# Pharmaceutical Companies, Off-Label Promotion And *Qui Tam* Actions

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

The False Claims Act (FCA), as amended by the Federal Enforcement Recovery Act of 2009 (FERA), prohibits knowingly presenting a false or fraudulent claim to the federal government, and extends to those who submit or "cause" the submission of such claims. In pharmaceutical actions, most false claims *qui tam* actions brought by whistleblowers involve off-label promotion, kickbacks, pricing allegations, and reimbursement abuses. Although these start out as civil lawsuits, they often end with the Department of Justice (DOJ) pressing charges against the pharmaceuticals manufacturer. That was the case in the recently settled whistleblower action brought against UCB SA, the manufacturer of the epilepsy treatment drug Keppra. The pharmaceuticals maker settled the suit by pleading guilty on June 10 to a misdemeanor charge of misbranding its product by promoting its use for unapproved purposes. The company was forced to pay civil and criminal damages of more than $34 million.

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 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%, of the cases involved allegations of health-care fraud. In 2009, the total number of federal *qui tam* suits jumped to 433; a whopping 280, or nearly 65%, of those suits 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 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 for pharmaceuticals companies.

When an off-label promotion *qui tam* claim is made, what steps should a pharmaceutical company take?

## Off-Label Promotion Defined

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. Section 502 of the FDCA requires that the labeling of pharmaceutical products be accurate, and § 505 governs labeling and other communications that can establish a product's new, intended use. Promoting a product for an unapproved use could violate one or more sections of the FDCA, though physicians are free to prescribe drugs for an off-label use if they so choose.

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 available only 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 *Qui Tam* Action Is Initiated

Many activities occur behind the scenes before a company ever learns about a *qui tam* suit. 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 whistleblower, or 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).

After a relator and his or her attorney determine if a case is feasible, the attorney writes 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, but it is not served on 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. All the while, the company's representatives may know nothing about these proceedings.

## When an Action Against the Company Is a Possibility

If the government chooses to pursue a case and unseals it, the company must spring into action.

First, it should retain outside counsel due to the sensitivity of the issues and the need to protect confidentiality.

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At the same time, a company should preserve all relevant documents and begin the process of gathering them. In some situations the government will collect all copies of all hard copy documents from a company.

It is very important during this stage that in-house counsel and outside counsel impress 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 the company never want to know less than the government. At a minimum, an investigation should involve interviewing company employees, and the company should consider interviewing the whistleblower before he or she becomes a party opponent. During this process, care should be taken to avoid running afoul of FCA anti-retaliation provisions. All aspects of communication during the investigation should be kept confidential and, in order to best preserve the attorney-client privilege, only outside counsel and, perhaps, in-house counsel should be present at the interview.

When the DOJ and a U.S. attorney's office become involved in a case, it usually generates media attention, so a media liaison to handle all media matters related to the *qui tam* action should be appointed. 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 they create 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. The media liaison should consult with in-house and outside counsel when drafting press releases and handling media inquiries. Consider also having outside counsel retain a public relations firm, as this may provide additional protection of attorney-client privilege in that outside counsel would have a direct attorney-client relationship with the public relations firm.

Keep in mind that shareholder litigation may 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. It 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 "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).

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

- 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 too large, meet too frequently, or are 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.

On May 20, 2009, FERA amended 31 U.S.C. § 3729(a)(2). This section of the FCA previously imposed civil 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 a civil liability on anyone who "knowingly makes, uses or caused to made or used, a false record or statement material to a false of 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.

### Anti-Retaliation Provisions

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. The FCA now covers retaliation against those who actually file a *qui tam* action as well as those who plan to file such an action but never do; those who blow the whistle internally or externally without filing a *qui tam* action; or those who refuse to participate in the wrongdoing. The FCA's protections also extend to family members and colleagues of whistleblowers, as well as contractors and agents of the discriminating party

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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 violate the anti-retaliation provisions of the FCA, which could lead to lawsuits by individuals protected by those provisions.

**CONCLUSION**

Becoming the subject of a *qui tam* action is obviously a serious matter for any pharmaceutical company. In addition to the civil damages that may result, these whistleblower suits can quickly turn into federal criminal actions. However, if a company acts proactively once a case is unsealed and vigorously defends itself, it has a better chance of avoiding becoming swept away in a "perfect storm."

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