



Enforcement Trends Demand Stronger Compliance Strategies in 2009

Industries regulated by the Food and Drug Administration (FDA) can no longer bury their heads in the proverbial sand. It is official. The False Claims Act (FCA) is a clear and viable threat to both pharmaceutical and device companies.

On November 10, the Department of Justice released its fiscal year fraud and false claims statistics. Health care company payments accounted for the vast majority of the fraud settlements — a shocking \$1.12 billion out of a total of \$1.34 billion in settlements and judgments. Moreover, the largest single recoveries came from just three pharmaceutical-related companies — Cephalon Inc., Merck & Co., and CVS Caremark Corp — accounting for more than \$640 million in fraud settlements. Yet those 2008 record amounts were dwarfed on January 15, 2009, when the Eastern District of Pennsylvania and 30 states announced a staggering \$1.4 billion settlement with Eli Lilly & Co. This astronomical settlement is likely the largest-ever health care fraud settlement, greatly exceeding the 2006 Tenet Healthcare settlement.

Industries regulated by the FDA and involved with manufacturing, marketing, and sales of drugs, devices, and biologics cannot afford to ignore the two key issues that will be forefront in the minds of FDA compliance officers and the Department of Justice: off-label marketing and financial relationships between industry and health care practitioners. Now more than ever, a comprehensive compliance strategy to discourage and prevent whistleblower activity should be undertaken immediately. The recent FCA enforcement activities — and massive monetary recoveries by whistleblowers — demonstrate the effective incentive structure behind the FCA and will likely spark a tidal wave of whistleblower complaints.

False Claims Act Basics

The False Claims Act imposes civil liability (and up to treble damages) on any person who knowingly presents or causes to be presented a “false or fraudulent claim for payment or approval by the state” or a “false record or statement to get a false or fraudulent claim paid or approved by the state.” The False Claims Act is not enforced directly by the FDA. Rather, the Department of Justice, often in conjunction with state government attorneys, work with program agencies such as the Department of Health and Human Services and the FDA to investigate and bring FCA cases. Penalties range between

\$5,000 and \$10,000 per claim and, given the claims-based nature of the health care system, these penalties can add up very quickly.

The whistleblower provisions of the FCA have proven to be a key enforcement tool in 2008. Under the FCA, private citizens are encouraged to bring a qui tam case on behalf of the government. The key incentive for qui tam plaintiffs, in addition to recovering attorney’s fees and costs, is the personal recovery of 15 to 25 percent of the proceeds recovered if the government prosecutes the case, and 25 to 30 percent of the proceeds recovered if the whistleblower brings the case alone. Whistleblowers suffering retaliation as a result of bringing a qui tam case are entitled to all necessary relief to make the employee whole, including full reinstatement of their position and benefits.

Learning From Recent Enforcement Actions

The bulk of the claims against pharmaceutical and drug companies in 2008 fell into three categories:

- “off-label” advertising and use of the product,
- inappropriate financial relationships between vendors and health care practitioners, and
- complex reimbursement schemes that resulted in federal health care programs paying inflated prices for products.

To be liable for a “false claim” based on off-label marketing of a product, the manufacturer must have engaged in unlawful or fraudulent conduct in the promotion of a drug or device product. In order to be liable for a “false claim” based on inappropriate financial relationships, the restrictions of the Anti-kickback Statute must have been violated. But drug and device manufacturers do not submit claims to government health care programs like Medicare and Medicaid. So how can they be directly liable when health care practitioners are involved in the prescribing of the drug or device? These cases use a “causation theory,” which posits that the actions of the drug or device manufacturer “caused” the health care practitioner or facility to submit a “false claim” to a government health care program.

The January 2009 Eli Lilly settlement of \$1.4 billion relates to the antipsychotic drug Zyprexa. According to the Department of Justice press release, Zyprexa was approved by the FDA only for treatment of schizophrenia and certain bipolar disorders in adults but was actively marketed by Eli Lilly for sleep disorders and dementia in elderly patients. The allegations are that Eli Lilly had a focused marketing campaign (“5 at 5,” or 5 mg at 5 pm for sleep disorders, and “Viva Zyprexa,” which targeted primary care physicians) that resulted in misbranded drugs introduced into interstate commerce (a violation of the Food, Drug, and Cosmetic Act) and false claims to government health care programs (an FCA violation). There were four whistleblower cases, all brought by Eli Lilly sales representatives involved in the off-label marketing campaigns. The four whistleblowers will share 18 percent of the total recovery, or approximately \$78 million.

The September 2008 Cephalon Inc. settlement of \$425 million resolved four whistleblower cases (also brought by sales representatives) relating to three drugs — Provigil, Gabitril, and Actiq. The allegation is that Provigil, approved to treat sleep apnea or shift-work sleep disorders, was marketed off-label by Cephalon to treat fatigue associated with schizophrenia and attention deficit disorders. Gabitril, approved for treating epileptic seizures, was marketed off-label for anxiety and insomnia. And Actiq, approved to treat cancer patients with extreme pain, was marketed off-label for general pain indications. The off-label practices were brought to the attention of the FDA by a sales representative.

In February 2008, Merck entered into a \$650 million settlement to resolve two whistleblower cases. One alleged that Merck offered deep discounts to health care facilities for using large quantities of the drugs Zocor and Vioxx, but failed to offer the same discounts to the Medicaid program. The second alleged that Merck regularly entered into arrangements (training, consulting, and research agreements) with physicians aimed at inducing them to purchase Merck products. Here, both a sales representative and physician whistleblower will share in the recovery.

Establishing Effective Compliance Strategies

First and foremost, FDA-regulated companies should undertake measures to ensure that all products are marketed according to the applicable FDA approval or clearance. Often, corporate marketing divisions are separate from and do not report to the regulatory affairs division. As information is gathered from the field about potential indications and uses, the marketing strategy may evolve without the necessary internal and/or FDA approvals or clearances. In fact, many times the regulatory affairs personnel are not aware of the marketing strategies being employed nor the specific product claims being made. If they had been involved in the decision making relating to

marketing claims and targeted audiences, appropriate FDA approval pathways could be evaluated and obtained — completely eliminating the potential for misbranding violations and off-label FCA claims.

Second, FDA-regulated companies should take time to understand the fine line between off-label marketing and appropriate distribution of literature discussing unapproved uses. On January 13, 2009, the FDA issued the final guidance “Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drug and Approved or Cleared Medical Devices” available at www.fda.gov/oc/op/goodreprint.html. This guidance clearly explains the FDA’s expectation that only full, unabridged versions of scientifically valid, peer-reviewed publications describing unapproved uses may be distributed. Moreover, dissemination of these publications must be completely separate from any promotional material or discussions. These recent changes to the FDA standards for marketing compliance indicate that the FDA intends to enforce off-label promotional violations, independent of FCA actions.

Finally, companies in FDA-regulated industries should develop internal mechanisms to limit the likelihood of whistleblower activity — both by sales representatives and health care practitioners. An internal compliance program, separate from the marketing division, should be established. Typically, the regulatory affairs division (combined with legal affairs involvement) is an appropriate and effective way to address the concerns of employees and customers. A hotline could be made available (especially to accommodate remote or field representatives) and a designated compliance officer should be charged with receiving and formally investigating complaints. More often than not, a concerned person attempts to achieve compliance within their company, but are ignored. Investigating and addressing employee concerns can not only prevent whistleblower FCA actions, but may also identify potential inappropriate sales and marketing tactics before they become massive off-label promotional campaigns.

For more information, please contact:

Robert J. Fleming Jr.
rfleming@hodgsonruss.com
716.848.1376

Bethany J. Hills
bhills@hodgsonruss.com
716.848.1554

Michelle L. Merola
mmerola@hodgsonruss.com
716.848.1686