Burgeoning Whistleblower Considerations for Health Care Employers

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Even as they endeavor to digest the formidable obligations imposed and on the horizon by virtue of the Patient Protection and Affordable Care Act (PPACA),[1] health care companies need to remain watchful for increased exposure to whistleblower claims for awards and employment protections. Enactment of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank),[2] together with amendments to the False Claims Act (FCA)[3] and the Sarbanes-Oxley Act (SOX)[4] and administrative interpretations, indicate significantly expanded coverage and a new need for vigilance.

Unquestionably, the health care sector of the U.S. economy is destined to receive heightened attention for its prominence, growth as a portion of gross domestic product, the importance of both public and private expenditures and impact on every person in the country. With such a growing impact, it is certain that individuals having sensitive non-public information about compliance and breaches will have an increasing role. More than ever, the legal environment presents the challenge of whether those individuals will bring information that is vital to a business and the sound management of its affairs home within the organization so appropriate responses may be formulated, or whether there will be a lure to take the information outside to enforcement agencies or courts for personal advantage.

Seen in that context, whistleblowers – those having information valuable to a business and its compliance objectives – have the potential to become partners in assuring that corporate leaders receive reliable information on which they can act to govern corporate affairs or reset a course, consistent with internal and externally imposed codes of conduct or ethics. But whistleblowers do not always proceed through internal channels as altruists committed to advancing corporate interests. Instead, many may be lured by personal interests and gain, opportunistically or even parasitically.

Whistleblowers and the False Claims Act

The FCA remains the federal government's primary weapon in its pursuit of health care companies. Amendments to the FCA, made through the Fraud Enforcement and Recovery Act of 2009 (FERA)[5] and PPACA, have made it easier for whistleblowers, known under the FCA as *qui tam* relators, to bring claims and to win enormous awards – 15 percent to 30 percent of the monies recovered.[6]

The Department of Justice (DOJ) recently reported that recoveries, settlements and judgments in cases involving health care fraud totaled $2.5 billion in FY 2010, representing 83 percent of the total fraud recoveries for that fiscal year.[7] Significantly, most of those cases were brought to the government by relators, who recovered $385 million for themselves. Since 1986, recoveries in *qui tam* cases have exceeded $18 billion and relators have obtained personally more than $2.8 billion.[8] As is evident, the potential for significant financial gain is both real and substantial. Moreover, companies face potentially ruinous fines and damage awards resulting from whistleblower activity – treble damages and the payment of a relator's costs and attorneys' fees, in addition to fines of $5,500 – $11,000 per false claim. This, of course, is in addition to the exposure to being excluded from participation in federal health care programs which can result in the event a FCA action is brought successfully against a company.

Significantly, the FCA is being pursued ever more broadly. For example, claims going to the quality of services rendered and products supplied – and not merely to financial and billing practices – are increasing. This is evidenced by a recent settlement of $750 million that yielded a $96 million award to a former global quality assurance manager who blew the whistle, citing pharmaceutical products claimed to be contaminated or adulterated and facility processes claimed to not control quality and the accurate formulation of ingredients.[9] In short, recent activity goes well beyond false or fraudulent invoicing, and exposure need not be based on recent statutory expansion of jurisdiction by PPACA or Dodd-Frank.

The SOX Whistleblower

Recent administrative interpretations of SOX whistleblower protections have moved the needle significantly beyond shareholder and securities frauds, the inspiration and predicate for SOX whistleblower protections enacted in the wake of the notorious Enron and WorldCom financial scandals. Administrative decisions thus far in 2011 reach far beyond threshold concerns for the "innocent investor." As a consequence, health care companies subject to Securities and Exchange Commission (SEC) jurisdiction by virtue of registered securities or reporting obligations are now squarely in an enlarged arena and exposed to whistleblower claims alleging retaliation for protected activity.

Ground for expansion of whistleblower protections was broken by a Department of Labor Administrative Review Board (ARB) opinion holding that a Lockheed Martin Director of Communications engaged in activity protected by SOX when she reported: (1) concerns that a vice president to whom she reported had developed paramours through Lockheed's Pen Pal Program, which was created to facilitate communications between Lockheed employees and U.S. soldiers serving overseas; and (2) her belief that costs associated with the vice president's travel and expensive hotels to rendezvous for intimate relations with soldiers, limousines and purchase of sex toys – not quantified in the decision – were charged to the federal government under an existing contract for the Pen Pal Program.[10] The vice president had used the mail to send letters soliciting prospective paramours, and her billing occurred by mail or wire of items to the U.S. government as part of the Pen Pal Program. The ARB affirmed a decision of an administrative law judge, finding that the employee engaged in protected activity for reporting misconduct related to mail fraud and wire fraud.[11]

A recent ARB opinion goes farther than the Lockheed decision to show the potential exposure of health care companies. A decision involving Parexel International, a publicly-traded company that tests drugs for drug manufacturers and others, shows that the ARB intends construing SOX whistleblower protections in a way that goes to core business activity – substantially beyond shareholder fraud and protection of innocent investors.[12] As SOX complainants, a manager having responsibility to ensure that data adhered to the Food and Drug Administration's "Good Clinical Practice" (GCP) standards and a nurse responsible for reporting accurate clinical data claimed that they suffered unlawful reprisals for their internal reports that time points were not recorded accurately, resulting in false clinical data. Although no shareholder fraud was alleged, the false data was alleged to have been communicated through the U.S. mail and by wire communications such as the Internet. Addressing the protected activity, the ARB interpreted SOX whistleblower protections expansively, ruling that:

- fraud against shareholders ranks as only one of six categories of frauds enumerated in SOX Section 806: mail fraud, wire, radio, television fraud, bank fraud, securities fraud, any rule or regulation of the SEC, or any provision of federal law relating to fraud against shareholders;[13]
- a complaint of shareholder or investor fraud is not required to establish SOX-protected activity;[14] and
- requiring a complainant to prove or approximate the specific elements of a securities law violation would contradict SOX's requirement that an employee have only a reasonable belief of a violation of the enumerated statutes.[15]

The *Parexel* opinion also establishes that a SOX whistleblower can assert a successful claim to statutory protection even without alleging – much less proving – materiality or shareholder reliance or loss.[16] If not reversed by an appellate court and if followed, and possibly expanded further by current and future ARB members, *Parexel* portends significantly more whistleblower claims by employees who observe and report incidents of compliance breaches and later suffer adverse employment actions that they claim are linked to their whistleblowing.

Further Expansion by PPACA and Dodd-Frank

PPACA provided additional tools for the whistleblower. In 2009, a number of amendments to the FCA were made through the enactment of FERA. Pertinent to any discussion about PPACA is the "reverse false claims" provision which appears in Section 3729(a)(1)(G) of the FCA, one of the results of FERA. This section extended FCA liability to one who "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or *knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government*" (emphasis added). Under this amended section, no affirmative step, such as the making of a false record or statement, is necessary to trigger liability; an "obligation" is defined to include the retention of an overpayment from the Government. Thus, if the Government pays too much, but the recipient fails to return it, the recipient is subject to FCA liability.

PPACA provided greater clarity with regard to the liability for overpayment retention. It defined as an overpayment any Medicare or Medicaid funds that a person received or retained which, after applicable reconciliation, the person was not entitled to. It also provided a deadline for reporting and returning the overpayment – the later of 60 days after an overpayment is "identified" or the date of the corresponding cost report. An overpayment retained after reconciliation is an obligation subject to FCA liability.

While the term "identified" is not defined (and will likely be the subject of fervent litigation in the near future), it is evident that overpayments will now become fertile ground for potential whistleblowers. This new liability exposure also expands the pool of individuals who could become potential relators.

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In addition, PPACA amended the FCA's public disclosure bar and original source exception. Before PPACA, a court did not have jurisdiction over an FCA matter brought based on the public disclosure of allegations 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 person bringing the action was the Attorney General or was the "original source" of the information. The 2010 PPACA amendment of the FCA expands the likelihood that relators who are not the original source of information will qualify for awards and narrows the public disclosure bar by removing a qualification concerning court "jurisdiction" with respect to an action "based upon the public disclosure of allegations or transactions…." In place of those measures, PPACA amends the FCA with language that: "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…." among other things "in a congressional, Government Accountability Office or other federal report, hearing, audit, or investigation."[17] In other words, PPACA removed the jurisdictional bar, and provided for the dismissal of a claim under these circumstances "unless opposed by the Government." Moreover, while previously an "original source" had to possess "direct and independent knowledge" of the information, PPACA relaxes that requirement and allows one with knowledge that "is independent of and materially adds to the publicly disclosed allegations or transactions" to satisfy the standard.[18] It also limited the definition of public disclosures to be only those from federal sources.[19]

These amendments also make it easier for a claim to be brought. They leave to the Government's discretion whether a case, based on publicly disclosed allegations and not brought by an original source, may proceed. They also narrow the potential public sources subject to preclusion and expand the definition of who can qualify as an original source. The end result of these changes: greater opportunity for potential relators and more risk areas for businesses.

Dodd-Frank

Like those in other industries, health care companies would be mistaken to believe that Dodd-Frank whistleblower protections are limited to matters affecting only financial services firms concerned with "Wall Street Reform and Consumer Protection" – as the legislation's name logically would connote. In fact, any company subject to SEC jurisdiction for registration or reporting that could potentially be investigated and sanctioned by the SEC is exposed to bounty awards and whistleblower protections of Dodd-Frank. A monetary award – of not less than 10 percent and not more than 30 percent – may be granted to one or more whistleblowers who voluntarily provide original information or analysis leading to the successful enforcement of a judicial or administrative action brought by the SEC or certain regulatory and enforcement authorities that results in monetary sanctions exceeding $1,000,000.[20] Among the potentially fertile areas that whistleblowers may target, outside of securities fraud and insider trading, are violations of the Foreign Corrupt Practices Act (FCPA),[21] concerning unlawful foreign trade practices.

The FCPA contains two types of provisions: (i) anti-bribery provisions, which prohibit corrupt payments to foreign officials, political parties, or political candidates to assist in obtaining or retaining business or securing an improper advantage, and (ii) accounting provisions, which impose certain record keeping and internal control obligations on companies whose securities are registered in the U.S. or that are required to file reports with the SEC. The FCPA is jointly enforced by the Department of Justice (DOJ) and the SEC, with DOJ having primary responsibility for enforcing the anti-bribery provisions while the SEC acts as the civil enforcement authority that enforces the accounting provisions. In recent years, both DOJ and SEC have significantly ramped up enforcement of the FCPA, leading to a dramatic increase in the number of cases and record settlement amounts. The pharmaceutical and medical device industries have become objects of particular focus of this increased enforcement. DOJ believes that the pharmaceutical and medical device industries are particularly vulnerable to public corruption due to the fact that foreign governments frequently regulate, operate, and finance health systems and state owned health care facilities in their countries.

By incentivizing individuals with knowledge of a compliance breach to go outside an organization to an enforcement agency, Dodd-Frank's lure of rich bounty awards could undermine otherwise effective corporate compliance programs. Furthermore, protection against discharge or other adverse employment actions is available to a whistleblower who possesses a "reasonable belief" that information provided in an appropriate manner to the SEC relates to a "possible" securities law violation (or certain violations of SOX) that has occurred, is ongoing, or is about to occur.[22] The protections against employment reprisals are available even if the whistleblower does not satisfy requirements, procedures, and conditions to qualify for a bounty award.[23]

Conclusion

Actions by the legislative and executive branches create unprecedented whistleblower incentives and protections. Virtually no business can compete with the rich awards available to FCA relators or Dodd-Frank tipsters – nor should it. But if businesses are to effectively manage their affairs, they need to be assured that each individual having valuable information of compliance breaches shares that information in a constructive manner that serves organizational interests. A strong code of conduct showing the organization's commitment to compliance by its visible action is essential to a convincing message that the organization takes these matters seriously. Moreover, a "culture of compliance" works best when adopted from the top down so it resonates within the organization; thus, it is critical to show employees that senior management takes compliance seriously. As part of this demonstration, employees need to understand that meeting compliance standards is a factor of success measurement, considered in evaluations, advancement opportunities and compensation.

Strong controls and devices as part of the compliance program to monitor, detect and address violations become an essential companion to announced policies, reinforced by orientation, periodic scheduled training and acknowledgments and compliance certifications. Waiting until a compliance breach – or internal or published reports of one – has occurred loses the opportunity to get ahead of issues and control them, with consequential fallout. Issues of this nature frequently are best addressed by appropriate investigation and decision making in real time. This also shows potential whistleblowers that the organization will act swiftly and appropriately when an issue arises – that by acting internally, they will be taken seriously and can be part of the solution. It gives sound reason to look internally and not externally.

Of course, follow up with a complaining employee to confirm that something was done with a complaint sends a reinforcing message, even if the matter, the organization's appropriate treatment of it and the response remain confidential.

Clearly, not all whistleblowers want to "fix" the problem. But to reach those who want to be part of the solution, giving a reason to work with the organization, not against it, can yield tangible dividends. ■

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1 Pub. L. No. 111-148, 124 Stat. 119 (2010).

2 Pub. L. No. 111-203, 124 Stat. 1376 (2010).

3 *See* 31 U.S.C. §3730.

4 *See* 18 U.S.C. §1514A.

5 Pub. L. No. 111-21, 123 Stat. 1617 (2009).

6 31 U.S.C. §3730(d)(1) and (2).

7 *See* Press Release, Department of Justice, *Justice Department Recovers $3 Billion in False Claims Cases in Fiscal Year 2010* (Nov. 22, 2010).

8 *Id.*

9 *Analysis: U.S. whistleblower awards rise as fraud cases grow*, Reuters, October 29, 2010. [http://www.reuters.com/article/2010/10/29/us-whistleblowers-awards-analysis-idUSTRE69S4LZ20101029].

10 *Brown v. Lockheed Martin*, ARB No. 10-050, ALJ No. 2008-SOX-049 (ARB Feb. 28, 2011). (The decision does not indicate whether an FCA claim was filed as well.).

11 *Id.* slip op. at 9-10.

12 *Sylvester et al. v. Parexel International LLC*, ARB, No. 07-123, ALJ Nos. 2007-SOX-39 and 42 (May 25, 2011).

13 *Id.* slip op. at 20.

14 *Id.* slip op. at 19.

15 *Id.* slip op. at 22.

16 *Id.* slip op. at 22.

17 31 U.S.C. §3730(e)(4).

18 *Id.*

19 *Id.*

20 15 U.S.C. §78u-6(b)(1).

21 15 U.S.C. §§78dd-1, et seq.

22 17 C.F.R. §§240.21F-2(b)(1)(i),(ii).

23 17 C.F.R. §§240.21F-2(b)(1)(iii).