [with RJL Sciences] to introduce bioelectrical impedance analysis (BIA) in its software on the market without FDA approval,” he asserted, “Serono also manipulated the device to its advantage.”

According to Sullivan, Serono, through its promotion, effectively made BIA the litmus test in diagnosing AIDS wasting and therefore succeeded in continuing to have Serostin prescribed by physicians for patients who may not have needed the drug.

Equally egregious, he added, was that Serono employees directly administered the BIA test to patients and interpreted the test data for doctors. According to Sullivan, this was “the very test and data” used in determining whether their drug should be prescribed. Today, such activities are expressly prohibited by the HIPAA patient confidentiality rules, he noted.

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Left unanswered, he says, is whether specialty pharmacies or doctors will be charged. Sullivan refused to speculate about that at the press conference.

**Whistleblowers receive $52 million**

The investigation leading to the global resolution was initiated in 2000 in Massachusetts after a former Serono Labs employee filed a False Claims Act suit. Four other employees filed similar suits in Maryland and Connecticut. As a result of the settlement, the private individuals who filed the whistleblower suits will share in approximately $51.8 million.

The investigation was conducted by the FBI, the FDA's Office of Criminal Investigations, the HHS OIG, the Department of Labor's Employee Benefits Security Administration, Boston Regional Office, and the U.S. Postal Service's Office of Inspector General. Assistance in the investigation was also provided by the New York State Attorney General's Special Projects and Medicaid Fraud Control Unit, the Medicaid Fraud Control Unit in Florida's Attorney General's Office, the Medicaid Fraud Section of the New Jersey Attorney General's Office, and the California Department of Justice.

Former DOJ attorneys assess the broader implications of the Serono settlement

According to former DOJ attorneys Lawrence Freedman and Laura Laemmle of Patton Boggs in Washington, DC, the Serono resolution has implications for pharma beyond the specifics of this case. “The key fact that should be taken away from this resolution,” says Laemmle, “is that Food, Drug and Cosmetic Act violations will continue to be the engine of the most serious criminal and civil health care fraud investigations.”

Here are four other key points Freedman and Laemmle highlight:

- The potent combination seen here of distinct off-label sales and marketing conduct, clear financial incentives targeted to high-prescribing physicians, and high Medicaid expenditures are more likely than ever to come to the attention of prosecutors, through whistleblowers or otherwise.

- Medicaid expenditures are a serious priority for both federal and state prosecutors who, in this case, investigated Medicaid fraud allegations for four years.

- Serious problems can arise when a sales force “creates a market” for a drug or device beyond the strictly construed approved label and supporting clinical trials.

- Device manufacturers that make non-intrusive devices, such as the BIA devices and software in this case, must evaluate their sales and marketing efforts in light of the approved uses or risk criminal and civil prosecutions.

Finally, says Freedman, it is clear that the Office of Consumer Litigation of the Justice Department, the Commercial Litigation Branch of the Justice Department, and the Criminal Divisions of the U.S. Attorney's Office — driven by a flood of *qui tam* allegations — will continue to drive enforcement against pharmaceutical and device manufacturers.
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