A Perfect Storm

By Randall L. Christian, Jason H. Casell, and Francisco T. Rivas

Qui Tam Actions in the Pharmaceutical Industry

Type the phrase "qui tam" into your favorite search engine and look at the list of results. You will see pages and pages of plaintiffs' law firms touting how they have successfully recovered millions of dollars on behalf of their clients.

But what exactly is a "qui tam" action, and why have these lawsuits risen so sharply since the late 1980s? "Qui tam" derives from the Latin phrase "qui tam pro domino rege quam pro se ipso in hac parte sequitur," which means "who as well for the king as for himself sues in this matter."

Qui tam actions date back to medieval England, and most of the original 13 colonies enacted qui tam legislation. But it was not until 1863, when Congress passed the False Claims Act (FCA) at the urging of President Abraham Lincoln, that these actions became codified in modern American law. The FCA came into being largely in response to fraudulent suppliers who sold the Union army faulty ammunition, rancid food, and lame horses and mules. The 1863 FCA established civil and criminal penalties and included a qui tam provision permitting a private party, or whistleblower, to sue on behalf of the government and to recover 50 percent of the damages. A "whistleblower" could file what became known as "parasitic" claims because the law permitted him to file a civil suit after learning that a grand jury had criminally indicted a war profiteer.

By 1943, Congress had amended the FCA, effectively gutting the role of whistleblowers so that they could only sue under the qui tam provisions if the government was otherwise unaware of the information underlying the action. The money that they could recover was also reduced to a maximum of 25 percent if the government declined to become involved in a case and 10 percent if the government became involved.

Between 1943 and 1986, individuals filed relatively few qui tam actions under the FCA, and whistleblowers faced uphill battles maintaining the claims that they brought. But congressional interest in the FCA was renewed in the 1980s with the indictments of numerous, leading federal contractors. In 1986, to combat fraud committed against the government, Congress amended the FCA, specifically defining fraudulent intent and expanding liability for submitting false claims resulting from ignorance or reckless disregard for the truthfulness of the information in a claim.

The current FCA, as amended by the Federal Enforcement Recovery Act of 2009 (FERA), prohibits knowingly presenting a false or fraudulent claim to the federal government. This extends to those who "cause" the submission of a false claim, not just those who submit claims. "Knowingly" refers to actual knowledge, reckless disregard, or deliberate ignorance of the falsity of the information. The amendment does not require specific intent to defraud. Violators face fines of $5,000 to $11,000 per claim, plus treble damages.

The FCA qui tam provisions permit private parties, or whistleblowers, to file suit on behalf of the United States. The whistleblower, called a "relator," shares in any eventual recovery, which can range from 15 to 30 percent. A relator's total share is determined by the government and divided among relators if more than one is involved in a case.

A relator's attorney must write a complaint that includes all of the relator's knowledge of the alleged fraud and also serves a written disclosure statement to the Department of Justice (DOJ) for the relator with the DOJ listing known and relevant facts. Sometimes whistleblowing can have a "race to the courthouse" element. The first whistleblower to file a case under the FCA preempts all others. This rule is designed to encourage whistleblowers promptly to report fraud.

The action is filed under seal for 60 days while the DOJ investigates, and the DOJ may seek extensions for good cause, which may last for years. During the sealed investigation period, the government's attorneys and investigators meet with the relator and his or her attorney to review the case.

Under the FCA, a relator cannot have acquired his or her information from public sources unless the relator is an "original source" of the information, defined under the FCA as someone who has direct and independent knowledge of the information and who has reported it to the government before filing a case. This "public disclosure" bar helps to ensure that qui tam suits are not filed by people who have not contributed anything to uncovering the important elements of cases.

At the conclusion of the sealed investigation period, the DOJ must decide whether to intervene and prosecute the case or decline to intervene. If the government opts to join a case, the government and the relator's attorney jointly conduct the case, with the government acting as the lead counsel. If the government decides not to intervene, the relator may pursue the case individually. The DOJ can later intervene upon a showing of good cause.

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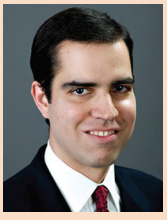


In pharmaceutical actions, most false claims involve off-label promotion, kickbacks, pricing allegations, and reimbursement abuses. This article focuses on false claims involving off-label promotion.

What Is Off-Label Promotion?

The Food, Drug, and Cosmetic Act (FDCA) requires that all a product's labeling be consistent with the product's approved use or uses, as indicated by the Food and Drug Administration (FDA). This requirement includes accompanying materials such as visual aids, statements made by sales representatives when marketing products to physicians, and product claim ads, which must exhibit "fair balance," meaning that a drug's advertising must present the risks and benefits of that particular drug.

Promoting a product for an unapproved use could violate one or more sections of the FDCA. Physicians are free to prescribe drugs for an off-label use, but the FDCA prohibits pharmaceutical companies from urging doctors to prescribe drugs for unapproved uses. Section 502 requires that the labeling be accurate, and Section 505 governs labeling and other communications that can establish a product's new, intended use. To determine whether a company has engaged in off-label promotion, the government examines, among other things, statements by sales representatives, incentives for off-label uses, references to unapproved uses in the marketing of business plans, and safety concerns with unapproved uses. Whether a drug is approved by the FDA for a particular use will primarily determine whether a prescription for that drug is reimbursable by government payors. In most cases, government reimbursement is only available for covered outpatient drugs, which do not include drugs prescribed for off-label uses. A medically accepted indication is one approved under the FDCA or included in certain drug compendia, such as the American Hospital Formulary Service Drug Information and American Medical Association Drug Evaluations.

The financial incentives created by the FCA have led to an explosion of whistleblower lawsuits and federal investigations. As of September 2009, the DOJ was actively investigating 996 whistleblower cases, up from 875 cases in 2008. Health-care fraud represents the majority of these cases. For example, in 1987, only three of the 30 total new federal qui tam lawsuits, or 10 percent, of the cases involved allegations of health-care fraud. In 2009, the total number of federal qui tam suits jumped to 433, and a whopping 280, or nearly 65 percent, of those alleged health-care fraud. Partly in response to this explosion of qui tam activity, the federal government authorized $165 million to permit the DOJ to hire fraud prosecutors and investigators for 2010 and 2011. The combination of the huge amounts of money at stake for companies, large recoveries for whistleblowers and their attorneys, and vast government resources to prosecute these cases constitute the elements of a perfect storm.

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Examples of Large Qui Tam Recoveries

In the largest health-fraud settlement in history, Pfizer paid $2.3 billion in September 2009, including $1.3 billion in criminal fines, for off-label marketing of the painkiller Bextra and several other drugs. Six whistleblowers shared a payment totaling more than $102 million from the federal share of the civil recovery.

Eli Lilly paid $1.4 billion in January 2009 to settle investigations into allegations of illegal marketing of its antipsychotic drug Zyprexa. Lilly's settlement included a $515 million criminal fine, one of the largest health-fraud-related fines ever imposed on a corporation. Sales representative Robert Rudolph and other relators shared a $78.8 million recovery.

Most recently, in October 2010, Novartis Pharmaceuticals agreed to pay $422.5 million to resolve criminal and civil liability stemming from the off-label marketing of one of its drugs. The company agreed to plead guilty to a misdemeanor and pay a $185 million combined criminal fine and forfeiture for the off-label promotion of Trileptal in violation of the FDCA. The FDA approved Trileptal as an anti-epileptic for the treatment of partial seizures, but not for psychiatric, pain, or other uses.

Novartis also agreed to pay $237.5 million to resolve civil allegations under the FCA that the company unlawfully marketed Trileptal and five other drugs, and thereby caused false claims to be submitted to government health-care programs. Specifically, the civil settlement resolves allegations that Novartis illegally promoted Trileptal for a variety of uses, including psychiatric and pain uses, which were not medically accepted indications and, therefore, not covered by those programs.

The civil settlement also resolves the qui tam lawsuits filed. As part of the resolution, the whistleblowers, all former Novartis employees, will receive payments totaling more than $25 million from the federal share of the civil recovery.

Process: Off-Label Promotion Qui Tam Actions Initiated by Sales Representatives

Before a company ever learns about a qui tam suit, people engage in many activities behind the scenes. First, a whistleblower, generally a present or past employee of a targeted company, approaches an attorney with information about the company's alleged wrongdoing. As mentioned, the law requires the relator to be an original source, a concept clarified by the Supreme Court in *Rockwell International v. United States ex rel. Stone*, 549 U.S. 457 (2007). In this case, the Court held that in an FCA qui tam action based on publicly disclosed allegations, the requirement that a relator must be the original source of the informa-

tion is jurisdictional and may be raised at any time, a meritorious relator must have "direct and independent knowledge of the information on which the allegations are based," as required by 31 U.S.C. §3730(e)(4)(B), and the government's intervention in the case does not provide an independent basis of jurisdiction that bootstraps a relator into becoming an original source.

A relator must have knowledge as an original source of off-label marketing tactics such as

- Creating financial incentives for physicians to write prescriptions for the off-label use of FDA;
- Targeting high prescribers and key opinion leaders;
- Paying kickbacks to physicians for off-label "research";
- Paying kickbacks tied to sales representative incentive compensation payments;
- Paying "unrestricted educational grants" for off-label promotion; and
- Paid travel, expensive dinners, or lavish gifts.

After a relator and his or her attorney determine if a case is feasible, the attorney will write a legal complaint incorporating the relator's knowledge of alleged fraud and files it in federal district court, which places it under seal. The relator will also sign a written disclosure statement listing all known relevant facts that the attorney will file with the DOJ. Following the filing of the complaint in federal district court, the court seals the complaint, and it is not served to the defendant. Rather, the government then has 60 days to investigate and determine whether to intervene. The government will often ask for a time extension to investigate, and a case may remain under seal for a year or longer.

What to Do When You Learn of a Possible Action Against Your Company

If the government chooses to pursue a case and unseals it, a company should take numerous steps. First, a company should retain outside counsel. In conjunction with outside counsel, a company should preserve all relevant documents and begin the process of gathering them. Some information may not be available to a company to prepare its defense, and in some situations the government will collect all hard copy documents from a company. It is very important during this stage that in-house counsel and outside counsel prevail upon senior company management the importance of conducting an internal investigation. This is the best way to educate counsel of the existence and extent of potential liability and is critical to mounting a successful defense. Attorneys representing a company never want to know less than the government. At a minimum, an investigation should involve interviewing company employees and interviewing the whistleblower, without running afoul of FCA anti-retaliation provisions, addressed later in this article. All aspects of communication during the investigation should be kept confidential in an effort to preserve the attorney-client privilege.

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When the DOJ and a U.S. attorney's office become involved in a case, it usually generates media attention. A company should prepare for this by appointing a single media liaison to handle all media matters related to the qui tam action. Do not let your company be caught off guard. Whether a company uses its internal public affairs department or hires an outside public relations firm will probably depend on the case issues and potential exposure a case creates for the company. The greater a company's potential exposure, the more it makes sense for the company to hire an outside public relations firm that specializes in crisis management. Whether a company employee or a specialist retained specifically for the situation, the media liaison should draft press releases and handle media inquiries as needed in consultation with in-house and outside counsel. Consider having outside counsel retain a public relations firm as this may provide additional protection of attorney-client privilege. Keep in mind that shareholder litigation frequently will ensue as a result of the probable decline in market cap of a company once an investigation becomes public.

When a case is unsealed, the next crucial step is to attack the pleading. Federal Rule of Civil Procedure 9(b) applies in FCA cases. Fed. R. Civ. P. 9(b) requires that in "alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Courts have rejected relators' arguments that Fed. R. Civ. P. 9(b) does not apply to FCA cases. *See, e.g.*, *United States ex rel. Karvelas v. Melrose Wakefield Hosp.*, 360 F.3d 220, 228 (1st Cir. 2004), *cert. denied*, 543 U.S. 820 (2004).

The Fed. R. Civ. P. 9(b) standard requires that a relator must "set forth the 'who, what, when, where, and how' of the alleged fraud." *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 903 (5th Cir. 1997). In complex healthcare cases, a relator may allege "schemes" but must have "some examples of actual false claims." *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1314 n.25 (11th Cir. 2002). A plaintiff must show that the defendant made a false record or statement for the purpose of getting a false claim paid or approved by the government, and the defendant's false record or statement caused the government to actually pay a false claim, either to the defendant itself or to a third party. *Hopper v. Solvay Pharmaceuticals*, 588 F.3d 1318, 1327 (11th Cir. 2009).

On May 20, 2009, FERA amended 31 U.S.C. §3729(a)(2). This section of the FCA previously imposed liability on anyone 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." The provision now imposes liability on anyone who "knowingly makes, uses or caused to be made or used, a false record or statement *material to a false or fraudulent claim*." This change took effect retroactively as if enacted on June 7, 2008, and it applies to all claims under the FCA that were pending on or after that date.

Some examples of specific evidence that a relator could use to establish off-label marketing include:

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- Monthly or annual prescription tracking reports on targeted physicians;
- Invitations to physicians to dinners or resort weekends;
- Sales training PowerPoint slides or sales training manuals;
- Copies of sales-coaching sheets used to coach sales representatives and medical liaisons on language to use when promoting drugs to physicians;
- Advisory boards that are either too large, too frequent, or used more for promotion rather than to elicit information *from* health-care providers;
- "Homemade" promotional pieces;
- "Ride-along reports," which are reports made to district managers or regional managers when riding along on visits to doctors. Many companies have switched to reports with drop-down menus to avoid free-texting from sales representatives;
- Bonus payout reports;
- Business plans such as tactical plans, strategic plans, brand plans, and plans of action that include health-care providers who would not normally prescribe a product if marketed on-label (*e.g.*, FCPs for oncology products); and
- Copies of correspondence or e-mails with physicians regarding contracts for research.

Anti-Retaliation Provisions

The FCA at 31 U.S.C. §3730(h)(1) provides that any "employee, contractor, or agent shall be entitled to all relief necessary to make that employee, contractor, or agent whole, if that employee, contractor, or agent is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee, contractor, or agent on behalf of the employee, contractor, or agent or associated others in furtherance of other efforts to stop 1 or more violations of this subchapter." Relief is defined as including "reinstatement with the same seniority status that employee, contractor, or agent would have had but for the discrimination, 2 times the amount of back pay, interest on the back pay, and compensation for any special damages sustained as a result of the discrimination, including litigation costs and reasonable attorneys' fees." 31 U.S.C. §3730(h)(2).

Courts have ruled that to establish a violation, an employee must satisfy three elements: (1) the employee must have been engaged in conduct protected by the FCA; (2) the employer must have known that the employee was engaged in such conduct; and (3) the employer must have discriminated against the employee because of his or her protected conduct. *See Mendiondo v. Centinela Hosp. Med. Ctr.*, 521 F.3d 1097, 1103 (9th Cir. 2008); *Karvelas*, 360 F.3d at 235; *Schuhardt v. Washington Univ.*, 390 F.3d 563, 566 (8th Cir. 2004).

To be engaged in activity protected under the FCA, a person must be "acting in furtherance of efforts to stop" a violation of the FCA. To further an action, a person "must be investigating matters which are calculated, or reasonably could lead to a viable FCA action." *United States ex. rel. Hopper v. Anton*, 91 F.3d 1261, 1269 (9th Cir. 1996).

With respect to employer knowledge, if an employee never used terms such as "'illegal,' 'unlawful,' or 'qui tam action' in characterizing his [or her] concerns," then the employee would not have protection under the FCA, nor would merely raising concern over compliance with a regulation sufficiently inform the employer that the employee was engaged in qui tam efforts, and the employer would not have the requisite knowledge to form "retaliatory intent." *Robertson v. Bell Helicopter Textron, Inc.*, 32 F.3d 948, 951–52 (5th Cir. 1994).

If a relator cannot demonstrate reprisal, then he or she cannot establish a violation of the provision. Specifically, an employee must supply sufficient facts from which a reasonable jury could conclude that the employee was discharged "because of activities which the employer had reason to believe were taken in contemplation of a *qui tam* action against the employer." *McKenzie v. Bellsouth Telecommunications, Inc.*, 219 F.3d 508, 518 (6th Cir. 2000).

Amending the FCA through FERA in 2009 broadened the anti-retaliation provisions of the FCA to protect not only employees, but also contractors and agents of federal contractors. Representative Howard Berman (D-Calif.), the House sponsor of the FCA amendment explained that "this amendment will ensure that Section 3730(h) protects physicians from discrimination by health care providers that employ them as independent contractors, and government subcontractors from discrimination and other retaliation by government prime contractors."

Congressman Berman further explained that the purpose of this amendment was to make clear that the FCA covers the following types of retaliation:

- Retaliation against not only those who actually file a qui tam action, but also against those who plan to file a qui tam action but that never is filed, who blow the whistle internally or externally without filing a qui tam action, or who refuse to participate in the wrongdoing;
- Retaliation against the family members and colleagues of whistleblowers; and
- Retaliation against contractors and agents of the discriminating party who have been denied relief because they are not technically employees.

It is extremely important that a company facing a potential qui tam action maintain focus on responding to the action or underlying issues and not run afoul of the anti-retaliation provisions of the FCA protecting potential whistleblowers.

Conclusion

Becoming the subject of a qui tam action is obviously a serious and unsettling matter for any pharmaceutical company. However, if a company acts proactively once a case is unsealed and vigorously defends itself, the company has a good chance of avoiding becoming swept away in a perfect storm.