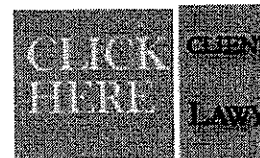


# MASSACHUSETTS LAWYERS WEEKLY

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From the November 14, 2005 Massachusetts Lawyers Weekly.

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## News Story

### \$700M drug settlement could spark whistleblower suits

#### Boston becoming a hub for False Claims Act cases

By David E. Frank

Attorneys say that the largest pharmaceutical civil settlement ever recovered in the United States under the federal whistleblower statute could lead additional employees to come forward and encourage more lawyers to file suit in Boston.

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As part of the settlement, Serono, Inc., a Swiss pharmaceutical manufacturer with offices in Rockland, agreed to plead guilty in U.S. District Court in Boston last month and pay more than \$700 million in criminal fines and civil damages for its role in the illegal marketing of an AIDS drug.

The settlement comes at a time when lawyers and judges have already noted a sharp increase in the number

of whistleblower claims in Massachusetts.

During a meeting with the media earlier this month, U.S. District Court Judge Patti B. Saris remarked that the number of cases being brought under the False Claims Act at the Moakley Courthouse is way up, particularly in the pharmaceutical industry.

"For a variety of reasons, there's no doubt that we've seen an increase," she said.

Robert M. Thomas Jr. of Boston, who represented one of the five whistleblowers in the Serono case, pointed to a number of factors that have led more and more individuals to make the difficult decision to speak out against companies.

"Success breeds success," he said. "When you've got a statute that is well-designed to handle

these types of claims, a federal prosecutor's office in Boston that's got deep experience in this area, and now a large amount of publicity around major drug company settlements, it's only natural that you'd see an increase."

He added that with the number of cases on the rise, concern has grown nationwide that the Department of Justice may not be able to devote additional but necessary resources to account for the increased demand.

"You end up with offices like Boston or Philadelphia getting more and more cases, but still operating with the same number of U.S. attorneys," he said.

### **Serotism**

In 1996, the Food and Drug Administration granted Serono approval to develop Serotism, a human growth hormone used to treat AIDS wasting, which was then the leading cause of death amongst individuals suffering from the disease.

Around the same time, protease inhibitor drugs came on the market.

When used in combination with one another as an "AIDS cocktail," the inhibitor drugs dramatically curtailed the growth of the virus and made patients much less susceptible to AIDS wasting.

As a result, the demand for Serotism dropped and the company began to engage in a variety of illegal behavior designed to create an increased market for the drug.

The case came to the government's attention when five former Serono employees, on diverse dates, provided information to federal authorities about those practices.

The whistleblowers, also known as relators, informed the government that Serono responded to the decreased demand by engaging in sales campaigns aimed at redefining AIDS wasting in a way it hoped would create more demand for the drug.

Specifically, they presented information demonstrating that Serono conspired with a medical device manufacturer to introduce a computer software package used to calculate body cell mass and diagnose AIDS wasting even in the absence of weight loss.

Those efforts led to a significant increase in sales for Serotism.

The first count brought against Serono accused the company of disseminating the software before it had obtained FDA approval and of improperly training sales representatives to tell doctors that body cell mass was a key metabolic measurement.

In addition, it accused company employees of directly administering computer tests to patients in an effort to induce doctors to prescribe Serotism.

The second set of charges alleged that the company offered doctors free trips to a conference in France in return for their agreement to write up to 30 new prescriptions for the drug.

In October, a Serono subsidiary agreed to plead guilty to two counts of criminal conspiracy in connection with the investigation and pay a fine of nearly \$137 million.

The company also settled the government's civil claims, initiated by the whistleblowers, by paying \$567 million in damages.

Under the terms of the agreement, the whistleblowers, who by statute can earn between 15 and

30 percent of any settlement or judgment, are expected to receive 17 percent of damages recovered in the case.

### **They came to Boston**

So, with competent federal prosecutors' offices throughout the country, why are so many of these cases coming to Massachusetts?

"In the Serono case, I think it was probably a combination of the fact that the first complaint was filed in Boston, plus the fact that the Boston U.S Attorney's Office has a long track record with health care cases," Thomas said.

That record has attracted the attention of many lawyers and persuaded a growing number to file their claims here.

U.S. Attorney Michael J. Sullivan said that "the relators' bar is extremely sophisticated and they look across the country and see that our office is one of a handful, over the last number of years, that has had an interest and ability to dedicate resources to combating fraud in the health care industry."

Since most cases are filed under seal, Sullivan said he could not provide specific numbers, but agreed that his office has seen a steady and significant increase in cases over the last few years.

Carl Valvo of Boston, who represented whistleblower Christine Driscoll in the case, agreed that the reputation of the U.S Attorney's Office in Boston has undoubtedly contributed to the increased filings in Massachusetts, but noted that the nature of the state's economy could also be a factor.

"This district might be seeing more cases because we have a greater concentration of the economy involved with government contracting, whether in the health care, defense or public works fields, as exemplified by the Big Dig," he said.

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### **Working with the U.S. Attorney's Office**

Although the False Claims Act allows private lawyers to proceed with claims without the assistance of the U.S. Attorney's Office, which decides whether or not it wants to intervene and take over an investigation, lawyers agree it is much less appealing to move forward without them.

"It's a much tougher scenario without the government, because now you're up against well-financed defense firms with the costs and burdens of prosecuting, making it a more difficult prospect," said Robert M. Thomas Jr. of Boston, who represented one of the five whistleblowers in the Serono case.

But with so much demand for the government's attention, Thomas said that it was critical for his firm to thoroughly investigate his client's allegations before presenting them to the prosecution.

In an effort to persuade the U.S Attorney's Office to intervene, Thomas focused his initial efforts on ensuring that the claims complied with the law's public disclosure requirements and rules that the whistleblower be the first to file in federal court.

He speculated that there were a number of factors about the case that interested the prosecutor's office, including the diversity of the claims, the fact that there were multiple

allegations of fraud and the size of the potential damages.

Thomas and Carl Valvo of Boston, the lawyer who represented whistleblower Christine Driscoll in the case, both acknowledged that the projected monetary damages also had to be a critical consideration leading prosecutors to take on the case.

"I've never known the government to sneeze at \$100 million," Thomas said.

He added: "When you've got different relators providing information on specific instances of conduct with respect to a drug that had a very high dollar revenue stream, that tends to be the kind of thing that gets the government interested in following up."

U.S. Attorney Michael J. Sullivan concurred that those factors were relevant in his office's assessment of the case.

His investigation revealed that 85 percent of the prescriptions filled out for the highly expensive drug, funded by taxpayers, were unnecessary.

"If you think about what was happening in the mid-1990s, many AIDS patients were dying from complications associated with AIDS wasting, so you had a vulnerable patient community that was willing to try anything to prolong their life. And it was obvious they were taken advantage of by the pharmaceutical company," Sullivan said.

### Competition

While the skill level of the U.S. Attorney's Office in Boston creates confidence that prosecutors will competently handle cases, Thomas said that the increased workload also raises concern that matters that do not attract their attention may remain at the bottom of the pile.

Such a possibility means that lawyers, who often take the cases on a contingency basis, risk devoting their own limited resources to a case that may go nowhere.

Thomas noted that while the Boston office clearly has earned its good reputation, the downside is that it has brought on a huge volume of work.

"You don't know when you file something here whether you're giving it to an assistant U.S. attorney who has so much work that [he's] not going to get to it," said Thomas.

He emphasized that the resource problem is not limited to Boston.

"As the number of cases goes up and the presumptive amount of fraud goes up, you don't see a corresponding increase in resources provided by the Department of Justice. And that's a concern not only in Boston but everywhere," Thomas said.

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