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Keeping the Whistle Away From the Whistleblower: The Laboratory Compliance Officer's Role in Qui Tam Avoidance

Do you, as a laboratory compliance officer, want to spare your employer the disruption, expense, and burden of a government enforcement action? The answer, of course, is "yes." The most effective and efficient way of doing so is to take steps to reduce the likelihood that a whistleblower will bring a qui tam action against your laboratory. Why? Because most government enforcement actions begin with the filing of a qui tam complaint by a whistleblower. And laboratories have been the subject of many qui tam cases.

What Is the Role of Whistleblowers in Health Care Enforcement?

Reports issued by the U.S. Department of Justice (DOJ) confirm that the vast majority of cases that it has opened since 2008 have been the result of qui tam complaints. These cases are brought to the government by those with knowledge about conduct that they deem to be fraudulent. These complaints are authorized by the federal False Claims Act, which encourages the filing of such suits through the promise to whistleblowers of a share of the federal recovery, usually in the range of 15 percent to 30 percent. These payments to whistleblowers are known as whistleblower's share.

The role of these cases in federal enforcement is most dramatically illustrated by reviewing the numbers. In 2008, the DOJ opened 291 new False Claims Act cases; 231 (79 percent) of them came from whistleblowers. In 2009, the DOJ opened 312 new cases; 278 (92 percent) of them came from whistleblowers. In 2010, the DOJ opened 424 new cases; 383 (95 percent) of them came from whistleblowers. And in 2011, the DOJ opened 454 new cases; 417 (91 percent) of them came from whistleblowers. Thus, qui tam cases filed by whistleblowers have escalated at dramatic rates.

The role of whistleblowers is confirmed by the following statistics:

- Since 1996, private individuals have initiated more than 7,800 qui tam actions.
- In 2011, whistleblowers were the source of 91 percent of health care False Claims Act cases (compared with 35 percent in 1991).

A similar picture emerges from a review of the settlements and judgments secured by the government during this time frame:

Year	Non-Qui Tam	Qui Tam
2008	$162,108,253	$953,405,040
2009	$238,081,424	$1,394,619,974
2010	$539,043,024	$2,011,445,536
2011	$178,147,545	$2,257,683,198

You, as a compliance officer, should take note of the growing importance of whistleblowers and qui tam cases in government enforcement and may wish to consider whether you have a new job to do in seeking to avoid the filing of qui tam cases against your laboratory. Creating a qui tam avoidance program seems to fit within the compliance officer's role. But a natural question is what is such a program and what can it do? Answering the following questions will help you create such a program.

Who Are the Whistleblowers?

A first task is to recognize who whistleblowers are. Looking at who brought some of the cases that were settled in 2011 is a good first step.

Novo Nordisk	Oscar Montiel, a former medical liaison. Ian Black, a former U.S. Armed Forces physician.
KV Pharmaceuticals	Constance Conrad, who is described as having some 30 years' experience in federal health care programs—she is also a relator in the Healthpoint Ltd. qui tam (filed in 2011) and other past cases.
Medtronic	Kathy Onwezen, clinical specialist in the Cardiac Rhythm Management Sales and Sales Support Division. Elaine Bennett, sales representative at Boston Scientific's Cardiac Surgery Division (competitor). Alan Brill, senior tachyarrhythmia field engineer and responsible for the training and education of Medtronic's field staff. Adolfo Schroeder, (unknown).
Guidant, LLC	Robert A. Fry, former sales agent for Guidant.
GE Healthcare Inc.	James Wagel, a pharmaceutical representative selling Bristol-Myers's radiopharmaceutical drug Cardiolite.
LHC Group Inc.	Judy Master, who discovered the fraud while she worked for a consulting firm LHC had used.
Medline Industries	Sean Mason, formerly employed by Medline in positions related to customer contracts and account management.
Fresenius Healthcare	Julie Williams, former employee of subsidiary Renal Care Group. Dr. John Martinez, nephrologist.
Maxim Healthcare (2011)	Richard West, a disabled Medicaid patient in Ocean City, N.J.

Thus, whistleblowers can be sales representatives, physicians, trainers, consultants, patients, current employees, former employees, competitors, and customers, just to name a few. Most often, they seem to be current or former employees who are unhappy about the way they have been treated.

Whistleblowers file qui tam suits for a variety of reasons: some are crusaders who want to improve the way the defendant operates while others are professional whistleblowers who bring such suits against numerous defendants and do so, at least in part, to gain payment of whistleblower's share.

So, in developing a qui tam avoidance program, it is useful to think about these two types of whistleblowers.

How to Minimize Risk of a Qui Tam Suit

Crusaders often bring qui tam suits because they feel that they have not been heard and their concerns have not been addressed. Crusaders can be frustrated current or former employees. As a general matter, crusaders bring their concerns to the company before they file qui tam suits. Thus, one way to think about whistleblowers who are current or former crusader employees is that they are human resource problems gone bad. So, how does one minimize the risk of that outcome?

First, strengthen your relationship with the laboratory's human resources professionals and work together in this effort.

Second, make sure that all compliance complaints are investigated and that the complainants (if they have identified themselves) know that you are looking into their concern and that you are taking it seriously. If the allegation raises significant issues, consult knowledgeable counsel about how to conduct an internal investigation; it may be advisable to have external counsel conduct the inquiry under the attorney-client privilege.

If the complainant is anonymous, ask counsel how to manage an internal investigation under such circumstances and still deal, if possible, with the need to inform employees that compliance is on the job. The risk with anonymous complaints is that the complainant feels that inadequate attention is being directed to the complaint and that the matter should be brought to the government's attention through the filing of a qui tam suit. This really does happen.

Third, walk the talk. Periodically ask all employees whether they have any compliance questions or concerns, and, if they do, ask them to tell you what those concerns are, reminding them that they will be protected from retaliation. If they report that they have no compliance concerns or questions, ask that they sign and date a form saying that. If they report compliance concerns, ask that they list them on the form and sign and date it. This completed form will give you a work list from which to begin your inquiries and will create a record that you asked and the information on the form is what you were told.

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Fourth, carefully plan all reductions-in-force to reduce the risk that such actions will create whistleblowers. Consult employment and health care counsel experienced in such matters to assist you in planning and executing the reductions.

Fifth, conduct comprehensive exit conferences with all departing employees. Remind them of how important compliance is to the laboratory and ask them to help you by providing you with all of the information they have about all of their compliance concerns, if any. Ask that they sign and date a statement listing the concerns that they have reported, and, if they have said that they have no concerns, ask that they sign and date a statement saying that.

Other Whistleblowers

Other crusaders can be independent contractors hired by the laboratory, patients served by the laboratory, customers of the laboratory, and competitors to the laboratory. How can you deal with them? Make sure that they know that you have an active and comprehensive compliance program. Make your policies available to them. Ask that they communicate with you if they have any compliance concerns and respond quickly if and when you learn that they do; take their concerns seriously and make sure that they know that you do.

How can a compliance officer deal with the possibility of a professional whistleblower? This category of whistleblower is more difficult to deter. Keeping a list of those who have served as whistleblowers can be helpful, but this is a daunting and difficult task.

What other steps can a laboratory compliance officer take to avoid qui tam cases? Of course, having an active, comprehensive, and effective compliance program is one key to avoiding qui tam cases. However, laboratories with such programs have found themselves defending cases brought by qui tam whistleblowers. So, what else can you do?

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Testing how your compliance program is being perceived is a first step. How visible is the program? Do those subject to the program believe that it is part of the fabric of the laboratory's operations and culture? Do they believe that complaints are handled promptly and adequately? Do they feel that they are heard?

The issue of self-disclosure is increasingly important, given the fact that failure to disclose and refund Medicare Part A and Part B overpayments within 60 days is now an independent ground for violation of the False Claims Act and will thus likely be the basis for qui tam suits and whistleblower scrutiny.

Making sure that your compliance program is keeping up is an important second step. When a qui tam case has been settled, new whistleblowers can be created who bring similar suits against similar types of entities. This has happened to laboratories. So, be vigilant about settlements and new cases and make sure that your compliance program addresses the issues raised by them and does so in a highly visible way.

Similarly, consider how you are going to incorporate new regulatory requirements into your compliance program.

Finally, carefully consider when and how to make disclosures to the government. This is probably an area where counsel should be consulted. The issue of self-disclosure is increasingly important, given the fact that failure to disclose and refund Medicare Part A and Part B overpayments within 60 days is now an independent ground for violation of the False Claims Act and will thus likely be the basis for qui tam suits and whistleblower scrutiny.

Is it worth the time and effort to implement a qui tam avoidance program? Without a doubt, it is—your laboratory will thank you!

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