

December 16, 2010

Whistleblower cases lead to record government recoveries for drug company fraud

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The U.S. Department of Justice (DOJ) recovered a record \$2.5 billion in health care fraud in fiscal year 2010, most of it in prosecutions that began as whistleblower cases filed under the False Claims Act, the agency announced last month.

"Under Attorney General Eric Holder's leadership, our aggressive pursuit of fraud under the False Claims Act has resulted in the largest two-year recovery of taxpayer dollars in the history of the Justice Department," Assistant Attorney General Tony West said in a statement. "Nowhere is this more apparent than in our success in fighting health care fraud."

The recovered funds, which made up 83 percent of the year's total civil fraud recoveries, were a result of the DOJ's stepped-up efforts to prosecute pharmaceutical companies and their executives. Last week, the agency announced settlements with Abbott Laboratories, Inc., Roxanne Laboratories, Inc., and B. Braun Medical, Inc., that amounted to more than \$421 million over kickback schemes. The companies allegedly inflated their average wholesale prices, misrepresenting the prices they actually charged. This announcement followed several other high-profile settlements over pharmaceutical company wrongdoing.

"The prospect of having to pay a substantial False Claims Act settlement serves as an additional deterrent against deceitfully marketing drugs and marketing unreasonably dangerous drugs," said Howard Janet, a Baltimore lawyer who handles False Claims Act cases. "So, if the DOJ more aggressively prosecutes these cases, drug companies will have another reason to think long and hard before unnecessarily exposing consumers to serious harm like breast cancer, heart attack, stroke, and even death."

Still, some plaintiff lawyers have expressed concern that drug companies see large settlements as simply a cost of doing business.

"Companies were looking at this as a game," said Stephen Sheller, a Philadelphia lawyer who represents whistleblowers. "They would get caught and pay the money, but it didn't come close to compensating for their misconduct." Sheller was involved in three cases that prompted record-breaking DOJ settlements over off-label marketing within the last two years: settlements of \$520 million with Astra Zeneca, \$1.4 billion with Eli Lilly, and \$2.3 billion with Pfizer.

The DOJ's prosecution of individual pharmaceutical executives for their involvement in illegal activities may serve as another deterrent.

"Imposing personal financial liability on high-level executives cannot help but put even more pressure on the industry to avoid doing business as usual and thereby improve drug safety," Janet said.

The DOJ indicted Lauren Stevens, a former GlaxoSmithKline attorney and vice president, last month for obstructing a federal proceeding, concealing and falsifying documents, and making false statements to the FDA during investigations into off-label marketing.

"Where the facts and law allow, the Justice Department will pursue individuals responsible for illegal conduct just as vigorously as we pursue corporations," West said in a statement about Stevens's indictment.

These developments are good for drug safety, Sheller said, noting that if a whistleblower had come forward about problems with Vioxx, many people who were harmed by the drug might not have been. "This mess can be cleaned up," he said. "Whistleblower statutes and serious criminal prosecutions will help clean it up."