

# What Every Pharmaceutical And Medical Device Company Should Know: False Claims Act Cases Based On Off-Label Promotion Promise To Increase With The Healthcare Act And The Bad Ad Program

By Kai Peters, Edward R. Fitzgerald and Jack B. McCowan

FOR MANUFACTURERS of prescription drugs and medical devices, preventing the “off-label” promotion of their products (i.e., marketing the product for uses for which it was not approved) has always been a top concern and issue on which significant company time and resources have been expended. With the 1938 enactment of and subsequent amendments to the Food, Drug, & Cosmetic Act (the “FDCA”),<sup>1</sup> the federal government has had at its disposal a focused statutory scheme directed specifically at preventing off-label promotion of prescription drug and medical devices by their manufacturers, and the ability to impose potentially significant criminal and civil penalties for companies found to be in violation. Accordingly, the FDCA has been the traditional vehicle by which the off-label promotions of prescription drug and medical device products has been policed and has provided a predictable statutory rubric by which a manufacturer could properly understand and assess its potential liability for any alleged off-label advertising and promotion and related compliance efforts.



*Kai Peters is a partner in the San Francisco office of Gordon & Rees LLP and a member of its Drug and Medical Device group. Mr. Peters has extensive*

*experience in and specializes in complex civil litigation, including product liability, class actions, and mass tort litigation, and pharmaceutical and medical device law. He also specializes in acting as outside general counsel for businesses on a broad range of their corporate, commercial, and litigation matters and in that capacity has extensive experience in all aspects of contracting drafting and negotiation, including commercial and clinical trial agreements. He is an alum of the IADC Trial Academy (Stanford, 2005).*

*Edward Fitzgerald is an associate in the San Francisco office of Gordon & Rees LLP and a member of its Drug and Medical Device group. Mr. Fitzgerald represents businesses*



*and individuals in a broad range of complex civil litigation matters including business torts, breach of contract actions, and product liability cases, with an emphasis on representing manufacturers and distributors of regulated consumer products. He also has extensive*

<sup>1</sup> 21 U.S.C. §§ 301 et seq.

*experience in the handling of class actions and mass torts, and frequently consults on regulatory compliance matters, handling of and responding to government investigations, and avoidance of liability.*



*Jack B. McCowan, Jr., is a partner in the San Francisco office of Gordon & Rees LLP and a member of the firm's Drug and Medical Device and Commercial Litigation practice*

*groups. His practice is equally divided between drug, medical device and other product liability litigation and commercial litigation*

More recently, however, an increasing number of False Claims Act (the “FCA”),<sup>2</sup> actions predicated on the off-label promotion of drugs and medical devices have been filed against manufacturers, giving rise to new concerns about the potential liability of companies that have engaged in purportedly violative advertising or promotion of their products. The basic premise for such claims, which may be brought by the federal government or by private parties, is that manufacturers who have knowingly engaged in the off-label promotion of their prescription drug or medical device products, and which have received payments from Medicare or Medicaid as a result of such off-label promotion, have committed a fraud upon the government and are accordingly punishable under the FCA. Plaintiffs’ attorneys have capitalized on this

increasingly developed area of the law, and have begun to file similar claims based on the qui tam provisions of the FCA (as “relators”), or have sought to represent those whistleblowers who, by statute, are entitled to significant percentages of the civil damages awarded to the federal government in these actions.

To appreciate the full weight of this increased use of the FCA as a weapon against off-label advertising and promotion of prescription drugs and medical devices, one needs to look no further than reports of numerous recent settlements entered into by companies against whom FCA-based allegations have been made. In the last two years alone, a number of such lawsuits initiated by the federal government and private parties have resulted in billions of dollars of settlements, including but not limited to the following:

- AstraZeneca paid \$520 million to settle criminal and civil claims related to its promotion of the psychiatric drug Seroquel. Such actions alleged that AstraZeneca had improperly promoted Seroquel for use in the treatment of insomnia;<sup>3</sup>
- Also in 2010, Novartis paid \$442 million to settle criminal and civil actions concerning its antiepileptic drug Trileptal, which it had allegedly promoted for use in treating psychiatric

<sup>3</sup> See <http://www.beckershospitalreview.com/lists-and-statistics/20-largest-false-claims-cases-of-2010.html>.

<sup>2</sup> 31 U.S.C. §§ 3729 et seq.

issues, pain, and other conditions;

- Allergan paid \$600 million in 2010 to settle criminal and civil actions related to its alleged off-label promotions of the drug Botox; and
- In 2009, Pfizer paid \$2.3 billion to settle criminal and civil actions relating to its off-label marketing of Bextra. It was alleged that Pfizer attempted to promote Bextra for the treatment of acute surgical pain, despite being limited in its approval for pain related to osteoarthritis, rheumatoid arthritis and primary dysmenorrhea.<sup>4</sup>

Further, the DOJ in 2009 announced that FCA lawsuits have now overtaken FDCA actions, stated that there is reason to believe this trend will continue,<sup>5</sup> and strongly suggested that future actions may not be restricted simply to claims involving alleged off-label advertising and promotion.<sup>6</sup>

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<sup>4</sup> See <http://www.stopmedicarefraud.gov/pfizerfactsheet.html>.

<sup>5</sup> See [http://www.fdalawblog.net/fda\\_law\\_blog\\_hyman\\_phelps/2009/10/fda-compliance-directors-and-others-predict-where-the-fda-spotlight-will-shine.html](http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2009/10/fda-compliance-directors-and-others-predict-where-the-fda-spotlight-will-shine.html).

<sup>6</sup> See *id.* Consistent with this statement, the federal government recently filed a complaint in intervention in *United States ex rel. Allen v. Guidant LLC*, 708 F. Supp.2d 903 (D. Minn. 2010), in which it is alleged that the defendant medical device manufacturer violated the FCA by knowingly selling implantable cardiac devices that purportedly contained a potentially fatal defect that may cause the devices to short-circuit.

Based on the recent actions of the federal government to apparently expand the ability to bring FCA actions, there is every reason for drug and medical device manufacturers to be concerned about these statements. Critically, recent statutory amendments to the FCA and enforcement initiatives announced by FDA suggest that both federal and private FCA actions against pharmaceutical and medical device manufacturers will increase in number. The linchpin of these increased enforcement efforts is the amendment of the FCA by the Obama administration's recent healthcare reform legislation<sup>7</sup> to make it easier for the federal government and private parties to initiate and pursue FCA actions.<sup>8</sup> Building on these amendments, the FDA has also recently announced the implementation of its "Bad Ad Program,"

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<sup>7</sup> The Patient Protection and Affordable Care Act, 111 P.L. 148, and the Health Care and Education Reconciliation Act of 2010, 111 P.L. 152, (collectively the "Healthcare Reform Legislation") were respectively passed on March 23, 2010 and March 30, 2010. The ultimate fate of the Healthcare Reform Legislation remains uncertain as there have been constitutional challenges to the Healthcare Reform Legislation. One court has even found it to be unconstitutional in its entirety. See *State of Florida v. United States*, No.: 3:10-cv-91, 2011 U.S. Dist. Lexis 8822 (N.D. Fla. Jan. 31, 2011).

<sup>8</sup> Though the focus of this article is on liability under the FCA for off-label promotion of prescription drugs and medical devices, the Healthcare Reform Legislation also includes significant amendments to Anti-Kickback Statute (the "AKS"), 42 U.S.C. § 1320a-7b(b), which explicitly provide that a violation of the AKS constitutes a false or fraudulent claim under the FCA.

an outreach initiative directed at physicians that seeks their assistance in monitoring and policing advertising and promotion for prescription drugs and medical devices.<sup>9</sup> The federal government has also implemented a policy banning company executives who have committed fraud on the government from entering into future contracts with federal health programs,<sup>10</sup> increasing the odds of significant settlements of any FCA claims for fear of such significant repercussions and underscoring the need to be prepared that the company does not risk an FCA lawsuit.

Taken together, the message from the federal government to drug and medical device manufacturers is very clear – the threat of and potential exposure from FCA claims is here to stay. This article briefly examines the FCA and its application to claims brought against drug and medical devices companies, recent changes to federal laws and administration policies that will likely increase the frequency and potency of such actions, and some recommended strategies for handling such situations.

## I. Legal Analysis

### A. The False Claims Act and its Application to Drug and Medical Device Companies

#### 1. Background on FCA Claims Brought Against Drug and Medical Device Manufacturers

Generally speaking, the FCA<sup>11</sup> renders persons or entities who make false claims to the government liable for damages up to three times the amount of the erroneous or improper payment plus mandatory penalties for each false claim submitted. Specifically, 31 U.S.C. § 3729(a) states that persons or entities are liable under the FCA where they “knowingly present[], or cause[] to be presented, a false or fraudulent claim for payment or approval.” Where such a “false claim” for payment has been made, the federal government may bring a civil action to enforce the FCA.<sup>12</sup> The statute also contains a *qui tam* provision authorizing private persons to bring, as relators, civil actions on behalf of the United States<sup>13</sup> and the federal government has the option to intervene in a *qui tam* action and assume primary responsibility over it.<sup>14</sup>

In the case of prescription drug and medical device manufacturers, many FCA claims are premised upon allegations that manufacturers knowingly engaged in the off-label promotion of their products and that those actions caused the manufacturers to improperly obtain payments from Medicare or Medicaid for the purchase of the products.<sup>15</sup> It is

<sup>9</sup> See <http://www.fda.gov/Drugs/Guidance/ComplianceRegulatoryInformation/Surveillance/DrugMarketingAdvertisingandCommunications/ucm209384.html>.

<sup>10</sup> Anna Edney, *Drug-Firm Executives Under New Scrutiny in Medicare Fraud*, THE WASHINGTON POST, November 9, 2010.

<sup>11</sup> 31 U.S.C. §§ 3729 et seq.

<sup>12</sup> 31 U.S.C. § 3730(a).

<sup>13</sup> 31 U.S.C. § 3730(b).

<sup>14</sup> See *id.*

<sup>15</sup> See, e.g., *United States ex rel. Poteet v. Bahler Medical, Inc.*, 619 F.3d 104 (1st Cir. 2010), *Hopper v. Solvay Pharmaceuticals, Inc.*, 588 F.3d 1318 (11th Cir. 2009), *United*

important to note that most courts have determined that the mere fact of violating FDA regulations does not translate into liability for causing a false claim to be filed.<sup>16</sup> Indeed, the claimant must generally show that the defendant manufacturer: 1) made a false statement or engaged in a fraudulent course of conduct; 2) that was made or engaged in with the requisite scienter; 3) which was material; and 4) caused the government to pay out money or to forfeit moneys.<sup>17</sup> However, in the many cases involving whistleblowers, whether they are participating as a witness for the federal government or bringing the action as a relator, the hurdles presented by these elements are often not difficult to surmount.<sup>18</sup>

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States ex rel. Piacentile v. Sanofi Synthelabo, Inc., No. 05-2927, 2010 U.S. Dist. Lexis 137895 (D. N.J. Dec. 31, 2010), United States ex rel. Bennett v. Medtronic, Inc., No. H-08-3408, 2010 U.S. Dist. Lexis 105018, \*53 (S.D. Tex. Sept. 30, 2010).

<sup>16</sup> See *Hopper*, 588 F.3d at 1328; see also *Bennett*, 2010 U.S. Dist. Lexis 105018 at \*53.

<sup>17</sup> See, e.g., United States ex rel. Longhi v. Lithium Power Techs., Inc., 575 F.3d 458, 467 (5th Cir. 2009); see also *Hopper*, 588 F.3d at 1326, *Bennett*, 2010 U.S. Dist. Lexis 105018 at \*43, *Piacentile*, 2010 U.S. Dist. Lexis 137895 at 16-17.

<sup>18</sup> A recent article published in the New England Journal of Medicine suggests that 90% of health care fraud cases are qui tam actions initiated by whistleblowers with “direct knowledge of the alleged fraud to initiate the litigation on behalf of the government.” Aaron S. Kesselheim et al., *Whistle-Blowers’ Experiences in Fraud Litigation against Pharmaceutical Companies*, NEW ENGLAND JOURNAL OF MEDICINE, May 13, 2010.

Whether or not the government intervenes in such cases, the relator is eligible to collect a portion of any damages awarded.<sup>19</sup> Accordingly, though the FCA provides a financial incentive that encourages would-be relators to expose instances of fraud, it also attracts persons looking to capitalize on alleged acts of fraud that have already been exposed by others. To protect against such parasitic qui tam actions, the FCA contains a provision disallowing qui tam actions that are premised upon prior public disclosures of fraud.<sup>20</sup> This provision is often referred to as the “public disclosure” bar.

## 2. Use of the Public Disclosure Bar as a Defense in Qui Tam Actions

Prior to the passage of the recent Healthcare Reform Legislation, the ability of a defendant to utilize the public disclosure bar as a defense to a qui tam action was broadly construed, relatively speaking.

Specifically, the ability of an FCA defendant to use this defense was predicated on a three-fold inquiry: 1) whether there has been a prior, public disclosure of fraud; 2) whether the prior disclosure of fraud emanated from a source specified in the FCA’s public disclosure provision; and 3) whether the relator’s qui tam action is “based upon” that prior disclosure of fraud.<sup>21</sup> For this purpose, the FCA provided three classes of sources or contexts for such public

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<sup>19</sup> 31 U.S.C. § 3730(d).

<sup>20</sup> 31 U.S.C. § 3730(e).

<sup>21</sup> See, e.g., *Poteet*, 619 F.3d at 109.

disclosures that bar qui tam actions, which were identified in 31 U.S.C. § 3730(e)(4)(A) as follows:

No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.<sup>22</sup>

The scope of these categories have generally been applied broadly in the defense of FCA claims. Notably, several courts previously found that “[a] prior, public disclosure of fraud occurs ‘when the essential elements exposing the particular transaction as fraudulent find their way into the public domain.’”<sup>23</sup> Thus, any transactions or allegations discussed in federal or state civil court filings, or administrative actions at the federal, state, or even local level, would qualify as a public disclosure barring a qui tam action.<sup>24</sup> The majority of the courts subscribe to the general rule that “a

disclosure is ‘public’ if it is generally available to the public,” and that any qui tam claims based upon such disclosure should therefore be dismissed unless the relator was the “original source” of such disclosure.<sup>25</sup> Further, for the purpose of this section, “original source” means an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the government before filing an action under this section which is based on the information.<sup>26</sup>

### **B. Changes to Federal Law and Policies That Will Give Rise to Increased FCA-Based Claims**

Sweeping changes have since been made to the FCA by virtue of the recently passed Healthcare Reform Legislation, the most critical of which involve limitations on the ability to use the public disclosure defense, and a broadening of the definition for original sources of such disclosures. These changes, coupled with other policy initiatives by the federal government, suggest that both the government and private parties will be able to bring FCA claims against drug and medical device manufacturers more easily and will have greater success in prosecuting such claims.

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<sup>22</sup> 31 U.S.C. § 3730(e)(4)(A) (2009) (emphasis added); *see also* United States ex rel. Paranich v. Sorgnard, 396 F.3d 326, 333 (3rd Cir 2005).

<sup>23</sup> *Poteet*, 396 F.3d at 110; *see also* United States ex rel. Ondis v. City of Woonsocket, 587 F.3d 49, 54 (1st Cir. 2009).

<sup>24</sup> *Poteet*, 396 F.3d at 110, *see also* Graham County Soil and Water Conservation Dist. v. United States ex rel. Wilson, 130 S. Ct. 1396, 1405-1406 (2010).

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<sup>25</sup> *Poteet*, 396 F.3d at 110, *see also* United States ex rel. Maxwell v. Kerr-McGee Oil & Gas Corp., 540 F.3d 1180, 1185 (10th Cir. 2008), United States ex rel. Feingold v. AdmindaStar Fed., Inc., 324 F.3d 492, 497 (7th Cir. 2003).

<sup>26</sup> 31 U.S.C. § 3730(e)(4)(B) (2009).

## 1. Limitations to Public Disclosure Defense

With the passage of the healthcare reform legislation, Congress has significantly limited the contexts in which disclosures are presumptively made public and which therefore subject any qui tam action premised thereon to dismissal. Specifically, 31 U.S.C. § 3730(e)(4)(A) now reads as follows:

The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed:

- (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party; or
- (ii) in a congressional, Government Accounting Office, or other Federal report, hearing, audit, or investigation; or
- (iii) from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.<sup>27</sup>

The critical changes enacted with these amendments include the ability of the government to object to dismissal based on the public disclosure bar, stripping such defense of the jurisdictional effect it was previously

given, as well as limiting the contexts from which public disclosures may be taken in civil litigation to filings in “federal” actions in which the government is a party. Based on these amendments, qui tam actions premised upon disclosures made in state civil filings or federal filings in which the government or its agent is not a party, or that are made in state or local administrative hearings – both of which had previously been appropriate contexts from which the subject allegations or transactions would have been deemed a public disclosure – may not now be used as a proper basis for asserting the public disclosure defense. In sum, the general rule that “a disclosure is ‘public’ if it is generally available to the public” is no longer true in FCA-based qui tam actions.

Congress has also simultaneously broadened the definition of “original source” as that term is used in 31 U.S.C. § 3730(e)(4)(B). As indicated in the statutory language above, the original source provisions of the FCA effectively provides a savings clause for actions brought by the “original source” of the information upon which an FCA lawsuit was based. Accordingly, irrespective of whether information is publicly disclosed, the person who is the “original source” of such information may nonetheless proceed with the initiation and prosecution of a qui tam action.

Following the revisions imposed by the Healthcare Reform Legislation, the term “original source” is now defined as follows:

For the purposes of this paragraph, “original source” means an individual who either (1) prior to a public

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<sup>27</sup> 31 U.S.C. § 3730(e)(4)(A)(2011) (emphasis added).

disclosure ... has voluntarily disclosed to the government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegation or transaction, and who has voluntarily provided the information to the Government before filing an action under this section.<sup>28</sup>

Based on this revision to the definition of “original source,” which had previously required that such persons have “direct and independent” knowledge of the information at issue, the federal government has relaxed this standard to allow more qui tam suits by those without “direct” knowledge. Relators now need only have information that is “independent of and materially adds to the publicly disclosed allegation or transaction,” greatly expanding the pool of potential relators that may bring a qui tam claim.

## 2. Policy Initiatives Supporting Future FCA Claims

The significance of these amendments are underscored when considered in connection with recent policy initiatives by FDA and other branches of the federal government which appear to reach out to potential whistleblowers or other supporters of FCA-based claims against drug and medical device manufacturers.

An excellent example of such a policy is the FDA’s “Bad Ad Program,”

an outreach initiative which effectively seeks to deputize prescribing physicians in its efforts to crack down on the off-label promotion of prescription drugs. As explained by the FDA, the “Bad Ad Program” is an outreach program administered by the Division of Drug Marketing, Advertising, and Communications that is intended to “educate healthcare providers about the role they can play in helping the agency make sure that prescription drug advertising and promotion is truthful and not misleading.”<sup>29</sup> The purpose of such program is to “help healthcare providers recognize misleading prescription drug promotion and provide them with an easy way to report this activity to the agency.”<sup>30</sup> Given the nature and express purpose of this program, there is a considerable threat that such initiative may be used by the FDA as a means of culling evidence and identifying potential whistleblowers who will be able to support an FCA lawsuit. Moreover, such programs may ultimately cause physicians to bring qui tam claims themselves, as it appears the “Bad Ad Program” will provide them the tools and ability to more easily recognize advertising and promotions that are off-label. This is especially concerning for drug manufacturers given the significantly relaxed definition provided for “original sources” in the FCA, thereby potentially causing the “Bad Ad Program” to be an FCA claim recruitment tool.

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<sup>29</sup> <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/DrugMarketingAdvertisingandcommunications/ucm209384.htm>.

<sup>30</sup> *Id.*

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<sup>28</sup> 31 U.S.C. § 3730(e)(4)(B)(2011).



The prospect of increased future FCA claims is also supported by recent proclamations by the federal government regarding bans on drug and medical device executives who have allegedly engaged in acts of healthcare fraud.<sup>31</sup> Specifically, the Department of Health and Human Services' Office of the Inspector General has stated that executives can be barred from contracting with federal health programs when they knew, or if the inspector concludes they should have known, about fraud at their firms.<sup>32</sup> Based on this threat, the risk posed by an FCA claim to a drug or medical device manufacturer is compounded by the threat of future lost business, and may therefore facilitate the process by which settlements are reached in such cases.

With these new policies, there can be little doubt that drug and medical device manufacturers can expect an increase in FCA-based claims in the future and must accordingly devote company time and resources to protect against such claims.

## **II. Recommendations for Further Handling**

### **A. Development of a Compliance Program**

Simply put, there is no magic pill for protecting a drug and medical device company against the threat of an FCA lawsuit. In large part, companies should emphasize to their sales representatives and others interacting with physicians and

device users the changed landscape and adverse consequences of off-label promotion. To that end, companies should be careful to do what has always been required of them by the FDCA with regard to the advertising and promotion of their products—namely, developing a compliance program that oversees the training of their sales representatives and employees in charge of marketing such that they understand the significant ramifications of off-label advertising and promotion. To this end, companies and their lawyers should develop a program that includes, but is not necessarily limited to, the following:

- Training for all sales representatives regarding the FDA-approved uses for their drugs and medical devices, including examples of promotions that are permissible and those which would be considered off-label;
- Explanations of the key statutes, regulations, and product approvals to company sales representatives and marketing personnel which outline the parameters of their discussions with physicians and other customers who purchase their drugs and medical devices; and
- Specific instructions and training to sales representatives on how to handle questions from physicians regarding the appropriate uses of the prescription drugs or medical devices being sold, including possibly reporting such questions to the manufacturer so

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<sup>31</sup> Anna Edney, *Drug-Firm Executives Under New Scrutiny in Medicare Fraud*, THE WASHINGTON POST, November 9, 2010.

<sup>32</sup> *Id.*

it can evaluate the most appropriate responses to questions involving potential off-label uses.

In making these recommendations, it is important to note that, despite the need for the manufacturer's sales representatives and marketing personnel to limit their discussions about any prescription drug or medical device product to those uses for which it was approved by the FDA, a physician's independent decision to use a particular product off-label is a medical decision that is both permissible and in fact encouraged by the FDA.<sup>33</sup> Accordingly, though company sales representatives and marketing personnel are prohibited from affirmatively promoting the off-label use of their prescription drug and medical device products, they are under no obligation to dissuade physicians from using them in a manner for which such products were not approved.

### **B. Handling of Potential Whistleblowers**

In addition to developing a sturdy compliance program, it is also important to have policies and procedures in place that address the treatment of whistleblowers who may become government witnesses or *qui tam* relators. Critically, with the increased incentive for employees, physicians and other business partners to make reports of alleged off

label marketing, whether the assertions are warranted or not, companies should be well prepared as to how to handle these whistleblowers.

To avoid potential physician whistleblowers who could be part of the Bad Ad program, companies should continue to avoid off label promotion or marketing. However, companies should need not actively discourage off label use, as the limited regulation of a physician's off-label uses of a product by the FDA "is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine."<sup>34</sup>

For whistleblowers who are employees of the company, the following are some examples of how to handle the employee:

- **No Retaliation:** Ensuring that a whistleblower is not retaliated against is important to protect against any possible employment claims that may be brought by the employee for adverse employment actions taken as a result of their work, and which may be a violation of state or federal law.
- **Potential Monitoring of Communications:** Instituting a policy that allows for the monitoring of employees' use of firm resources, including the use of firm emails and computers, may help protect against inappropriate mining of confidential, trade secret, sensitive, and privileged

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<sup>33</sup> See *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 350 (2001); see also *In re Gilead Sciences Securities Litigation*, 536 F.3d 1049, 1051 (9th Cir. 2008).

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<sup>34</sup> See *Buckman*, 531 U.S. at 350.

information to fuel actions against the company. Specifically, monitoring e-mail, Internet usage, and file access may assist in the identification of potential problems and evidence that would otherwise be used in an FCA action before such a lawsuit is instituted. However, companies must be sure that such monitoring is allowed in your particular state or jurisdiction and that applicable employee policies adequately disclose the company's policy in this regard. Moreover, to the extent an employee has already initiated his or her assistance in the prosecution of an FCA claim, the company must be careful not to single that employee out for monitoring, as such conduct may be perceived to be a form of retaliation.

- **Employee Leaving Organization:** It is very important to clearly identify those materials that are the property of the company and which must be collected prior to the employee leaving its employment. This includes the development, initiation and implementation of policies which ensure that all company documents and resources (i.e., laptops, cell phones, and the like) are collected prior to any employee's departure.
- **Disciplinary Action:** Where it is determined that employees are engaging in off-label promotion, the company should consider the

appropriate response, including additional emphasis and training on the prohibited behavior or possibly termination. The ability of the government or a private party to succeed in bringing an FCA claim requires evidence that the company had the appropriate intent to defraud the federal government. Accordingly, policies and/or other efforts by the drug or medical device company which clearly demonstrate an effort to protect against the type of prohibited, off-label promotions at issue in these cases may be helpful in demonstrating the lack of intent by the company to perpetrate the alleged fraud.

### III. Conclusion

The future promises to bring increased risks of criminal and civil lawsuits against manufacturers of pharmaceuticals and medical devices. The best defense is to be well prepared to both prevent and to defend against such actions.