COMPLIANCE WEEK
THE LEADING INFORMATION SERVICE ON CORPORATE GOVERNANCE, RISK, AND COMPLIANCE

Huge Fines, Record Whistleblowers Mark 2013 FCA Enforcement

By Jaclyn Jaeger

The Department of Justice completed an active year for False Claims Act enforcement in 2013, thanks to a record number of whistleblower claims and civil fraud recoveries. With a backlog of cases already building, don't expect any let-up this year.

The FCA, one of the government's most powerful weapons against fraud, prohibits companies from overcharging or otherwise defrauding the U.S. federal government. Individuals who discover fraud can sue on the government's behalf—known as qui tam claims—and collect up to 30 percent of the proceeds of a successful lawsuit.

Such whistleblowers had a good year in 2013. The Justice Department recovered $3.8 billion in settlements and judgments from civil cases involving fraud against the federal government last year, marking the second largest annual recovery in FCA history. This figure is surpassed only by the $5 billion in recoveries in 2012, which included the record $3 billion healthcare fraud civil and criminal settlement GlaxoSmithKline reached with the government in July 2012, arising from the off-label, unapproved marketing and promotion of several of its drugs.

2013's FCA penalties also included a blockbuster penalty: a $2.2 billion settlement the Justice Department reached with Johnson & Johnson to resolve civil and criminal charges that it illegally promoted the off-label use of its drugs Risperdal, Invega, and Natrecor. The complaint also alleged that J&J paid kickbacks to physicians.


Blume

The massive penalties "demonstrate the vigor with which the government is pursuing companies," says Robert Blume, a partner with law firm Gibson, Dunn & Crutcher. "They are making the message of stronger and stricter enforcement known by jacking up the dollar amounts of some of these settlements."

Healthcare Fraud

As in previous years, Justice Department fraud statistics revealed that most of the recoveries—$2.6 billion—of the $3.8 billion collected in FCA penalties in 2013 came from settlements of fraud charges committed against federal healthcare programs, most of which can be attributed to the Medicare and Medicaid programs administered by the Department of Health and Human Services.


Ford

Drug and medical device companies are especially vulnerable to FCA enforcement, given the life sciences industry's exposure to the government via Medicare and Medicaid, particularly as it concerns off-label marketing—that is, promoting a drug to treat an illness without the Food & Drug Administration's specific approval.

Significant FCA settlements that the Justice Department reached with pharmaceutical companies in 2013—in addition to the J&J case—include the $1.5 billion deal struck with Abbott Laboratories for the illegal promotion of its epilepsy drug Depakote, and a $762 settlement with Amgen for the illegal promotion of its anemia drug Aranesp.

> "They are making the message of stronger and stricter enforcement known by jacking up the dollar amounts of some of these settlements."
>
> Robert Blume, Partner, Gibson, Dunn & Crutcher

The Justice Department hopes the colossal sums will get the attention of the drug and medical devise industries. "The government's success in these cases is also a strong deterrent to others who would misuse public funds," Stuart Delery, assistant attorney general for the Justice Department's civil division, said in a statement.

Indeed it is, says Bernie Ford, managing director in the disputes and investigations practice at consulting firm Navigant. The cases highlight the importance of "having a robust auditing and monitoring process," he says. "That's an area where companies could use a lot of work."

"The reason many FCA resolutions are as large as they are is, in part, because the wrongful activity goes on for years and nobody finds it," Ford explains. He says companies, especially drug and medical device companies, should employ internal experts to analyze the data to identify irregularities or inconsistencies in the use of government funds. "That is crucial to avoiding an FCA claim," he says.

Pharmaceuticals also need to keep a careful watch out for kickbacks and other illegal payments and gifts to physicians and others. As in the J&J settlement, an increasing number of FCA cases include charges of violating the federal anti-kickback statute, says Ryan Hassanein, a partner in the litigation department of Morrison & Foerster. As a result, drug and medical device companies that get reimbursed by federal healthcare programs should, "strictly analyze all of the payment arrangements that they have to ensure that none of them run afoul of the anti-kickback statute," he says.

Procurement Fraud

The Justice Department also found great success in using the FCA to prosecute federal contractors for procurement fraud in 2013, which accounted for a record $887 million in settlements and judgments last year.

The bulk of that recovery was a $664 million judgment against defense contractor United Technologies. In the UTC case, an Ohio federal court judge found UTC liable for making false statements to the Air Force while negotiating the price of a contract for fighter jet engines. If the appellate court affirms the $664 million

Reprinted from Compliance Week, January 2014

judgment, which UTC has appealed, it would be the largest procurement recovery in history.

In addition to higher settlement amounts, legal experts say the Justice Department is increasingly expanding enforcement of the FCA into other industries. Application of the FCA "historically has been dominated by the defense, healthcare, and life sciences industries," says Hassanein. "Now you're seeing these cases popping up in many other contexts."

For example, one industry that may face more liability in 2014 is the financial services industry, especially with the establishment of the Financial Fraud Enforcement Task Force, says Blume. Historically, the federal government would work with financial institutions to remedy any issues of non-compliance associated with the receipt of federal funding.

The government changed its tune, however, after the financial crisis. Now, the Justice Department is increasingly utilizing the FCA to target financial institutions that receive federal funding. "They're really going to crack down and

FCA RECOVERIES

This excerpt from the Department of Justice details overall False Claims Act recoveries from health care fraud in 2013:

The $2.6 billion in healthcare fraud recoveries in fiscal year 2013 marks four straight years the department has recovered more than $2 billion in cases involving health care fraud. This steady, significant and continuing success can be attributed to the high priority the Obama Administration has placed on fighting health care fraud. In 2009, Attorney General Eric Holder and Health and Human Services Secretary Kathleen Sebelius announced the creation of an interagency task force, the Health Care Fraud Prevention and Enforcement Action Team (HEAT), to increase coordination and optimize criminal and civil enforcement. This coordination has yielded historic results: From January 2009 through the end of the 2013 fiscal year, the department used the False Claims Act to recover $12 .1 billion in federal health care dollars. Most of these recoveries relate to fraud against Medicare and Medicaid. Additional information on the government's efforts in this area is available at StopMedicareFraud.gov, a Webpage jointly established by the Departments of Justice and Health and Human Services.

Some of the largest recoveries this past fiscal year involved allegations of fraud and false claims in the pharmaceutical and medical device industries. Of the $2.6 billion in federal healthcare fraud recoveries, $1.8 billion were from alleged false claims for drugs and medical devices under federally insured health programs that, in addition to Medicare and Medicaid, include TRICARE, which provides benefits for military personnel and their families, veterans' healthcare programs and the Federal Employees Health Benefits Program. The department recovered an additional $443 million for state Medicaid programs.

Many of these settlements involved allegations that pharmaceutical manufacturers improperly promoted their drugs for uses not approved by the Food and Drug Administration (FDA)—a practice known as "off-label marketing." For example, drug manufacturer Abbott Laboratories Inc. paid $1.5 billion to resolve allegations that it illegally promoted the drug Depakote to treat agitation and aggression in elderly dementia patients and schizophrenia when neither of these uses was approved as safe and effective by the FDA. This landmark $1.5 billion settlement included $575 million in federal civil recoveries, $225 million in state civil recoveries and nearly $700 million in criminal fines and forfeitures. In another major pharmaceutical case, biotech giant Amgen Inc. paid the government $762 million, including $598.5 million in False Claims Act recoveries, to settle allegations that included its illegal promotion of Aranesp, a drug used to treat anemia, in doses not approved by the FDA and for off-label use to treat non-anemia-related conditions.

The department also settled allegations relating to the manufacture and distribution of adulterated drugs. For example, generic drug manufacturer Ranbaxy USA Inc. paid $505 million to settle allegations of false claims to federal and state healthcare programs for adulterated drugs distributed from its facilities in India. The settlement included $237 million in federal civil claims, $118 million in state civil claims and $150 million in criminal fines and forfeitures.

Adding to its successes under the False Claims Act, the Civil Division's Consumer Protection Branch, together with U.S. Attorneys across the country, obtained 16 criminal convictions and more than $1. 3 billion in criminal fines, forfeitures and disgorgement under the Federal Food, Drug and Cosmetic Act (FDCA). The FDCA protects the health and safety of the public by ensuring, among other things, that drugs intended for use in humans are safe and effective for their intended uses and that the labeling of such drugs bears true, complete and accurate information.

In other areas of healthcare fraud, the department obtained a $237 million judgment against South Carolina-based Tuomey Healthcare System Inc., after a four-week trial, for violating the Stark Law and the False Claims Act. The Stark Law prohibits hospitals from submitting claims to Medicare for patients referred to the hospital by physicians who have a prohibited financial relationship with the hospital. Tuomey's appeal of the $237 million judgment is pending. If the judgment is affirmed on appeal, this will be the largest judgment in the history of the Stark Law.

The department also recovered $26.3 million in a settlement with Steven Wasserman M.D., a dermatologist practicing in Florida, to resolve allegations that he entered into an illegal kickback arrangement with Tampa Pathology Laboratory that resulted in increased claims to Medicare. Tampa Pathology Laboratory previously paid the government $950,000 for its role in the alleged scheme. The $26.3 million settlement is one of the largest with an individual in the history of the False Claims Act.

Source: Justice Department.

focus on that," says Blume.

Whistleblower Claims

The biggest threat to companies continues to lurk from within. More whistleblowers raised FCA matters in 2013 than in any year in the FCA's history, dating back to its enactment in 1863.

According to Justice Department fraud statistics, of the total FCA recoveries last year, $2.9 billion came from cases first filed as whistleblower lawsuits. In total, whistleblowers collected $387 million in rewards in 2013.

Whistleblowers also played a significant role in the filing of new FCA cases. Out of the 846 new FCA matters—referrals and investigations—brought in fiscal year 2013, 753 were qui tam actions, up from 652 brought in 2012, according to Justice Department fraud statistics.

Legal experts attribute the rise in FCA whistleblower claims to a confluence of factors, including legislative amendments to the Fraud Enforcement and Recovery Act of 2009 and the Affordable Care Act of 2010, both of which significantly simplified the process for whistleblowers and the government to file FCA claims.

Because FCA cases remain under seal for a few years to give the government time to investigate, Hassanein says, "we're just now starting to see the legislative amendments [to FERA and the ACA] play out in the courts." Those amendments in combination with some recent court decisions expanding the scope of liability under the FCA "make it somewhat easier for the government to aggressively pursue mandatory treble damages and civil penalties in these types of cases," he says.


Hassanein

Given the size of recoveries, including whistleblower share awards, "there is every reason to believe that the plaintiffs' bar will continue to file these cases at an aggressive pace," says Hassanein. For this reason, the government is "leveraging whistleblowers to ferret out potential fraud, and getting involved only in those cases that they believe are the most significant, or have the most likelihood of success," he says.

Companies fare much better in FCA cases where the Justice Department doesn't get involved, because "it's the whistleblower actions in which the government intervenes that yield the biggest recoveries," says Blume. Of the total $27.2 billion recovered by the government between fiscal years 1987 and 2013, qui tam actions in which the government declined to intervene recovered only $991 million, according to Justice Department fraud statistics.

The practical lesson to be learned from increased whistleblower activity is that "whistleblowers tend to go public with allegations of misconduct when their complaints are not handled adequately," says Blume. One way to proactively avoid an FCA whistleblower claim is to immediately address employee concerns, he says, and communicate with that employee any remedial measures that have been taken, so that they feel their concerns have been dealt with in an appropriate way. ■