

## EXPERT ANALYSIS

### Blowing the Whistle on Fraud In The Health Care Industry

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Suppose you are an employee of one of the largest drug retailers in the United States. In addition to the drugs you sell to the general public, your employer also sells pharmaceuticals to the U.S. government.

Through your work, you discover that the company is routinely charging government health programs more than it charges the general public for the same drugs.

When you notify your supervisor of the issue, your concerns are brushed aside. You know that it is wrong for the company to take advantage of taxpayers in this way, but you aren't sure what you can do about it.

According to Thomas Proctor, this was the situation in which he found himself at Safeway Pharmaceuticals, where he was employed as a licensed pharmacist at the end of 2013.<sup>1</sup>

Fortunately for Proctor, a 154-year-old statute called the False Claims Act exists, under which he was able to report this fraud to the U.S. Department of Justice and put himself in a position to receive a significant reward as a result. Lawsuits like Proctor's are known as "qui tam" actions, and the whistleblowers who bring them are referred to as "relators."

#### FCA'S ROLE IN COMBATING HEALTH CARE FRAUD

The FCA was passed during the Civil War in response to reports of theft and misappropriation of money that was meant to be spent on the war effort. After the war, the FCA lay largely dormant for several generations, until it was revitalized by a series of amendments that passed in 1986.<sup>2</sup> The act was further strengthened by additional amendments in 2009 and 2010.<sup>3</sup>

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The government's recovery stems from penalties the government levies against individuals and companies who are found to have violated the act, including between \$5,000 and \$10,000 per offense and three times the amount of damages the government sustained as a result of the fraudulent act.

In other words, if a company is caught defrauding the government out of \$10 million, it may be liable to the government for more than \$30 million.

Whistleblower-relators like Proctor have been a huge boon to the DOJ and to the American public. From 1987 through September 2016, the DOJ collected more than \$53 billion for U.S. taxpayers from companies alleged to have defrauded the government.<sup>4</sup> Of that, over 70 percent — nearly \$37.7 billion — came as a result of qui tam actions filed by whistleblowers like Proctor.



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Notably, almost \$34 billion of that \$53 billion was collected from companies in the health and human services industry.

Whistleblowers in the health and human services industry save taxpayers money and serve the public by identifying a wide range of conduct amounting to fraud against the government.

Some fraudulent schemes are as simple as the one alleged by Proctor. According to the court's opinion in the case, the company engaged in "a centrally controlled scheme to charge government health plans more than the general public for the same drugs, in order to receive a higher reimbursement than it was legally and contractually entitled to receive."

In the health care arena, many more violations occur when companies fail to keep promises they make to receive government contracts.

Some of the most common such violations involve off-label marketing, kickbacks, failure to report adverse events and violations of current good manufacturing practices.

These violations may form the basis for what are known as "false certification" FCA claims, which come in two types:

Within the theory of false certification, there are two further categories: express and implied false certification. A defendant violates the FCA under express false certification when, in conjunction with a request for federal funds, it certifies that it is in compliance with regulations that are requirements for payment. An FCA violation occurs under implied false certification when a defendant submits or causes to be submitted a request for payment without disclosing that it is in violation of a regulation that affect[s] its eligibility for payment.<sup>5</sup>

Resolving a split in the lower courts, the U.S. Supreme Court in *Universal Health Services Inc. v. United States* recently confirmed that these types of violations can form the basis for a qui tam action.<sup>6</sup>

## WHAT TO KNOW WHEN CONSIDERING BLOWING THE WHISTLE

Health care industry whistleblowers often have a wide array of concerns, but three questions consistently arise:

- What kinds of information or documentation are needed to support a viable qui tam claim?
- Would removing records that support their claims place them in violation of the patient privacy requirements of the Health Insurance Portability and Accountability Act?
- What protections do they have against retaliation for reporting their employer's fraud to the government?

The remainder of this analysis will address these three questions.

### *The need to be specific*

The most important thing prospective whistleblowers should know is that the information they provide must be specific. The court in the Safeway case explained it this way:

Because the FCA is an anti-fraud statute ... the claims under it are subject to the heightened pleading requirements of [Federal Rule of Civil Procedure] Rule 9(b). Therefore, a party must state with particularity the circumstances constituting fraud. The requirement of pleading fraud with particularity includes pleading facts that make the allegation of fraud plausible. The complaint must state the identity of the person making the misrepresentation, the time, place and content of the misrepresentation, and the method by which the misrepresentation was communicated to the plaintiff.

Due to the heightened pleading requirements for qui tam actions, a whistleblower seeking to bring such an action must possess detailed information about the fraud before the commencement of

a lawsuit; they will not be able to access such information through discovery before their lawsuit is subject to dismissal. Thus, a whistleblower should be able to answer these questions with specificity:

- What fraud is occurring, i.e., what misrepresentations are being made to the government?
- If the fraud is a “false certification,” then what rules, regulations or statutes is the company violating?
- How widespread is the fraud, and how has the company systemically condoned or encouraged it?
- Over what period of time did the fraud occur, and is it ongoing?
- What is the impact of the fraud on the government or the public?

This last question is particularly important in false-certification cases in light of the Supreme Court’s decision in *Universal Health Services*, which emphasized the importance of whether compliance with a particular rule or regulation was material to the government’s decision to pay a claim.

In that case, the high court made clear that “not every undisclosed violation of an express condition of payment automatically triggers liability. Whether a provision is labeled a condition of payment is relevant to but not dispositive of the materiality inquiry.”

The court went on to state that:

The materiality standard is demanding. The False Claims Act is not an all-purpose anti-fraud statute, or a vehicle for punishing garden-variety breaches of contract or regulatory violations. A misrepresentation cannot be deemed material merely because the government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment. Nor is it sufficient for a finding of materiality that the government would have the option to decline to pay if it knew of the defendant’s noncompliance. Materiality, in addition, cannot be found where noncompliance is minor or insubstantial.

In addition to describing evidence that it deemed insufficient to establish materiality, the court provided an example of evidence that would likely suffice: namely, evidence that the government “consistently refuses to pay claims” in the majority of cases based on similar forms of noncompliance.

Because materiality must also be pleaded, a whistleblower whose qui tam action would proceed under a false-certification theory should be prepared to show with specificity how his company’s statutory or regulatory violations would be material to the government’s decision to grant the company’s contract and subsequently pay its claims.

### **Avoiding HIPAA violations**

Whistleblowers in the health care industry face an added complication in compiling the specific information necessary to sustain a qui tam case: If their use of company records places them in violation of HIPAA, they could be subject to significant financial penalties and even jail time.

Moreover, even if an individual is not held personally liable for a HIPAA violation, a qui tam action may be significantly weakened if the violation renders key evidence inadmissible.

HIPAA prohibits the communication or dissemination of what is generally known as “protected health information,” which is defined in the statute’s implementing regulations as “individually identifiable health information ... [m]aintained in electronic media; or ... [t]ransmitted or maintained in any other form or medium.”

“Individually identifiable health information” is in turn defined as information that “identifies the individual” or provides enough details so “there is a reasonable basis to believe the information

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can be used to identify the individual.” This limitation can prove difficult for whistleblowers, who may need to rely on documents containing such information to establish the fraud they are alleging.

To avoid a situation where HIPAA would shield illegal conduct from disclosure, the regulations implementing HIPAA contain a whistleblower exception to the general privacy rule. Under Rule 502(j), a whistleblower may not be held liable for a HIPAA violation if he meets two requirements:

- The whistleblower “believes in good faith that the covered entity has engaged in conduct that is unlawful or otherwise violates professional or clinical standards, or that the care, services, or conditions provided by the covered entity potentially endangers one or more patients, workers, or the public.”
- The disclosure is made to either “[a] health oversight agency or public health authority authorized by law to investigate or otherwise oversee the relevant conduct or conditions of the covered entity or to an appropriate health care accreditation organization for the purpose of reporting the allegation of failure to meet professional standards or misconduct by the covered entity;” or to the whistleblower’s attorney for the purposes of seeking counsel regarding his legal options and obligations under HIPAA.

Proctor, the plaintiff in the Safeway qui tam action, successfully used the whistleblower exception to protect himself from liability under HIPAA and ensure that his evidence was admissible.

His initial disclosures of protected health information to his attorneys were for the purpose of seeking counsel under the HIPAA whistleblower exception, and that disclosure was therefore protected by the exception.

His attorneys then filtered the information using aliases and otherwise coded the information so that no PHI was included in the qui tam complaint.

The court noted that the “applicable regulation permits a covered entity to utilize a coding system unrelated to the identity of the patient so long as the code is not capable of being translated in order to identify the individual.”

Finding that the coded information did not identify any patients, the court rejected the defendant’s motion to dismiss on the basis that Proctor’s allegations were based on PHI.<sup>7</sup>

### ***Protections against retaliation***

Finally, individuals with knowledge of fraud on the government should be aware that the FCA provides whistleblowers robust protections against retaliation.

Under 31 U.S.C.A. § 3730(h), employees are protected from retaliation for filing qui tam lawsuits or engaging in lawful activities in an attempt to stop a violation of the FCA (i.e., fraud against the government).

To prove a claim of retaliation under the act, the plaintiff must establish three elements: “(1) he engaged in ‘protected activity’ ... (2) his employer knew of these acts; and (3) his employer took adverse action against him as a result of these acts.”<sup>8</sup>

Although there is some controversy about the scope of protected activity under the statute, recent decisions indicate that the broadened scope of protected activity implemented under the 2009 amendments to the FCA is becoming more widely accepted.<sup>9</sup>

Employees who have suffered retaliation under the FCA have three years to bring their claim in court. Successful FCA retaliation plaintiffs are entitled to reinstatement (or front pay in lieu thereof), two times the amount of back pay, compensatory damages and attorney fees.

Retaliation claims under the FCA may be filed concurrently with a qui tam action, and the dismissal of an FCA retaliation claim does not necessitate the dismissal of the related qui tam claim.<sup>10</sup>

Importantly, because FCA retaliation claims are not allegations of fraud, they are not subject to the heightened pleading standards of Federal Rule of Civil Procedure 9(b).<sup>11</sup>

## CONCLUSION

Because the government cannot be everywhere at once, whistleblowers are often the public's first line of defense against fraud. And the numbers of health care industry whistleblowers are only growing.

In the health and human services industry, the DOJ collected under \$1 billion in penalties every year from 1987 until 2001 and over \$2 billion in a year only once between 2001 and 2009 — but it has collected over \$2 billion per year every year since 2010.<sup>12</sup>

Returning this money to the government, so that it may be put to proper use on behalf of the taxpayers, is a crucial service provided by whistleblowers across the country.

## NOTES

- <sup>1</sup> See *United States v. Safeway Inc.*, No. 11-cv-3406, 2016 WL 7017231 (C.D. Ill. Dec. 1, 2016).
- <sup>2</sup> False Claims Amendments Act of 1986, Pub. L. No. 99-562, 100 Stat. 3153 (1986).
- <sup>3</sup> Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21 § 4, 123 Stat. 1617 (2009); Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 10104(j)(2), 124 Stat. 119 (2010); Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. No. 111-203, § 1079A(c)(1), 124 Stat. 1376 (2010).
- <sup>4</sup> See U.S. DEP'T OF JUSTICE, FRAUD STATISTICS – OVERVIEW (2016), U.S. Dep't of Justice, <http://bit.ly/2kkoene>.
- <sup>5</sup> *U.S. ex rel. Bergman v. Abbott Labs.*, 995 F. Supp. 2d 357, 366 (E.D. Pa. 2014) (citing *U.S. ex rel. Wilkins v. United Health Grp. Inc.*, 659 F.3d 295, 305 (3d Cir. 2011)).
- <sup>6</sup> *Universal Health Servs. Inc. v. United States*, 136 S. Ct. 1989 (2016).
- <sup>7</sup> For a more detailed discussion of the HIPAA whistleblower exception, see Michael Filoromo, *HIPAA Exceptions: How Healthcare Workers Can Blow the Whistle*, KATZ, MARSHALL & BANKS, LLP: WHISTLEBLOWER LAW BLOG (Apr. 7, 2016), <http://bit.ly/2j5Zqy8>.
- <sup>8</sup> *Glynn v. EDO Corp.*, 710 F.3d 209, 214 (4th Cir. 2013).
- <sup>9</sup> See generally Michael Filoromo and David Marshall, *Recent Cases Reflect that Broadened Scope of FCA Is Catching On*, KATZ, MARSHALL & BANKS, LLP: WHISTLEBLOWER LAW BLOG (May 13, 2016), <http://bit.ly/2k9izBa>.
- <sup>10</sup> *U.S. ex rel. Ramseyer v. Century Healthcare Corp.*, 90 F.3d 1514, 1522 (10th Cir. 1996).
- <sup>11</sup> *Mendondo v. Centinela Hosp. Med. Ctr.*, 521 F.3d 1097, 1103 (9th Cir. 2008).
- <sup>12</sup> DOJ Fraud Statistics, *supra* note 4.



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