Whistleblowers Take On Off-Label Marketing

Widely Reported Successes and Significant Financial Rewards Breeding More Lawsuits

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When the election dust settles and pundits regroup to write about 2010, many will identify healthcare reform as the hot-button topic of the year. However, many will summarize the obvious (Congress' sweeping reform measures) and miss other trends that have more quietly emerged on the healthcare horizon, including increased government pursuit of whistleblower claims.

Attorney General Eric Holder of the United States Department of Justice (DOJ) and HHS Secretary Kathleen Sebelius, together with U.S. Attorneys nationwide, have spent much of the last 12 months announcing indictments, settlements, and new initiatives stemming from employees' complaints.

They range from the recent $750 million settlement entered into with GlaxoSmithKline for the manufacturing and sale of defective drugs to a renewed scrutiny of durable medical equipment, prosthetics, orthotics, and supplies fraud by mom-and-pop suppliers. A review of the government's announcements relating to these cases makes one enforcement trend clear—whistleblowers have focused their efforts on off-label marketing, the government is listening, and together they are reaping big rewards.

Long-Standing Framework

The Food, Drug and Cosmetic Act of 1938 makes it illegal to distribute labeling that accompanies a drug and prescribes, recommends, or suggests that the drug may be used for unapproved uses [21 U.S.C. § 331(d)]. Section 331(a) of the same statute makes it a crime to market a drug with labeling that bears inadequate directions for use, or which is false or misleading.

Drug companies that are alleged to have violated these provisions of the Act may be liable for a wide variety of civil and criminal penalties as well as a negative presumption and increased review in future marketing efforts. Since 1986, the False Claims Act (FCA), 31 U.S.C. § 3729 et seq., has given whistleblowers (or relators, in FCA terminology), who are the first to inform the government of alleged off-label marketing, some protection against retaliation resulting from filing a civil lawsuit on behalf of the government. The FCA also gave relators comfort that, should the government support their claims, they could recover a significant percentage of the damages, fines, and fees collected by state and federal governments.

It is unknown how many off-label marketing whistleblower lawsuits are filed each year. These cases are filed under seal (i.e., they are not publicly available), and they remain under seal for

months or years while the government investigates the allegations and decides whether to intervene, i.e., join in the lawsuit.

The government does not intervene in all of such suits, and relators do not always pursue their claims where the government declines to support their cause. However, the combination of expanded press coverage of healthcare issues and the irresistible story of do-gooders—not to mention the potentially significant financial reward—has led to more reports of huge whistleblower settlements. The last few months have been no exception.

In September, Forest Laboratories pleaded guilty to a felony charge of obstructing justice, a misdemeanor charge of distributing Levothroid (an unapproved drug), and a misdemeanor charge of illegally promoting Celexa for treating children and adolescents suffering from depression. Included among the consequences for the plea were a $150 million criminal fine, a $149 million FCA settlement, and an agreement to forfeit $14 million in assets to the federal government.

According to court filings, Forest Labs had illegally directed the promotion of Celexa for pediatric use in sales calls, hired outside speakers to talk to pediatric specialists, submitted inaccurate information to the FDA, and obstructed justice by distributing as much Levothroid as possible before expiration of a warning letter deadline. Forest also admitted it had obstructed justice by submitting inaccurate information to the FDA during the course of its investigation. The whistleblowers who brought certain of these acts to the government's attention will recover $14 million from the federal share of the civil settlement amount.

Approximately one week after the Forest Labs plea was announced, DOJ intervened on behalf of two whistleblowers who have alleged that Wyeth marketed the kidney transplant drug Rapamune, an immunosuppressant, for use in heart, lung, liver, pancreas, and islet cell transplants, even though the FDA had approved it only for use in kidney transplants.

The complaint alleges misbranding and off-label marketing for several years' time. Nineteen states and the District of Columbia have joined the suit, which whistleblowers filed in 2005.

Astute followers of qui tam cases may recall that this is not the first time in recent history the government has intervened on behalf of relators against Wyeth. For example, in May 2009, the U.S. and 16 states intervened in an action alleging that the company failed to give the government the same discounts it provided to private drug purchasers. That suit is ongoing.

On the heels of the Wyeth announcement, on September 30, DOJ informed the public it had reached a $422.5 million settlement with Novartis. In that case, Novartis agreed to pay $185 million in criminal fines and forfeitures for the off-label promotion of Trileptal as an anti-epileptic drug for the treatment of partial seizures but not for any psychiatric, pain, or other approved uses.

Novartis also agreed to pay $237.5 million to resolve civil FCA allegations that the company unlawfully marketed Trileptal and five other drugs, and submitted false claims for

reimbursement. The settlement resolved four separate whistleblower lawsuits, for which relators (and their attorneys) will recover more than $25 million.

These are just the latest in a busy 2010. Johnson & Johnson, Ortho-McNeil, and Eli Lilly are among other drug companies to have settled with the government and/or pleaded guilty to off-label marketing charges. The pleas and settlements reflect over $1 billion in payments to state and federal governments.

Recent DOJ announcements tout its recoveries from FCA lawsuits, and set the recovery amount at $4.4691 billion since January 2009 alone. While not all of these cases were initiated by whistleblowers, even if they received the minimum recovery permitted under the FCA (15%), they could collect over $400 million.

The Tip of the Iceberg?

The FCA has long provided an incentive and a safe haven for relators to bring fraud and abuse to the government's attention. Why, then, does there appear to be a 2010 increase in the number, type, and size of claims brought by whistleblowers, particularly in off-label marketing cases?

While there may be many contributing factors (including an increase in the use of wiretaps and the increased scope of civil investigative demands), we think there are two primary reasons for the trend. The most clear of these is simply an overall change in the healthcare enforcement environment.

Past whistleblower success is breeding more disclosures, a more vigilant press is reporting those successes, and prosecutors' offices are cooperating now more than ever, resulting in more resources to investigate relators' claims. A greater allocation of resources also means the government can pay attention to and even investigate a greater number of whistleblower claims, rather than those with easy targets or which result in a direct harm to patients.

Courts, too, may be in on the action—more frequently extending the time governments have to investigate whistleblower claims. This may explain the long-term and coordinated effort involved in cases like the Wyeth Rapamune suit, which is still in its nascent stages as far as the court's docket shows.

The second reason is that we are now seeing that more whistleblower actions have very little to do with the 2010 environment. Simply put, it takes time to investigate a relator's claims of fraud and abuse. Often, a relator sees something she believes is "not quite right." However, to file a complaint that will get a prosecutor's attention, she must first investigate her claim, hire an attorney, and meet with the government. Then the government—usually with many state and federal authorities coordinating efforts—takes its own time to review the claims and conduct its own investigation.

Since the statute of limitations for most criminal cases is five years and FCA cases may be brought within six years of a filed claim, the government does not have to make an immediate

decision whether the suit has merit. This year's interventions are the result of whistleblower complaints filed in the last five years.

As Holder and Sebelius continue to announce and pursue enforcement efforts, employees who perceive fraud and abuse are more likely to speak up, hire a lawyer, or both. Recovering many millions of dollars is certainly worth a few years of patience to a whistleblower.