Whistleblowers:
Treat Them With Kid Gloves

by John R. Fleder

Introduction

Two food companies purchase adulterated and misbranded products from their respective suppliers. The purchased products are not actually "pure" products (as the suppliers claimed), but rather "chemical concoctions" of ingredients that the suppliers manufacture to look, taste and smell like pure products. These concocted products are naturally much cheaper.

Both companies are nationally known food companies. Employees of both companies raise serious concerns internally, both in writings and in meetings. The concerns are that the suppliers' products are phony, and that the food companies' products are not what the labels say they are. The Food and Drug Administration (FDA) ultimately learns that both companies sold adulterated and misbranded products, and that they had received warnings about the integrity of the products from the companies' own employees.

These facts would suggest that both companies' conduct could result in similar harsh treatment from the federal government. Each company violated the Federal Food, Drug, and Cosmetic Act (FDCA) and conceivably did so with fair warning that they were violating that Act. However, one company (and its top executives) was criminally prosecuted. That prosecution resulted in serious consequences for the company.

In contrast, even though the conduct of the other company was thoroughly investigated, the government never initiated criminal charges, and its investigation never became public information.[1] Why?

In the case of the first company, upper management ignored or ridiculed the concerns raised by the company's employees. At trial, the defense could not point to a single document that reflected any concern about the validity of the disgruntled employees' allegations, any effort to refute those concerns, or any remedial action taken as a result of the allegations. In contrast, the second company sought to address, in written communications and in meetings, each of the concerns that the company's lower-level employees had raised.

Criminal prosecutions initiated for violations of the FDCA frequently, if not commonly, involve situations where current or former company officials provide federal investigators with information that the company has intentionally violated the FDCA. Evidence that a company and its officials have intended to violate the law is what most federal prosecutors look for in deciding whether to bring criminal charges against a company and its executives. It is hard to downplay the importance to prosecutors of getting evidence from company "insiders" that proves that the company intentionally violated the law.

In fact, the Department of Justice (DOJ) announced last fall that whistleblower lawsuits, where a person seeks a monetary bounty, have overtaken the FDCA case referral system whereby potential cases go from FDA to DOJ. It indicated that although many such whistleblower suits have been filed in the off-label use arena, DOJ expects that similar suits will be filed in other areas, such as when companies' products are not safe and companies have not timely reported safety issues to FDA. DOJ even predicted future whistleblower cases in the food area, even though most FDA-related whistleblower cases have involved drugs or devices.[2]

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I. Whistleblower Statutes

There are a number of federal statutes that authorize private persons to initiate law suits against companies that allegedly violate federal laws. Perhaps the best known, and most commonly used, statute is the federal False Claims Act (FCA), 31 U.S.C. § 3729 *et seq.* The FCA prohibits the filing of false claims for payment by the United States or the making of a false statement to avoid payment of an obligation to the United States. Violations of the FCA are subject to treble damages and civil penalties. The Attorney General can initiate a FCA action. Alternatively, the FCA allows for *"qui tam"* enforcement, where private citizens (Relators) can initiate and attempt to litigate FCA actions on behalf of themselves and the federal government.

Qui tam actions are commenced by a Relator filing a civil complaint in a federal district court. The action is filed under seal, meaning that there is no public record that the case has been filed, and the public cannot review the complaint. The FCA provides the federal government with an opportunity to join the lawsuit on behalf of the United States, or alternatively, to allow the Relator to pursue the case on his own. However, there is typically an important middle step. DOJ conducts an independent review of the allegations and, in certain instances, conducts a secret investigation intended to facilitate a decision about whether it should join the case. That investigation can include reviewing documents and speaking to persons (often current or former company employees) knowledgeable about the allegations contained in the Relator's complaint.

The government generally works closely with the Relator to assemble a case against the company. Sometimes those employees, current or former, are visited at their homes by government agents. The company being investigated often has little or no role in that investigation, and may not even know of the existence of the lawsuit or investigation for years.

The dangers to a company are many. Its internal company secrets (including documents) are provided to the government without notice to the company. The company has little or no ability to respond quickly to the allegations. More troublesome is that the company, which is unaware of the lawsuit or the allegations on which it is based, often does not change the practices which are at issue in the case. This "failure" to change the practices could well lead to increased damages and penalties sought by the Relator and/or the DOJ.

There have been many recent FCA cases brought against companies regulated by FDA, where the defendants have been accused of engaging in practices that allegedly violated the FDCA. For instance, in 2009, Pfizer and Eli Lilly collectively paid over $3.7 *billion* to resolve FCA cases. The Relators received in excess of $180 million as their share of the money collected from the companies.

Many whistleblowers argue that the financial rewards they receive are not adequate to compensate them for what many persons believe is the end of their careers in an industry. Put another way, would a prospective employer hire someone who was a recognized whistleblower at another company? The answer is probably no in most instances. Nevertheless, in the recently announced *qui tam* off-label use settlement involving AstraZeneca, the media reported that the former sales representative who filed the lawsuit against the company was the same person who filed the Lilly case.[3]

The FCA also contains a specific provision that seeks to protect certain "whistleblowers." An employee who is discharged or demoted, etc. by his employer because of lawful actions taken in furtherance of an FCA action is entitled to court-ordered relief "to make the employee whole" including reinstatement, back pay and other monetary relief.[4]

Another statute employed to protect so-called whistleblowers is the Sarbanes-Oxley Act of 2002.[5] It provides "whistleblower protection for employees of publicly-traded companies by prohibiting their employers from retaliating against them for providing information or cooperation in certain investigations.[6]

II. Dealing With Whistleblowers

With these statutorily-created incentives in place to reward and protect whistleblowers, an obvious question is: how then do companies deal with whistleblowers and potential whistleblowers? That is actually a simple question to answer: carefully!

Employees often have what they consider to be important "grievances" with management. Nevertheless, frequently employees who do not like being supervised or managed will complain to fellow employees about trivial matters, or topics as to which the employee lacks enough information to express justifiable criticism. A person is not a whistleblower just because he claims to have a grievance. Indeed, companies must be able to separate valid concerns raised by employees from meritless whining. The company is certainly not legally or otherwise obligated to make changes simply because some employee raises a concern.

However, think about the damage that a whistleblower can do to a company if that person takes his concerns outside of the company. As noted above, whistleblower lawsuits can cause great damage to a company, including potential monetary judgments and embarrassment. Even the filing of an unmeritorious case will typically result in costly attorneys' fees. In addition, company officials can find their day-to-day jobs complicated by having to be deposed or otherwise become involved in the defense of the case.

As a result, companies should have procedures in place to deal with persons who raise internal concerns about the company's practices. Here are a few examples of procedures that companies can consider:

Exit interviews—Companies should take particular care to ask departing employees, particularly those who have voiced discomfort about company practices, to provide detailed information about any practice the employee found objectionable. The company can then conduct an investigation, if warranted. Having an exit interview record of the employee's complaint makes it harder for the employee to later claim that he had orally complained about topics that were not covered in the exit interview. Outside counsel should be brought in to advise the company as to how to handle a departing disgruntled employee so that proper steps can be taken to make certain that the company generates a solid record in the event the employee later sues the company. Appropriately (but carefully) responding to an exiting employee's concerns can sometimes mollify the employee, and avoid the risk that the employee will take his concerns outside the company. Also, fixing any real, as opposed to asserted, problems that the exiting employee raises can give a company a head-start before the government raises those same concerns if the employee approaches the government.[7]

Responding to a Whistleblower's Concerns—So-called whistleblowers often raise concerns about a company's practices in one-on-one meetings, emails, larger meetings, and memos that are circulated to other employees. Whistleblowers will often secretly tape record conversations where they raise concerns to supervisors, hoping that the supervisor will say something that the whistleblower can later cite against the company. Disgruntled employees may also write memos to their own files seeking to document what allegedly occurs in a conversation or meeting.

When the government conducts an investigation, the whistleblower will often provide the government with the whistleblower's internal "warning" statements and documents. That will typically be a one-sided presentation of what has actually occurred in the company. All too often, company supervisors will choose to ignore a whistleblower's complaints. Alternatively, the supervisors may choose to provide an oral response to the employee, but never document that a response was given or put in writing the nature or substance of the response. A problem then arises when a case comes to court and the whistleblower's allegations are presented to support the proposition that the company was put on specific notice that the whistleblower believed that the company had engaged in wrongful practices. What is the company's response? If (as in the case of the second company mentioned at the beginning of this article), the company can provide the government with contemporaneously written notes, emails or memos refuting the whistleblower's allegations, the company can be well on its way to proving that it took the employee's complaints seriously and contemporaneously refuted them. However, if management does not contemporaneously write a document that refutes the allegations, the company will almost certainly have great difficulty proving to either the government or a jury that the company provided the appropriate response to the complaining employee.

Try to Keep the Disgruntled Employee's Concerns within the Company—If a current or former employee takes concerns to the government, it is almost certainly too late for the company to take remedial actions. Once a company learns that a government investigation has commenced, the company will get little to no credit for subsequent remedial steps that it may take. In contrast, if the company learns from a complaining employee that the company has engaged in some type of improper practice *and* the company initiates remedial action, the company has made a record that it corrected a problem even without the threat of a government action. Moreover, if other employees hear that concerns are taken seriously by their employer, those employees too will be likely to address their concerns within the company, rather than running to the government or filing a lawsuit.

Of course, these comments do not suggest that companies should change their practices just because an employee has complained or because the company fears that the employee might complain or sue. Companies have every right to refuse to alter a practice if the company makes a good-faith determination that the employee's allegations are without merit.

III. Should the Company Self-Report a Problem to FDA?

This is one of the hardest issues that arises for companies regulated by FDA. If a company self-reports an FDCA violation, will the government reward or punish the company? The Act itself, FDA regulations and FDA's public statements provide little, if any, clear guidance. Companies often decide to let the "sleeping dog rest," thereby choosing not to self-report violations. This strategy has undoubtedly worked in companies' favor on many many occasions as FDA never learns of the problem and thus never takes action against the company.

On the other hand, every employee is a potential whistleblower. Today's happy employee can be terminated simply due to a company's need to downsize. Many company employees who are unhappy when they are terminated look for revenge. They often seek legal counsel knowledgeable about the protections and remedies available to whistleblowers. A decision by a company to keep an FDA-related problem within the company (and thus not self-report to the FDA), leaves the company at risk that the employee will contact FDA or some other government agency. Once the government commences an investigation of the company, such as by issuing a subpoena, it is usually too late for the company to maintain control of the situation.

There is no "one size fits all" resolution to this quandary. What is clear is that the company's decision to self-report, or not self-report, a so-called whistleblower's concerns could turn into a decision that could impact the survival of the company.

Conclusion

People become whistleblowers for many reasons, including to get revenge. Many people do so hoping to recover money. The monetary rewards available to whistleblowers, and the recoveries from companies regulated by FDA, prove that the whistleblower industry is a fast-rising and potentially troublesome worry for companies. No company can keep all current and former employees from providing information to the government in all instances. However, every company should examine its procedures for dealing with employees' FDA-related concerns, and devise or maintain policies that minimize the risks that a current employee will become a whistleblower who takes his or her concerns to the government or the courts.

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1 The author participated in the prosecution of the first company and supervised the investigation of the second company when he was employed by the DOJ.

2 Remarks by Eugene M. Thirolf, Director, Office of Consumer Litigation, Civil Division, DOJ to FDLI Enforcement Conference, Oct. 2009.

3 *See Whistleblower Twice Over: First Lilly, Now AstraZeneca*, Wall Street Journal, Apr. 28, 2010, *available at* http://blogs.wsj.com/health/2010/04/28/whistleblower-twice-over-first-lilly-now-astrazeneca/tab/print/. Astra Zeneca agreed to pay $520 million to settle claims that it had illegally marketed a drug for uses that FDA had not approved.

4 31 U.S. C. § 3730(h).

5 18 U.S.C. § 1514A.

6 *See* Livingston v. Wyeth, Inc., 520 F.3d 344 (4th Cir. 2008) (discharged employee alleged that he had complained about company's failure to implement a training program concerning FDA-related matters).

7 Some companies attempt to have departing employees sign a release to bar subsequent suits against the company. In United States v. Purdue Pharma L.P., 600 F.3d 319 (4th Cir. 2010), the court examined such a release in the context of a FCA case. The Relator entered into a broadly-worded general release that barred him from suing the company. Thereafter, he filed a FCA action. The court affirmed dismissal of the case on the ground that the release barred the FCA action. It is noteworthy that the government was aware of the conduct alleged in the Relator's Complaint *before* he filed his action.