

BEWARE

OF FALSE

CLAIMS ACT

In-house Counsel Beware:

The False Claims Act Might Impact Your Business



YOU HAVE ALL SEEN THE HEADLINES trumpeting the government's latest recovery of tens, or even hundreds, of millions of dollars for fraud committed by healthcare providers. For example, in June 2009 the Office of Inspector General (OIG) of the Department of Health and Human Services announced that it expected recoveries of more than \$2.4 billion for the first half of fiscal year 2009. The primary weapon used by the government to recover such vast sums has been the civil False Claims Act (FCA), a statute originally enacted to reach fraud by government contractors that has also been used extensively against healthcare providers for more than 15 years. Two features of the FCA make it a particularly potent weapon. First, it imposes liability of treble damages plus potentially ruinous civil penalties. Second, the FCA permits whistleblowers to initiate an action in the name of the United States in return for 15-30 percent of any recovery by the government.

Until now, those of you who work for companies that are neither government contractors nor healthcare providers have been able to largely ignore the FCA and watch from the sidelines. Not anymore. As a result of the financial meltdown of 2008-2009, Congress amended the FCA to (1) apply to companies that receive, directly or indirectly, federal Troubled Asset Relief Program (TARP) stimulus or other bailout funds; and (2) make it easier for whistleblowers and the United States to initiate and prosecute an FCA action. For example, under the revised FCA, if your company applies for a loan from a bank that has received federal bailout funds or is insured by a recipient of such funds, the FCA may now apply to the loan transaction and you ignore the FCA at your peril. You can protect yourself and your company by adopting and implementing a compliance program that sets forth standards of lawful and ethical conduct, educates employees about those standards and monitors their adherence.

By Charles R. Ching, Harry R. Silver and Laura Laemmle-Weidenfeld

The False Claims Act

A brief overview of the history of the FCA will put the 2009 amendments in perspective and provide necessary background to those of you who will have to deal with the act for the first time.

The FCA imposes liability for knowingly presenting a false or fraudulent claim for payment. 31 USC § 3729(a). The statute was enacted in 1863 in response to repeated reports of war profiteers selling the Union Army's lame horses, boxes of "sugar" filled with sand and other similarly defective products.¹ The FCA contained a bounty hunter provision that permitted a private citizen to initiate an action on behalf of the United States and provided for the recovery of double damages, with the government and the bounty hunter each receiving one-half. In that manner, the wrongdoer was penalized, the government made whole and the bounty hunter rewarded. This type of action was and is known as *qui tam*, an abbreviation of a Latin phrase referring to one who sues on behalf of the sovereign as well as himself. The bounty hunter, or whistleblower, is known as the relator.²

The act was not substantially amended until 1943, following a Supreme Court ruling that a relator was entitled to the 50 percent bounty even though he had literally copied a criminal indictment and incorporated the allegations into a *qui tam* complaint.³ The Roosevelt administration, incensed that relators could profit by giving the government back its own information, sought the total repeal of the *qui tam* provisions of the FCA. When Congress refused, the administration settled for the next best thing: rendering the *qui tam* feature virtually useless. The FCA was amended to provide that prior government knowledge of the allegations in a *qui tam* complaint was an absolute bar to the case. In addition, the bounty was reduced to 10-25 percent. Not surprisingly, the number of *qui tam* actions dwindled.⁴

The pendulum swung back in 1986, at the height of the Reagan administration's defense buildup. In response to reports of government purchases of \$600 toilet seats and \$400 hammers, Congress increased the bounty relators could recover and made it easier for relators to initiate actions and establish liability. Specifically, the 1986 amendments allowed relators to once again initiate FCA lawsuits based upon information that was already in the government's possession, as long as the relator was the "original source" of the information. 31 USC § 3730(e)(4)(A).



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Congress also eliminated specific intent to defraud as an element of FCA liability, requiring only the "knowing" submission of a false claim. 31 USC § 3729(a),(b). Finally, Congress increased the bounty to 15-30 percent of the government's recovery. 31 USC § 3730(d).

The 1986 amendments had the intended result, but not against the intended target. Soon after passage of the amendments, the defense buildup of the 1980s ended. By the mid-1990s, however, as reported by BNA's Medicare Report of June 14, 1996, Attorney General Reno had identified healthcare fraud as "one of the highest priorities" of the Justice Department. This was, in large part, due to the huge potential recoveries available against healthcare providers. Section 3729(a) of the FCA provides for treble damages plus a civil penalty of \$5,000-\$10,000 per claim, which has been adjusted for inflation to \$5,500-\$11,000 per claim. The penalties weren't that onerous when the act was applied to government contractors. A contractor working on a large defense contract would usually invoice the government once a month. A large urban hospital, however, submits hundreds of claims per day to Medicare and Medicaid. At \$5,500-\$11,000 per false claim, the potential damages became staggering for healthcare providers.

Not only did healthcare become a priority for the government, but relators also noticed the size of potential recoveries and, using the incentives provided by the 1986 amendments, turned their attention to the healthcare industry. By fiscal 2001, the transformation of the FCA from a government contracts statute to a healthcare statute was dramatically illustrated: As reported by the December 11, 2001 edition of BNA's *Federal Contracts Reporter*, 75 percent of the \$1.6 billion the government recovered in civil fraud actions was recovered against healthcare providers in Medicare and Medicaid cases. In November 2007, the Justice Department said that the United States obtained \$2 billion in settlements and judgments in fraud cases during fiscal year 2007. "Of the \$2 billion, \$1.45 billion is associated with suits initiated by whistleblowers under the False Claims Act's *qui tam* provisions." DOJ went on to state that "healthcare accounted for the lion's share of fraud settlements and judgments — \$1.54 billion." Finally, according to DOJ, "[t]his brings total recoveries since 1986, when Congress substantially strengthened the civil False Claims Act, to more than \$20 billion." A November

2008 Justice Department press release announced recovery of an additional \$1.34 billion in fiscal 2008.

The Fraud Enforcement and Recovery Act of 2009

Congress responded to the collapse of the financial and real estate markets, and the resulting bailout packages, by

Seven Elements of an Effective Compliance Program

- 1. Written Policies and Procedures and Standards of Conduct.** Compliance plans start with a written code of conduct or similar document that sets forth the company's expectations of ethics and compliance. This document helps set the tone and level of expectation for the organization. If certain conduct is prohibited, it must be clearly stated in the policies and procedures.
- 2. Compliance Officer and Compliance Committee.** Every organization with a compliance program should appoint a compliance officer to assume lead responsibility for compliance functions in the organization. It is critical that the compliance officer be provided the tools to do his or her job effectively, including adequate personnel and budget.
- 3. Training and Education.** Companies must provide clear training and education to all employees regarding how they are to perform their jobs and what risky behavior they should avoid. This training process should begin on their first day with the organization and should continue throughout their tenure.
- 4. Effective Lines of Communication.** Companies should ensure that there is a clearly understood method for communicating concerns about compliance issues, including confidentiality and non-retaliation policies.
- 5. Enforcement of Standards.** Your company must enforce compliance rules and regulations through well-publicized disciplinary guidelines. The seriousness with which an organization takes the compliance program is evidenced by how stringently and consistently it is enforced.
- 6. Monitoring and Auditing.** Regular internal audits are critical to monitoring the company's internal processes to ensure that the compliance program is working and that compliance problems are being avoided — or at least promptly identified and corrected.
- 7. Responding to Detected Problems.** When allegations of problems are brought to the attention of the compliance officer or other management, the company must have an established procedure under which it will investigate and rectify the problems.

enacting the Fraud Enforcement and Recovery Act of 2009 (FERA). In enacting FERA, Congress amended both the criminal code and the FCA. The Senate Report accompanying FERA explained:

As we learn more and more each day about the causes of this debacle, it is clear that unscrupulous mortgage brokers and Wall Street financiers were among the contributors to this economic collapse. With the new tools and resources in this bill, it will be easier to ensure that all of those responsible for these financial crimes are held accountable.⁵

FERA amended the definition of “financial institution” in the criminal code to make it applicable to mortgage lenders not insured or regulated by the government.⁶ FERA also made it a crime to make a materially false statement or willfully overvalue a property to influence an action by a mortgage lender⁷; and made the criminal federal fraud statute applicable to TARP and other stimulus funds.⁸

The financial meltdown also gave Congress the opportunity to broaden the scope of the FCA and, particularly, to overrule several court decisions interpreting the FCA in favor of defendants. In overruling these decisions, however, Congress appears to have overshot the mark and imposed potential FCA liability on businesses, industries and transactions that have nothing to do with “unscrupulous mortgage brokers and Wall Street financiers.”

The FCA Amendments Under FERA

Prior to its amendment by FERA, the FCA, in 31 USC § 3729(a)(1), imposed liability on any person who “knowingly presents, or causes to be presented *to an officer or employee of the United States Government or a member of the Armed Forces of the United States* a false or fraudulent claim for payment or approval.” (Emphasis added). The DC Circuit, in an opinion written by Judge (now Chief Justice) Roberts, ruled in *United States ex rel. Totten v. Bombardier Corp.*, 380 F.3d 488 (DCCir. 2004), that this section of the FCA must be read literally: A claim must be “presented to an officer or employee of the United States” for liability to attach. Since the allegedly false claim in *Totten* was “presented” to Amtrak, a government grantee, the court held that the claim did not come within the scope of the FCA. To remedy this, FERA deleted the italicized language from § 3729(a)(1) to ensure that “liability under section 3729(a) attaches whenever a person knowingly makes a false claim to obtain money or property, any part of which is provided by the government without regard to whether the wrongdoer deals directly with the Federal government.” (Senate Report at 11.) Thus, a false or fraudulent claim that is presented to a government contractor, subcontractor, grantee or sub grantee is now within the scope of the FCA.

FERA overruled another judicial decision, this one by the Supreme Court. Prior to FERA, section 3729(a)(2), imposed liability on any person who “knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim *paid or approved by the government.*” (Emphasis added). In *Allison Engine Co. v. United States ex rel. Sanders*, 128 S.Ct. 2123 (2008), the Supreme Court ruled that section 3729(a)(2) required the government or a relator to prove that the defendant intended the United States itself to pay the claim. Under this interpretation, there would be no FCA liability if a subcontractor submitted a false claim to a prime contractor unless it could be proven that the subcontractor intended to defraud the United States. In FERA, Congress deleted the italicized language and inserted the word “material,” so that the section now imposes liability on anyone who “knowingly makes, uses or causes to be made or used a false record or statement material to a false or fraudulent claim.” A similar change was made to § 3729(a)(3), which involves conspiracies to submit false claims.

Another significant change FERA made to the FCA was to expand the so-called “reverse false claims” provision to make it illegal to retain funds known to have been paid in error. The prior version of the statute’s “reverse false claims” provision made it unlawful to use a false record or statement to conceal, avoid or decrease an obligation to pay money to the United States. See 31 U.S.C. §3729(a)(7) (1986). Although the government often argued that this provision applied in circumstances where a defendant had received payment improperly (either following the submission of a false claim or simply in error) and failed to repay it, courts seldom adopted the government’s interpretation. The government itself rarely pursued in earnest, since typically these situations did not involve the use of a false record or statement to affirmatively conceal, avoid or decrease the obligation to pay money.

FERA expands the reverse false claim provision by, in effect, adopting the government position. It is now a violation of the FCA to “knowingly conceal[] or knowingly and improperly avoid[] or decrease[] an obligation to pay” the United States. 31 USC §3729(a)(1)(G). In other

Changes to the False Claims Act

- **Under the FERA amendments, the FCA no longer requires a false claim to be presented to an officer or employee of the United States for liability to attach.** The amended FCA imposes liability to anyone who knowingly presents or causes to be presented to a prime contractor, subcontractor, federal grantee or sub grantee.
- **The FERA amendments remove the requirement from the FCA, as interpreted by *Allison Engine*, that liability requires proof of intent to defraud the United States.** FERA deleted the language imposing liability for submitting a claim or statement designed “to get” false claims paid or approved “by the government.” The FCA now requires a false statement to be “material to a false or fraudulent claim.”
- **FERA extends liability to anyone participating in a conspiracy to decrease an obligation owed to the United States.** Until the FERA amendments, the FCA’s conspiracy section was limited to claims for payment, which courts had interpreted to exclude “reverse” false claims, or claims or statements made for the purpose of decreasing a liability to the government. The FERA amendments ensure that the conspiracy provision covers the reverse false claim situation. Using the Recovery Act as an example again, a grantee with a requirement for matching funds could be liable under the FCA for participating in a conspiracy to submit false claims or statements aimed at reducing the amount of matching funds.
- **FERA expands the definition of “claim” to include claims made to any “recipient” of funds where the money is to be spent or used “on the government’s behalf or to advance a government program or interest” if the government has provided, or will provide, “any portion of the money.”** This FERA amendment to the FCA substantially expands the scope of the statute to include false statements made to receive funds supplied, in whole or in part, by the government to advance a “government program or interest.” If providing funds to banks so that they can make loans or insurance companies so they can pay claims, false statements in loan applications and insurance claims are now actionable under the FCA.
- **FERA expands the scope of so-called “reverse false claims.”** Another significant change FERA imposed on the FCA is to expand the “reverse false claim” provision to make it illegal to retain funds known to have been paid in error. The new provision does not require the submission of any false record or statement, but simply the act of concealing or even merely avoiding the “obligation” to pay back funds.

words, the new provision does not require the submission of any false record or statement, but simply the act of concealing or even merely avoiding the “obligation” to pay back funds. The statute defines “obligation” very broadly, to include an “established duty, whether or not fixed,” that can arise from various relationships, statutes or regulations, or even “from the retention of any overpayment.” 31 USC §3729(b)(3).

The statute raises — but fails to answer — a number of practical questions. First, what is the significance of the modifier “improperly?” At what point does the retention of an overpayment give rise to liability? Is the organization exposed to liability between the time it first identifies the possibility that a claim was improperly paid and the date it cuts a refund check or otherwise offsets the claim? Or is a reasonable time period to repay the overpayment implied? And what if the overpayment was received more than six years ago, outside the statute of limitations for

federal common law claims — and arguably even the FCA? These and many other issues will likely become the source of heated debate in the context of upcoming investigations and litigation.

The most far-reaching change in the FCA brought about by FERA, however, is among the least noticed. Congress intended to address the district court decision in *United States ex rel. DRC, Inc. v. Custer Battles, LLC*, 376 F.Supp. 2d 617 (E.D.Va. 2006) which held that fraud involving Iraqi funds, administered by the United States on behalf of the Iraqi people, was not actionable under the FCA because the United States did not have title to those funds. The solution chosen by Congress was to define the term “claim” to mean “any request or demand . . . for money or property whether or not the United States has title to the money or property, that . . . is made to a contractor, grantee or other recipient if the money or property is to be spent or used on the government’s behalf or to advance a government program or interest . . .” if the United States has provided, or will provide, “any portion of the money or property.” 31 USC §3729(b)(2)(A). The statute contains no definition of “on the government’s behalf” or “a government program or interest.”

This truly radical change renders the FCA breathtaking in its scope. The new definition of “claim” literally means that any request for money made to any “recipient” of funds that have been or will be provided by the government “to advance a government program or interest” is within the scope of the FCA. If you do not think that this is groundbreaking change, consider who is receiving bailout funds and the purpose of those funds. *The Wall Street Journal* has reported that many small banks are receiving TARP funds. According to the *Journal*, Enterprise Bank, a small bank in Pennsylvania, “plans to funnel the money it got from the Treasury Department on June 12 into loans to fledgling businesses in western Pennsylvania.”⁹ This was obviously the “government program or interest” for which the money was provided. If any of those fledgling businesses in western Pennsylvania make a false statement in their loan applications, however, they well may be subject to suit under the FCA. Similarly, the government provided funds to insurance companies, presumably to allow them to continue paying claims to their policyholders. Certainly, the government provided some portion of any claims money paid by these companies. Under the amended FCA, a false statement made in support of a claim by a policyholder is arguably within the scope of the FCA.

One of the primary goals Congress sought to achieve in enacting FERA was the overturning of *Allison Engine*. Congress appears to have been more successful than many people realize. In *Allison Engine*, the Supreme Court stated that the FCA was not an “all-purpose antifraud stat-

ACC Extras on... The False Claims Act

ACC Docket

- *I Tell Them, I Tell Them Not: Deciding When and How to Disclose False Claims Act Lawsuits to Shareholders (Jan. 2008)*. Receiving a letter from the US government stating that a qui tam action has been filed against your company can be a nightmare for in-house attorneys ordered to stay quiet. This article helps you prepare for the tug-of-war between the laws and penalties that exist for violating a seal and those that require the disclosure of information to publicly traded companies. www.acc.com/docket/tellthem/jan_08

Webcast Transcript

- *The Federal False Claims Act — What Does It Mean for Nonprofit Organizations?* View this transcript on how the False Claims Act affects nonprofit organizations and companies. www.acc.com/webtrans/fca_nonprofits

Program Material

- *Government Contracts for the Generalist (Oct. 2008)*. This session delivered a primer on how contracting with federal agencies differs from private sector contracting and showed how to determine which statutes and regulations apply to your company. www.acc.com/govtcontracts_oct08

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ute.” 128 S.Ct. at 2130. As a result of FERA, that is exactly what the FCA has become.

How to Protect Yourself and Your Company

Healthcare providers and government contractors have long known that the best way to protect themselves against FCA liability was by adopting an effective compliance program. The first — and most obvious — reason for this is that an effective compliance program will prevent many compliance failures and will also alert the company to potential problems. In this manner, the potential for the submission of false claims can be minimized, if not eliminated. A second, less obvious reason is that the failure to have an effective compliance program can be deemed sufficient *scienter* to convert an innocent error or inadvertent regulatory requirement into fraud.

Even after the FERA amendments, the FCA still requires that a false or fraudulent claim be “knowingly” presented.¹⁰ The amended FCA still defines “knowing” and “knowingly” as actual knowledge that the claim is false, acting in deliberate ignorance of the truth or falsity of the information, or acting “in reckless disregard of the truth or falsity of the information.” The federal government takes the position — and the only court to address the issue agreed in a 2004 opinion — that an allegation that a company failed to maintain an *effective* corporate compliance program is sufficient under the FCA to allege that a company submitted false claims with “reckless disregard” of their falsity, even in the absence of any allegation that upper management had actual knowledge that false claims were submitted.¹¹

Creating an Effective Compliance Program

To be effective, a compliance program must have the support of the highest levels of the company. The board and senior management must be committed to the program and must evidence that commitment not only through direct written and verbal communications, but also by providing the necessary resources to the operation of the program. While organizations can vary significantly in size, industry and product, effective compliance programs have a number of common elements, often referred to as the “seven pillars of compliance.” These include implementing written policies and procedures; designating a compliance officer and committee; conducting effective training, education, internal monitoring and auditing; enforcing standards through well-publicized disciplinary guidelines; and responding promptly to detected problems and undertaking corrective action.¹²

Written policies and procedures. Compliance plans often start with a written code of conduct or similar document that sets forth the company’s expectations of ethics

and compliance. This document helps set the tone and level of expectation for the organization.

In addition, the organization must adopt specific written policies and procedures for key aspects of its operations, including those that carry the highest risk from an FCA liability perspective. Key policies and procedures can apply to all aspects of the organization’s business, such as vendor contracts, marketing, pricing, interactions with government representatives, reporting of compliance problems, and even specific manufacturing or audit processes. If certain conduct is prohibited, that prohibition must be clearly stated in the policies and procedures.

Compliance officer and committee. Every organization with a compliance program should appoint an officer to assume lead responsibility for compliance functions in the organization. In smaller organizations, this person may have additional responsibilities, whereas large organizations or organizations with a high level of compliance activity will likely limit his or her duties to compliance efforts. Regardless, it is critical that the compliance officer be provided the tools to do his or her job effectively, including adequate personnel and budget. The compliance officer should also be given a sufficiently senior title within the company to command the respect of the rest of the organization.

Citing concerns over independence and privilege, the government has strongly indicated a preference for having the compliance officer not report to either the chief financial officer or general counsel’s office. Regardless of the reporting structure’s details, the compliance officer should have authority to act and investigate compliance issues with a high level of independence and should have direct access to the board in the event that other reporting mechanisms fail.

The organization also needs a compliance committee to support the efforts of the compliance officer and to provide oversight. The committee should be comprised of high-ranking leaders of the organization with the authority to take necessary action.

Training and education. For employees to act responsibly within an organization and comply with its policies and procedures, they must know what those policies and procedures require and prohibit. Simply creating a binder or database of policies and procedures is ineffective at ensuring employees know what conduct is expected of them. Training and education is the single best way to avoid inadvertent compliance failures. Provide clear training and education to all your employees regarding how they are to perform their jobs and what risky behavior they should avoid. This training process should begin on their first day with the organization and should continue throughout their employment.

Effective lines of communication. Once you have established a strong compliance structure and you have trained your employees, you should ensure that there is a clearly understood method for communicating concerns about compliance issues. This must include confidentiality and non-retaliation policies so the employees will be comfortable. They should be encouraged to raise concerns with their supervisors, but many organizations also find it useful to establish a hotline or similar reporting mechanism whereby employees can anonymously communicate issues.

Auditing and monitoring. A compliance program also requires auditing and monitoring of the company's internal processes to ensure that the compliance program is working and that compliance problems are being avoided — or at least promptly identified and corrected. Regular internal audits are most critical. While some companies prefer using internal staff to conduct the audits, consider whether your organization has sufficient resources to execute audits and whether the individuals involved can be sufficiently objective.

Enforcing standards through disciplinary guidelines. Your company must enforce your compliance rules and regulations through well-publicized disciplinary guidelines. Having the best compliance policies, procedures and personnel in place will be useless unless your employees understand that the price for committing compliance violations is disciplinary action, up to and including termination. The seriousness with which your organization takes the compliance program is evidenced by how stringently and consistently it is enforced.

Responding to detected problems. The final element of an effective compliance program is establishing mechanisms to respond to problems that are brought to the company's attention and developing corrective actions to resolve those problems. When allegations are brought to the attention of the compliance officer or other management, the company must have an established procedure under which it will investigate and rectify the problems. This means conducting an investigation to get to the root cause of the issue and then correcting the problem moving forward, including analyzing whether any repayment must be made and/or whether the issue should be disclosed to the relevant government agency.

Good Employee Relations

One final way that you can protect your company is to make sure that management understands the importance of maintaining good employee relations. Remember that one of the reasons the FCA has become such a feared and dangerous weapon is that the qui tam provisions allow a private individual to initiate an action under the FCA. Because employees are the people most

likely to be aware of legal or regulatory violations, most relators are current or former employees. While there is a common perception that relators are only greedy individuals who see a qui tam action as a winning lottery ticket, in fact, many relators started out as conscientious employees who attempted to advise management that the company was not in compliance with applicable legal requirements. These employees are often ignored and treated as nothing more than abrasive troublemakers. This is a huge mistake.

If, for example, an employee in the billing department of a hospital tells management that the hospital is submitting Medicare claims that he or she believes are not in compliance with Medicare billing rules, the employee may well be right, in which case ignoring her can lead to disaster. Even if the employee is mistaken, however, if she is not satisfied that her complaints were taken seriously, she can quickly become disgruntled. As a result, a diligent — if annoying — employee has been transformed into a disgruntled employee (or former employee). From here, it is a short and easy step to qui tam relator.

You can prevent qui tam suits by taking all complaints, objections and questions seriously. This means treating a complaining employee with dignity and explaining that the complaint was taken seriously and was fully investigated. If the practice in question is consistent with applicable law, the employee should be given the reasons for this determination. Ensuring that all employees raising compliance allegations are treated with respect is key to limiting the likelihood that an employee will become a relator. ❏

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NOTES

- 1 *United States ex rel. Newsham v. Lockheed*, 722 F.Supp. 607, 609 (N.D. Cal. 1989).
- 2 *Id.*
- 3 *See United States ex rel. Marcus v. Hess*, 317 U.S. 537 (1945).
- 4 *See, United States ex rel. Springfield Ry. Terminal v. Quinn*, 14 F.3d 645, 649-50 (D.C.Cir. 1994); *United States ex rel. LaValley v. First National Bank of Boston*, 707 F.Supp. 1351, 1354-55 (D.Mass. 1988).
- 5 S.Rep. 111-10, 111th Cong., 1st Sess. at 2.
- 6 18 U.S.C. § 20.
- 7 18 U.S.C. § 1014.
- 8 18 U.S.C. § 1031.
- 9 *The Wall Street Journal*, June 27-28, 2009, at B1.
- 10 31 U.S.C. § 3729(a)(1)(A),(B).
- 11 *United States v. Merck-Medco Managed Care, L.L.C.* 336 F. Supp. 2d 438, 440-41 (E.D. Pa 2004).
- 12 *See, e.g.*, Department of Health and Human Services Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003).