

# Despite Setbacks, DOJ's Criminal Enforcement of the

The federal False Claims Act, 31 U.S.C. §§ 3729–3733, is a primary enforcement tool used by the U.S. Department of Justice (DOJ) to prevent fraud on the government relating to federal programs. Increasingly, the DOJ is steering its criminal enforcement program toward individuals and stepping up health care fraud investigations.

**BY JEFFREY L. BORNSTEIN, LEANNE E. HARTMANN,  
SUZAN ONEL, MICHAEL D. RICCIUTI, MARK RUSH,  
PAUL W. SHAW, AND JOSEPH A. VALENTI**

# False Claims Act and Related Statutes Marches On

## *Federal Contractors and Their Employees Must Remain Vigilant*

The federal False Claims Act (FCA or the Act), 31 USC §§ 3729–3733, is the primary enforcement tool used by the U.S. Department of Justice (DOJ) to prevent fraud on the government relating to federal programs. The statute may impose criminal and civil penalties for violation of standards for making claims on the government for payment. The statute permits not only the DOJ but also private parties to file civil FCA actions. Those private actions are called *qui tam* actions, and the parties who file them, known as “relators” or whistleblowers, are individuals who claim to have direct and independent knowledge of fraud and can bring civil suits against government contractors on behalf of the government. If successful, relators can obtain a share of the government’s recovery in an FCA lawsuit.

In addition to the FCA, the DOJ often brings claims under other statutes that complement the FCA. The FCA and statutes that complement it have been powerful weapons for the government. In 2012, the DOJ recovered nearly \$5 billion in

settlements and judgments under the FCA, a record yearly total which exceeded the previous yearly record by approximately \$1.7 billion. A senior DOJ official recently called the FCA “the most powerful tool we have to deter and redress fraud” and promised continued aggressive enforcement of the Act.

Most of the \$5 billion recovered by the DOJ in 2012, some \$3 billion, came from healthcare fraud actions. Healthcare fraud thus remains at the forefront of the DOJ’s FCA enforcement campaign, including cases targeting off-label marketing of pharmaceuticals. The DOJ’s focus is not just on bringing civil suits and criminal actions against companies. Increasingly, the DOJ is steering its criminal enforcement program toward individuals. Government contractors and their employees have been the subject of civil enforcement and criminal prosecution under the FCA and related statutes.

Recently, the DOJ suffered some potential setbacks in its FCA enforcement program. The legal theory underpinning some of the DOJ’s healthcare fraud strategy is under attack in the courts, and it lost a high-profile prosecution of an individual in a healthcare case, a persistent risk for the government in its enforcement in this area. Despite those issues, the DOJ shows no sign of slowing down its FCA enforcement efforts against either companies or individuals. Government contractors must be on the lookout for potential FCA cases against themselves or their employees.

### **Prosecutions of Companies and Individuals**

The DOJ’s focus is on prosecuting companies as well as their employees for criminal activity, including criminal violations of the FCA and related statutes. Focusing on individuals in addition to the corporations for which they work is nothing new.

The DOJ's guidebook for federal prosecutors, the *U.S. Attorney's Manual (USAM)*, makes clear in the "Principles of Federal Prosecution of Business Organizations" that even where corporations are indicted for criminal misdeeds, responsible corporate directors, officers, employees, or shareholders should not be ignored. "[P]rosecution of a corporation is not a substitute for the prosecution of criminally culpable individuals within or without a corporation." In fact, such prosecutions "may provide the strongest deterrent against future corporate wrongdoing." This concept was echoed by the leader of the DOJ's Criminal Division, Lanny Breuer, in October: "As I have said repeatedly, the strongest deterrent against corporate wrongdoing is the prospect of prison time. That is why I have put such a high priority on making sure that individuals are prosecuted when the evidence warrants prosecution."

Even so, the government's approach in pursuing individuals in white-collar cases carries with it some risk for the government. In general, cases against individual corporate employees are often hard for the government to win before juries (and sometimes judges), which may be wary of laying blame at the feet of individuals. Nevertheless, in 2012, the DOJ brought cases against individuals in a variety of contexts. The DOJ's fiscal year 2013 budget request and other public statements make clear that prosecuting companies and individuals in these areas remains a high priority.

### **Aggressive Investigatory Techniques in White-Collar Cases**

The DOJ is increasingly using techniques developed in "blue-collar" cases in white-collar criminal investigations, such as wiretaps, cooperating witnesses, search warrants (as opposed to grand jury subpoenas), and undercover sting operations. Often these techniques make prosecuting individuals in significant white-collar cases much easier for the government. Most prominently, the DOJ relied on wiretaps in the Galleon Management insider trading prosecution, in which Raj Rajaratnam, Galleon's founder, was tried and convicted in 2011, and sentenced to 11 years in prison. To bring that case to court, the government sought several wiretaps, including wiretaps for Rajaratnam's cell phone, a technique perfected in drug and organized crime prosecutions. The government alleged that Rajaratnam had used insider information to execute millions of dollars in trades, and at trial, the government relied heavily on wiretaps of Rajaratnam's conversations about the trades to bolster its claims that he paid for inside information from a collection of tipsters.

Increasingly, the DOJ is also using sting techniques in fraud cases, which, as in the Galleon matter, allow the government to record defendants engaged in allegedly incriminating conversations and use their words against them. For instance, in late 2011 in Massachusetts, the DOJ arranged a sting in which an undercover FBI agent posed as a hedge fund manager. The undercover agent met with corporate officers and others associated with seven "micro-cap" companies. The undercover agent promised to invest some of the hedge fund's money into the companies, allegedly in exchange for a kickback paid to the undercover agent through a dummy company. The negotiations, captured on video, left little to dispute as to exactly what happened at the meetings where the allegedly illegal scheme was discussed.

### **FCA in Healthcare**

The FCA and related statutes are among the government's most powerful tools in alleged healthcare fraud cases. Detecting and

prosecuting healthcare fraud has long been a priority for the DOJ. It remains so under the current administration.

In 2009, the DOJ and the U.S. Department of Health and Human Services (HHS) announced a new joint initiative to ensure prosecutorial coordination: the Healthcare Fraud Prevention and Enforcement Action Team (HEAT), a joint strike force implemented to detect, prevent, and prosecute Medicare fraud. Co-chaired by the deputy attorney general and deputy HHS secretary, the HEAT task force is composed of top-level law enforcement agents, prosecutors and staff from both departments and their operating divisions (assisted on a case-by-case basis by staff from the Centers for Medicare and Medicaid Services (CMS)), investigators from insurance companies, and local law enforcement personnel. The HEAT task force in Washington, D.C., is supplemented by nine field-level Medicare Fraud Strike Forces around the country. These strike forces have brought huge healthcare fraud actions, including the largest-ever case in 2011, which involved \$530 million in alleged fraudulent billing.

Healthcare companies that find themselves in HEAT's crosshairs generally settle for large sums and offer their full cooperation to the government to avoid suspensions or debarment, which would be crippling in their industry. Even then, employees may find themselves the target of criminal prosecutions for alleged FCA violations and other purported crimes.

For instance, one of the earliest HEAT settlements came in May 2009 when managed care provider Wellcare Health Plans, Inc. paid \$80 million in criminal penalties (\$40 million in restitution and \$40 million as a forfeiture) under a deferred prosecution agreement, which also imposed internal control requirements on the company. Wellcare also paid \$137.5 million to settle civil litigation brought by government entities stemming from similar alleged misconduct, including allegedly creating false documentation, misusing grant money, reporting false numbers to support reimbursements and grants, and fraudulently "upcoding" the severity of patient illnesses and the complexity of services rendered. This case originated with *qui tam* relators, who will *eventually* be paid at least \$25.4 million.

The brunt of the government's enforcement effort was not felt by the company alone. Numerous individuals associated with Wellcare were also criminally charged. An analyst pled guilty to a conspiracy charge, and five former executives, including the chief executive officer, chief financial officer, and general counsel, were indicted in March 2011 and are currently on or awaiting trial.

Another case, brought in September 2011, was against home healthcare provider Maxim Healthcare Services, Inc. Maxim paid a criminal penalty of \$20 million under a deferred-prosecution agreement (as well as a much larger civil penalty of approximately \$130 million) to settle claims that its offices nationwide allegedly submitted more than \$61 million in fraudulent billings over a six-year period to government healthcare programs for services not rendered or otherwise not reimbursable. Maxim, a privately held company based in Maryland, was charged in the U.S. District Court for the District of New Jersey after a *qui tam* relator (who will receive about \$15.4 million) brought the case to the government's attention. In addition to allegedly billing for services not rendered, Maxim also allegedly billed for services rendered by unlicensed facilities or untrained personnel. These billings were alleged to be "false claims" because the invoices and billing codes used were only appropriate if the facilities were licensed or the personnel were trained. The claimed fraud was

compounded by the alleged fraudulent use of licensing information from properly licensed facilities and the creation of fictitious documentation showing that personnel were properly trained. In addition to shelling out money, Maxim is obligated to continue its cooperation with the government (which continues to prosecute various individuals involved in the fraudulent billings) and to implement internal controls to prevent a recurrence of similar fraudulent activity. Many of these controls will be monitored directly by HHS' Office of the Inspector General, though Maxim also is required to retain and pay an independent monitor selected by the government.

In addition to the action taken against the company, eight former Maxim employees pled guilty to criminal felony charges arising out of the submission of these fraudulent billings. Among other things, these individuals allegedly forged documents (such as time sheets) to support fictitious claims and made false statements to government healthcare program officials regarding Maxim's activities. The former employees charged in this action ranged from senior executives and mid-management to a front-line nurse and a personal care assistant.

As evidenced by the prosecutions of individuals affiliated with Wellcare and Maxim, as well as numerous other cases, the government's focus on individual, and not just corporate, prosecutions in healthcare fraud cases is clear. On the HEAT website,<sup>1</sup> the government touts that since 2008, HEAT actions have led to a 75 percent increase in individuals charged with criminal healthcare fraud. Further, the DOJ notes that since 2007, more than 1,480 individuals have been charged for allegedly falsely billing Medicare more than \$4.8 billion. As a recent example, in October 2012, the DOJ charged 91 individuals—doctors, nurses, and other healthcare professionals—in an alleged \$430 million false billing scheme.

The DOJ also continued its focus on pharmaceutical fraud. Staggering "off-label marketing" settlements have been common for years and account for a significant portion of the funds the government recoups for FCA violations. For instance, in September 2008, Cephalon, Inc., paid a criminal fine of \$40 million, forfeited another \$10 million, agreed to compliance oversight, and settled related civil claims for \$374 million (\$258 million of which was for federal programs). Over a five-year period, Cephalon allegedly marketed three drugs for uses not approved by the U.S. Food and Drug Administration (FDA). By promoting the drugs for "off-label" uses, Cephalon caused providers to charge federal health insurance programs such as Medicare, Medicaid, TRICARE, and the Federal Employees Health Benefits Program for unapproved uses of the drugs not covered by the programs. This conduct was first reported by *qui tam* whistleblowers in the U.S. District Court for the Eastern District of Pennsylvania who will receive approximately \$46.7 million for bringing the initial action.

### Challenges in Prosecuting Individuals

In July 2012, the DOJ reached a record-setting \$3 billion criminal and civil settlement against GlaxoSmithKline (GSK), the largest healthcare fraud settlement in U.S. history, arising from alleged improper, off-label marketing of pharmaceuticals. GSK agreed to plead guilty to three criminal charges alleging violations of the federal Food, Drug, and Cosmetic Act (the FDCA) for promoting drugs for uses other than those approved as safe and effective by the FDA. In addition, GSK settled civil FCA claims and others arising from, among other things, promoting drugs for off-label, non-covered uses

and paying kickbacks to physicians to prescribe those drugs.

In connection with the GSK action, the DOJ indicted an individual (not an employee involved in alleged improper marketing, as has happened in the past). The indicted individual, GSK Vice President and Associate General Counsel Lauren Stevens, had been involved in a 13-month investigation undertaken to respond to FDA requests for information from GSK regarding alleged off-label marketing, a process which involved inside and outside counsel for GSK. The DOJ indicted Stevens on charges of making false statements and obstructing justice, alleging that she made materially false statements and concealed incriminating evidence when she responded to the FDA's request.

The Stevens prosecution highlights the difficulty the DOJ sometimes faces in prosecuting individuals. Although seen as aggressive when it was brought, the case ended in disaster for the DOJ. In May 2011, a federal judge in Maryland granted a defense motion for judgment of acquittal at the end of the government's case, concluding that Stevens acted in good-faith reliance on the advice of external and internal lawyers for GSK in responding to the FDA and that no reasonable juror could convict her based on the government's evidence. Such rulings are rare, as the judge in the Stevens case noted.

***One of the earliest HEAT settlements came in May 2009 when managed care provider Wellcare Health Plans, Inc. paid \$80 million in criminal penalties ... under a deferred prosecution agreement, which also imposed internal control requirements on the company.***

The result in the Stevens case illustrated not only the difficulty in prosecuting individuals for healthcare fraud, but the value of the defense strategy of putting the government to its proof at trial. Doing so has been successful for individuals in past healthcare fraud cases. For instance, in 2004, a federal jury in Massachusetts acquitted eight current and former employees of TAP Pharmaceuticals of conspiracy to pay bribes or kickbacks to doctors and hospitals, among other acts, in a healthcare fraud case. The acquittals, which followed a three-month trial and TAP's payment of \$885 million to settle related charges, were also seen as a blow to the DOJ's healthcare fraud prosecution strategy.

Bringing cases to trial sometimes works for companies as well as their employees. Although it is rare for the government to abandon a prosecution days after trial has commenced, the government did just that in a high-profile off-label marketing prosecution. In February 2012, the government dismissed a healthcare fraud case against Stryker Biotech LLC and several of its employees, including its president, five days after trial began. Apparently the government never spoke to surgeons whom the government contended had allegedly been defrauded by Stryker's alleged off-label marketing of spinal products. In the opening statement, Stryker's counsel told the

jury that the defense had spoken to these doctors, and they would testify they had not been defrauded. Apparently concluding that its case against the company was weak and that Stryker's president had acted in good faith, the government settled with Stryker on a misdemeanor charge and dismissed its case against the employees.

The Stevens and Stryker cases were plainly major setbacks for the DOJ. But those results do not mean that the DOJ will change course on pursuing both companies and individuals in healthcare fraud cases. Despite the dismissal of the indictment, Stryker still pled guilty to a misdemeanor for misbranding and paid a \$15 million fine. And the government has turned to a more aggressive theory in healthcare cases, charging corporate officers criminally with strict liability for failing to prevent or correct a company's alleged adulterating or misbranding of a drug that is introduced into interstate commerce. This theory, known as the "responsible corporate officer" doctrine, means that a corporate officer can be convicted even if he or she knew nothing about the alleged wrongdoing but was in a position to prevent it. Even though responsible corporate officer liability results only in a misdemeanor, it nonetheless exposes corporate officers to criminal prosecution on a theory against which there are few defenses and which can result in potential exclusion of the officer and his company from future participation in federal healthcare programs. The HHS inspector general has repeatedly stated that his office expects to make a number of referrals to the DOJ for criminal prosecution of individuals for healthcare fraud pursuant to the responsible corporate officer doctrine.

**Off-label marketing of pharmaceutical products is not expressly prohibited under the FDCA. Rather, the government has historically addressed the marketing of unapproved uses of approved drugs by alleging that the manufacturer of the drug has violated FDCA § 301(a) by introducing a "misbranded" drug into interstate commerce.**

#### **Off-Label Marketing—the DOJ's Theory Under Attack**

On December 3, 2012, a divided U.S. Court of Appeals for the Second Circuit held in *United States v. Caronia*<sup>2</sup> that the misbranding provisions of the FDCA do not criminalize "the truthful off-label promotion of FDA-approved prescription drugs." The two-judge majority in *Caronia* based its holding primarily on last year's U.S. Supreme Court decision in *Sorrell v. IMS Health, Inc.*,<sup>3</sup> which held that "[s]peech in aid of pharmaceutical marketing ... is a form of expression protected by the Free Speech Clause of the First Amendment." Although not a case brought under the FCA, the holding is significant to one of the government's core FCA theories—that promoting drugs for off-label uses and obtaining federal reimbursement for those sales can constitute an FCA violation.

The *Caronia* decision is a major blow to one of the government's theories of criminal liability for off-label marketing—that promotion of a drug through commercial speech for a use that does not appear on the labeling approved by the FDA for the drug is *itself* illegal under the FDCA or can form the basis for other claims, including FCA claims. Because it may have such a major impact on the government's strategy, it seems unlikely that *Caronia* will be the last word on the subject. Thus, while it remains to be seen whether *Caronia* is a watershed moment or a narrow departure from current law, it should embolden the pharmaceutical industry to continue to press the argument that providing factual information that is not false or misleading to physicians and patients about potential off-label uses of FDA-approved drugs should not be unlawful.

Alfred Caronia was a pharmaceutical sales representative for Orphan Medical, Inc., a company that manufactured Xyrem, a powerful central nervous system drug approved by the FDA in 2002 to treat narcolepsy patients who suffer from weak or paralyzed muscles. In November 2005, Xyrem was approved by the FDA to treat narcolepsy patients with excessive daytime sleepiness. In 2005, Caronia was hired as a specialty sales consultant to promote Xyrem, and began marketing Xyrem with the assistance of physicians paid by Orphan to speak to other physicians about the drug. That same year, the federal government began an investigation of Orphan and its paid physician consultant and, in the process, recorded two conversations in which Caronia made unprompted promotional statements regarding "off-label" uses of Xyrem to a physician. Caronia was tried and convicted by a federal jury in 2008 for conspiring to introduce Xyrem into interstate commerce for unapproved uses which render the drug "misbranded" under the FDCA, a misdemeanor.

Caronia appealed his conviction on the basis that the misbranding provisions of the FDCA unconstitutionally restrict his speech by prohibiting and criminalizing off-label promotion in the form of truthful and non-misleading promotion of an FDA-approved drug to physicians for off-label use, where such use is not itself illegal.

In December 2012, a divided three-judge panel of the Second Circuit, in a 52-page majority opinion, found that the government's interpretation of the FDCA in charging and trying the case criminalized the "simple promotion" of a drug's off-label use in violation of Caronia's First Amendment right to free speech. The majority rejected the government's contention that it did not prosecute Caronia for his speech itself, but rather that they used his speech as evidence of his intent to conspire to introduce Xyrem for an off-label purpose in violation of the FDCA. The Court reviewed the trial record and found "over forty times" where the government argued that Caronia's off-label promotion of Xyrem was *itself* a violation of the FDCA, and that neither the government nor the lower court limited the use of the promotional statements to evidence of intent, rather than as evidence of violations of the FDCA themselves. The jury instructions were equally as unequivocal regarding the statements as violations of the FDCA: "[T]he district court flatly stated to the jury that pharmaceutical representatives are prohibited from engaging in off-label promotion ... this specific instruction—together with the government's summation—would have led the jury to believe that Caronia's promotional speech was, by itself, determinative of his guilt."

Since it concluded that the government's theory criminalized Caronia's speech, the majority engaged in a lengthy First Amend-

ment analysis, relying heavily on the Supreme Court's decision and holding in *Sorrell*, which was rendered during the course of Caronia's appeal. In *Sorrell*, the Supreme Court held that speech in aid of pharmaceutical marketing was protected First Amendment speech. Relying on *Sorrell*, the majority found that the government's restriction of Caronia's speech is subject to heightened scrutiny on the basis that it was both "content-based" and "speaker-based."

Without specifying whether it was applying strict scrutiny or heightened scrutiny in this case, the majority held that the government's interpretation of the FDCA criminalizing Caronia's speech did not pass either test because it was not directly advancing the FDA's "interest in reducing patient exposure to off-label drugs or in preserving the efficacy of the FDA drug approval process because the off-label use of such drugs continues to be generally lawful." The majority recognized that while doctors are free under the FDCA to prescribe a drug for any purpose, whether it be an on-label or off-label use, the government had historically sought to criminalize marketing which promoted off-label uses, even if doctors used the drug for such a purpose. The majority stated that prohibiting the off-label promotion by a pharmaceutical manufacturer while allowing off-label prescription by doctors "'paternalistically' interferes with the ability of physicians and patients to receive potentially relevant treatment information [that] could inhibit, to the public's detriment, informed and intelligent treatment decisions." Further, the prohibition against truthful and not misleading promotion of off-label uses of drugs was not narrowly drawn to further the interests served by the restriction, listing various ways in which the government could inform, limit, or prevent off-label use of some or all FDA-approved drugs.

The majority seemingly sought to minimize the impact of its extensive and broad ruling, stating "we conclude simply that the government cannot prosecute pharmaceutical manufacturers and their representatives under the FDCA for speech promoting the lawful, off-label use of an FDA-approved drug." That statement, however, would seem to undermine the government's historically aggressive prosecutorial approach in off-label marketing cases.

In a 30-page, sharply worded dissent, Second Circuit Judge Debra Ann Livingston strongly condemned the majority's opinion and expressed concern that it could undermine the entire regulatory scheme for prescription drugs. "By holding ... that Caronia's conviction must be vacated ... the majority calls into question the very foundations of our century-old system of drug regulation."

Off-label marketing of pharmaceutical products is not expressly prohibited under the FDCA. Rather, the government has historically addressed the marketing of unapproved uses of approved drugs by alleging that the manufacturer of the drug has violated FDCA § 301(a) by introducing a "misbranded" drug into interstate commerce. Under this theory, the drugs are allegedly "misbranded" under FDCA § 502(f)(1) because they lack "adequate directions for use," since the off-label use would not be included in the drug's directions.<sup>4</sup> FDA's regulations define "adequate directions for use" as "directions under which the layman can use a drug safely and for the purposes for which it is intended."<sup>5</sup> The FDA's regulations further define "intended use" to mean "the objective intent of the persons legally responsible for the labeling of drugs."<sup>6</sup> The requisite intent to misbrand under the regulations can be demonstrated by "such person's expressions or may be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives."<sup>7</sup>

Drugs labeled as "prescription drugs" are exempt from the requirement to be labeled with "adequate directions for use" (in part because they cannot be used safely by a layperson) *provided* the drug's labeling contains

adequate information for its use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented.<sup>8</sup>

Therefore, the FDA and the DOJ have historically and routinely asserted that a manufacturer or distributor of a prescription drug can "misbrand" a drug by representing or advertising the drug for a use that is not adequately set forth in the drug's labeling. And marketing drugs for unapproved uses that are then paid for by federal healthcare programs can form the basis for an FCA claim.

From a policy perspective, the FDA has aggressively pursued misbranding cases to protect the integrity of the pre-approval process. The concern is that off-label promotion by drug companies creates a disincentive for the companies to pursue FDA approval of new indications which could lead to wide use of drugs for indications that have not been studied, reviewed, or approved by FDA, thereby potentially jeopardizing public safety.<sup>9</sup>

Drug manufacturers facing allegations of misbranding due to a lack of adequate directions for an unapproved use frequently enter into consent decrees with the government in order to avoid possible collateral consequences to an enforcement action, including debarment from federal third-party payor programs (e.g., Medicaid, Medicare Part D, Federal Supply Schedule, TRICARE, etc.). These consent decrees have often included an agreement on the part of the drug manufacturer to disgorge all profits gained as result of the sale of allegedly misbranded drug products, and may include fines and penalties paid to the government for violations of the FDCA or the FCA resulting from the submission of claims to Medicare or Medicaid for unapproved uses of the drug. State governments are also getting in on these cases.

Will the *Caronia* decision stem the tide of these high-stakes cases? Does it mean that pharmaceutical sales representatives can—at least in those states comprising the Second Circuit—truthfully answer questions from physicians related to off-label uses of drugs without fearing criminal retribution? Does it go further, and permit companies and their agents to make affirmative statements about off-label uses of their drugs in the absence of unsolicited requests? If the answer to the second or third question is yes, does that as the dissent suggests it could, begin to erode the broader purpose of the FDA's statutory and regulatory scheme, ultimately allowing pharmaceutical manufacturers to exert undue influence on physicians and leading to the sale of drugs for unapproved uses that could potentially harm patients?

The effect of the Second Circuit's ruling in *Caronia* remains to be seen. Assuming other courts embrace the majority's rationale, the government may have difficulty prosecuting pure speech-based claims that are not false or misleading, at least in instances where the marketer is responding to a question by a physician. That said, it is likely the government will continue to pursue these claims in such

a way as to make clear that statements promoting off-label usage are simply evidence of the intent of the person accused of the violation. In other words, it may be a situation where the government attempts to avoid the First Amendment issues in the way it charges the violations and argues its cases. On the other hand, courts may broadly construe the *Caronia* opinion to allow companies and their representatives to speak openly—so long as the statements made are truthful and not misleading—to physicians and patients about off-label uses of FDA-approved drugs.

It should be noted that even if the *Caronia* decision is widely adopted, the government will not be without tools with which it can enforce the prohibition against the marketing and sale of drugs for unapproved uses. Nevertheless, while the sledgehammer of the federal healthcare regulatory scheme cannot be taken lightly, companies and individuals may be emboldened to look harder at impending or actual charges relating to off-label marketing when evaluating a case and considering a possible settlement.

## Conclusion

The DOJ will continue to rely on the FCA and similar statutes as powerful tools and target companies and their employees with aggressive investigatory techniques and criminal charges. Companies and their employees thus must be aware of the scope and reach of this statute. To be sure, the best defense is to avoid the prospect of prosecution altogether with aggressive compliance practices to detect and prevent instances of fraud that can lead to FCA actions.

Because cases against individuals are often hard to win, the DOJ can be expected to continue to rely on investigatory tactics designed to use the employees' own words against them or on legal theories that leave them with little defense. Recognizing this, corporations should ensure they have implemented comprehensive corporate compliance programs, policies, and practices. Such programs will provide some protection for a company where an employee truly "goes rogue" and commits a crime. The DOJ will look to the company's compliance program, among a number of factors, to decide under its "Principles of Federal Prosecution of Business Organizations" whether to prosecute the corporation for the employee's offense. More generally, solid corporate compliance programs and practices can help avoid liability completely. Policies and practices requiring employees to obtain and rely on the advice of outside counsel before making decisions may provide a ready-made and persuasive defense if the government later questions the company's conduct. Further, company-required training on proper conduct may well alert employees to various forms of fraud, thus ensuring they do not stumble into traps set by the government.

But if a company's compliance program fails, and companies and their employees find themselves the focus of a government criminal investigation, they should not conclude that pleas or settlements are inevitable. Instead, corporations and their employees should carefully consider fighting government charges if the circumstances warrant. As noted above, sometimes fighting the government is the best defense. ☉

*Jeffrey L. Bornstein, Leanne E. Hartmann, Suzan Onel, Michael D. Ricciuti, Mark Rush, Paul W. Shaw, and Joseph A. Valenti are attorneys with K&L Gates LLP. Michael Ricciuti, Mark Rush, Jeffrey Bornstein, Joseph Valenti and Leanne Hartmann are members of the firm's Government Enforcement Practice Group.*

*Suzan Onel is Chair of the Firm's FDA Practice Group. Paul Shaw is a member of the Healthcare Practice Group. © 2013 Jeffrey L. Bornstein, Leanne E. Hartmann, Suzan Onel, Michael D. Ricciuti, Mark Rush, Paul W. Shaw, and Joseph A. Valenti. All rights reserved.*



## Endnotes

<sup>1</sup>HHS & DOJ, *Stop Medicare Fraud.Gov*, [www.stopmedicare-fraud.gov](http://www.stopmedicare-fraud.gov).

<sup>2</sup>703 F.3d 149 (2d Cir. 2012).

<sup>3</sup>131 S. Ct. 2653, 2659 (2011).

<sup>4</sup>In contrast, the promotion of a medical device for an off-label use causes the device to be either "adulterated" under FDCA § 501(f) (Class III devices) or "misbranded" under FDCA § 502(o) (for Class II devices) of the FDCA.

<sup>5</sup>21 C.F.R. § 201.5.

<sup>6</sup>*Id.* § 201.128.

<sup>7</sup>*Id.*

<sup>8</sup>*Id.* § 201.100(c)(1) (emphasis added).

<sup>9</sup>Note that the FDA has always recognized the ability of a healthcare provider to use a legally marketed product off-label in the practice of medicine. The FDA has also recognized that there are certain circumstances where the discussion of unapproved uses is not promotional and supports legitimate scientific and educational purposes. *See e.g.*, FDA, FDA GUIDANCE FOR INDUSTRY: INDUSTRY-SUPPORTED SCIENTIFIC AND EDUCATIONAL ACTIVITIES (1997) and FDA, FDA GUIDANCE FOR INDUSTRY: GOOD REPRINT PRACTICES FOR THE DISTRIBUTION OF MEDICAL JOURNAL ARTICLES AND MEDICAL OR SCIENTIFIC REFERENCE PUBLICATIONS ON UNAPPROVED NEW USES OF APPROVED DRUGS AND APPROVED OR CLEARED MEDICAL DEVICES (2009).

