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NEW RISK FROM **OFF-LABEL PROMOTIONAL ACTIVITY**

These False Claims Act cases are arguably improper.

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THE FALSE CLAIMS Act (FCA) [FN1] imposes liability for, and protects the federal government from, fraud in financial interactions; the law is intended to encourage individuals who are either close observers or involved in the fraud to report the alleged wrongdoing. [FN2] Accordingly, either the Attorney General or a private individual on behalf of the government, a 'qui tam relator,' may assert an FCA claim.

In the event the claim is brought by a qui tam relator, the relator stands to receive a portion of any recovered damages. The FCA provides both treble damages and fines of between $5,500 and $11,000 per fraudulent claim.

In the healthcare arena, the FCA protects the government against false claims for reimbursement from medical assistance programs including Medicaid or Medicare -- for example, claims filed for medical services not rendered or for overpriced medical services.

In a remarkable extension of the FCA, a recent trend has emerged toward using it to police off-label promotion and subjecting manufacturers to very large fines, despite the fact that the same fines would not be available under the Food, Drug and Cosmetics Act (FDCA). [FN3] This article will analyze the elements of the FCA and its application to pharmaceutical manufacturer's promotional activities and will address the emerging trend of using the FCA as a tool to extract enormous settlement amounts from manufacturers.

What Makes an FCA Case?

Generally, to establish a prima facie case pursuant to the FCA, the plaintiff must demonstrate that

(1) the defendant presented (or induced the presentment of) a claim for reimbursement by the federal government,

(2) the claim was false or fraudulent, and

(3) the defendant knew that the claim was false or fraudulent. [FN4]

Traditionally, and apparent from the elements of a prima facie case, the FCA applied to protect against the false claims of physicians, healthcare providers and patients for reimbursement from programs including Medicare and Medicaid.

However, in the new breed of FCA cases, the government or qui tam relators have begun to assert the statute against pharmaceutical manufacturers to police promotional activities, specifically promotion of an off-label use of an FDA approved product. These

cases are permitted despite the existence of specific federal regulation, including the FDCA, proscribing off-label promotional activity. The new breed of cases asserts FCA claims even if the off-label promotion contained truthful information or if the off-label use may have been legally prescribed and reimbursed by a government medical assistance program.

The efficacy of an FCA claim to police a manufacturer's truthful off-label promotion of its product is reflected in its power to induce settlement. To date, few courts have addressed whether the FCA is properly applied to manufacturers and truthful off-label promotional activities because the threat of treble damages and stiff fines encourage settlement, often at a terrific cost to the manufacturer.

The government's rationale for promoting such claims includes the purported deterrence 'vital to public health and safety' of pharmaceutical companies 'improperly marketing their drugs to doctors and patients to treat illnesses that these drugs are not approved to treat.' [FN5] According to a U.S. Attorney, '[t]he illegal marketing of prescription medications for unauthorized medical uses is a serious crime that poses significant public health risks [and] [d]rug manufacturers have a legal obligation to market their products only for medical uses that have been approved by the Food and Drug Administration as safe and effective.' [FN6]

Such protection is afforded by regulation of the Food and Drug Administration, which permits the manufacturer's promotion of a product only for the uses approved by the FDA and, generally, prohibits the manufacture's promoting any unapproved or 'off-label' uses. The FDCA provides statutory authority specifically to prosecute and fine a manufacturer for illegal off-label promotion. Accordingly, the promotional and information material provided by the manufacturer may only contain information pertaining to FDA approved uses.

However, physicians and healthcare providers legally and regularly prescribe and use pharmaceutical products for off-label purposes. [FN7] Allowing physicians to prescribe drugs for 'off-label' uses 'is an accepted and necessary corollary of the FDA's mission to regulate [pharmaceuticals] without directly interfering with the practice of medicine.' [FN8]

Some studies show that 25 to 60 percent of all prescriptions written in the United States prescribe a product for an off-label purpose. [FN9] In fact, the American Medical Association opines that failure to use a product for an off- label purpose may, in some cases, subject physicians to medical malpractice liability. [FN10] Further, such off-label prescriptions may be properly reimbursable by a government assistance program, including Medicare and Medicaid, if the treatment is 'reasonable and necessary.' [FN11]

The Risks and Concerns

Given that the prescription of a product for an off-label purpose is legal, that the reimbursement for the off-label use may be proper (if reasonable and necessary), and that the federal government has drafted legislation directly on point to police off-label promotional activity, the government's promotion of the FCA to recover large settlements from manufacturers' truthful but illegal off-label promotional activities poses significant risks to manufacturers and raises profound concerns about the fair and proper application of the FCA.

The traditional application of this law imposes liability against a defendant that knowingly submits a false claim for reimbursement from the federal government. In the healthcare arena, a traditional claim may assert that a healthcare provider submitted fraudulent bills

for reimbursement to Medicare or Medicaid.

For example, in December 2000, Columbia HCA pled guilty to criminal conduct and agreed to pay $731.4 million under the FCA (the company paid more than $840 million in criminal fines, civil penalties and damages for unlawful billing practices). [FN12] The allegations included claims that the company billed for unnecessary lab tests not ordered by physicians, 'upcoded' medical problems to receive higher reimbursements for more serious medical issues, billed the government for advertising under the guise of 'community education,' and billed the government for non-reimbursable costs incurred in the purchase of home health agencies around the country. [FN13]
This traditional case includes the elements necessary for a prima facie FCA claim: The company knowingly and intentionally submitted a false claim for reimbursement by a governmental entity.

The application of the FCA to a manufacturer of pharmaceuticals for providing truthful, albeit illegal (under the FDCA) promotional material stretches to an impossible limit the elements of a proper FCA claim.

The claims assert that the manufacturer induces, by promoting the off-label use, the filing of a fraudulent claim for reimbursement from a governmental entity, often Medicare or Medicaid. For example, in September 2007, Bristol-Myers Squibb agreed to settle in excess of $515 million in claims involving drug marketing and pricing practices. [FN14] The claims originated, and the settlement resolved, seven qui tam actions brought under the FCA. [FN15] The government alleged that the company knowingly and willful offered illegal remuneration to physicians and healthcare providers to induce use of the company's product. The FCA claim alleged that the remuneration resulted in the submission of false and fraudulent claims to federal reimbursement programs. [FN16] Further, the government alleged that the company knowingly promoted the use of one of its products for an off-label purpose. [FN17]

In the circumstances of a truthful but off-label promotional statement, the elements of an FCA claim seem non-existent.

The manufacturer issues no false statement, submits no claim, has no knowledge that a claim is filed, and induces no illegal act. In fact, in many cases, the truthful off-label promotion, though illegal pursuant to the FDCA, promotes the legal prescription or use for an off-label purpose.

Inducing a legal act fails to satisfy any of the elements of an FCA claim and should not be actionable. [FN18]

Liability under the FCA requires that the manufacturer knowingly induces a false claim. Because a physician or healthcare provider may legally use or prescribe a product for an off-label use and that prescription is reimbursable if a 'reasonable and necessary' treatment, the manufacturer will never know in advance that a false claim will be submitted.

Further, whether the off-label use is reimbursable is a question determined by an inquiry into the necessary and reasonable use and is resolved solely by an agency without input from the manufacturer. In such a circumstance, application of the FCA subjects the pharmaceutical manufacturer to liability for truthful (albeit off-label) promotion of a product when the off-label use and submission of the claim occurs without the manufacturer's knowledge, and the off-label use is subject to reimbursement (and thus not a 'false claim') if found to be reasonable and necessary.

Inappropriate Use of the Law

The recent trend of applying the FCA to police manufacturer's off-label promotional activities is an inappropriate extension of the Act. Federal regulation prohibits (and exacts reasonable fines for) the illegal off-label promotion of a product.

The FDCA, not the FCA, specifically governs the distribution in interstate commerce of prescription medications and prohibits a manufacture's distribution in interstate commerce of a new pharmaceutical drug unless the manufacturer demonstrates to the FDA that the drug is safe and effective for each of its intended uses. [FN19] Under the FDCA, the illegal act occurs when a manufacturer promotes the product for an off-label use and is not dependant on whether the off-label promotion provides truthful or fraudulent information.

Off-label promotion may be legal only if permitted by statute or under special circumstances. For example, the FDA, in 1996 and 1997, issued guidelines concerning off-label promotional activities, including guidelines permitting, under certain circumstances, a manufacturer's distribution of scientific articles written by independent authors discussing off-label uses, distribution of textbooks on off-label uses, and support of continuing medical education programs or seminars at which speakers discuss off-label uses.

For example, in 2005, Eli Lilly & Company was prosecuted pursuant to the FDCA and not the FCA. Eli Lilly pled guilty and was fined $36 million for promoting an off-label use (which the FDA eventually approved). In this case, Eli Lilly truthfully promoted the use of the drug but was found to have violated the FDCA because the company promoted the use of the drug prior to receiving final FDA approval for that specific use. [FN20]

Recent Caselaw

Recent cases indicate that the inquiry rests not with whether the manufacturer meets the elements of an FCA claim but rather whether a claim induced by off-label marketing, even if truthful, was ever submitted to the government.

In fact, two courts considering the FCA have rejected the argument that off-label marketing induces no false claim because a doctor is permitted to use a product for an off label purpose. Both courts held the FCA applicable to off-label marketing. [FN21]

Further, in a recent First Circuit case, U.S. ex rel. Rost v. Pfizer, the court considered an FCA claim asserted against a pharmaceutical company and arguing that the off-label promotion of a drug led to claims for reimbursement to the federal government. [FN22] The court recognized that

FCA liability attaches to a 'false or fraudulent claim for payment' or to a 'false record or statement [made] to get a false or fraudulent claim paid' by the government...but does not attach to violations of federal law or regulations, such as marketing of drugs in violation of the FDCA, that are independent of any false claim. [FN23]

The court found that the complaint failed to meet the specificity requirement and stated that although the complaint 'amply describes illegal practices in which Pfizer allegedly engaged...those practices, while illegal, are not a sufficient basis for an FCA action because they do not involve claims for government reimbursement.' [FN24]

Nevertheless, the court indicated that if the complaint properly alleged that false claims had been submitted to the government, the FCA allegations could stand against the manufacturer:

The submission of the alleged false claims here was not by [the manufacturer]; false claims were allegedly submitted by doctors who were allegedly induced and seduced by defendants into prescribing [the drug] for off-label uses to their patients, including federally insured patients. According to [the] complaint, more than half of all adult and a quarter of all pediatric sales of [the drug] are for off-label uses. Given that, it is a possible but not a necessary or even strong inference that doctors, persuaded by [the manufacturer's] financial and other incentives to prescribe [the drug] for off-label uses, have written such prescriptions even if the patient was federally insured. And it is not irrational to infer that, given the large percentage of children and the elderly who are insured under federal health programs, some false claims for [the drug] reimbursement were submitted to the government. [FN25]

In another 2007 case in the Northern District of Illinois, the court refused to dismiss a lawsuit filed by whistleblowers that alleged that two drug manufacturers promoted off-label uses of a drug, which enabled doctors to obtain fraudulent reimbursements from the government. [FN26] Again, the court found that '[w]hether false claims were submitted is critical to the alleged fraud, because without the submission of such claims there has been no fraud on the government.' [FN27]

Conclusion

Few cases present a pure inquiry as to whether a truthful promotion statement about off-label use will result in liability under the FCA.

However, recent settlements demonstrate that manufacturers will generally settle the claims rather than face the risk of treble damages. Two of the top 20 cases since 1986 asserting claims pursuant to the FCA include claims of illegal off-label marketing and resulted in huge settlements to the government and the qui tam relator. [FN28]
In October of 2005, Serono agreed to pay $704 million to settle a fraud case, which included allegations of kickbacks to doctors and pharmacies for recommending the drug and illegal off-label marketing of the drug. In May of 2004, Pfizer/Warner-Lambert agreed to pay $430 million to resolve a case alleging that the company defrauded Medicaid by illegally promoting a drug for off-label uses. In Pfizer/Warner-Lambert, $152 million will settle the false claims act aspects of the case. [FN29]

And so, whether a manufacturer will be liable under the FCA for truthful but illegal off-label promotion remains unclear because most cases settle out of court. However, what is clear is that the FCA exposes pharmaceutical manufacturers to extreme costs, in the form of fines and settlements, which manufacturers would not likely face pursuant to the FDCA.

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[Notes]

FN1. 31 U.S.C. §3729 et seq.

FN2. See e.g. United States. v. Sanofi-Synthelabo Inc., 2006 WL 1064127 *5 (E.D. Mo. April 21, 2006).

FN3. See, e.g., Ralph Hall and Robert Berlin, 'When You Have a Hammer Everything Looks Like a Nail: Misapplication of the False Claims Act to Off-Label Promotion,' 61 Food & Drug L.J. 653 (2006); Franklin v. Parke-Davis, 147 F. Supp.2d 39 (D. Mass. 2001).

FN4. 31 U.S.C. §3279(a)(1); United States ex rel. Schmidt v. Zimmer, 386 F.3d 235, 242 (3rd Cir. 2004); Rabushka ex rel. United States v. Crane Co., 122 F.3d 559, 563 (8th Cir. 1997); United States ex rel. Schuhardt v. Washington Univ., 228 F. Supp.2d 1018. 1023 (E.D. Mo. 2001); United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 225 (1st Cir. 2004) ('Evidence of an actual false claim is 'the sine qua non of a False Claims Act violation.") (quoting United States ex rel. Clausen v. Lab. Corp. of Am., Inc., 290 F.3d 1301, 1311 (11th Cir.2002)).

FN5. 'Officials from U.S. Department of Justice report latest developments, ' Biotech Business Week, Sept. 17, 2007 (quoting Assistant Attorney General Peter D. Keisler for the Tax Division).

FN6. Id (quoting U.S. Attorney Roslynn R. Mauskopf).

FN7. James M. Beck, Elizabeth D. Azari, 'FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions,' 53 Food & Drug L.J. 71, 80 (1998).

FN8. Buckman Co. v. Plaintiff's Legal Comm., 531 US 341, 350 (2001).

FN9. Id. (citing Fran Kritz, 'FDA Seeks to Add Drugs' Uses to Labels,' Wash. Post, March 29, 1997, at 11 (citing American Medical Association estimate of 40 percent to 60 percent)).

FN10. Id. (citing Fran Kritz, supra note 9, at 11) (quoting American Medical Association vice-president: '[i]n some cases, if you didn't use the drug in the off-label way, you'd be guilty of malpractice.').

FN11. Hall and Berlin, supra note 3.

FN12. Mark Taylor, 'The dust finally clears; HCA agrees to a whopping $840 million to settle litany of Medicare, Medicaid allegations,' Modern Healthcare Dec. 18, 2000; The False Claims Act Legal Center, Top 20 Cases, available at http://www.taf.org/top20.htm.

FN13. Id.

FN14. U.S. Federal News, 'Bristol-Myers Squibb to Pay More Than $515 Million to Resolve Allegations of Illegal Drug Marketing, Pricing,' Sept. 28, 2007.

FN15. Id.

FN16. Id.

FN17. Id.

FN18. See e.g. Franklin v. Parke-Davis, 147 F. Supp.2d 39 (D. Mass. 2001) (although

denying a motion to dismiss the FCA claim, the court stated, '[a] much closer question would be presented if the allegations involved only the unlawful -- yet truthful -- promotion of off-label uses to physicians who provide services to patients who are covered by Medicaid....').

FN19. See 21 U.S.C. §355(a) & (d); see also Franklin v. Parke-Davis, 147 F. Supp.2d 39, 44 (D. Mass. 2001).

FN20. Department of Justice, 'Eli Lilly and Company to Pay U.S. $36 Million Relating to Off-Label Promotion,' Dec. 21, 2005, available at http:// www.usdoj.gov/opa/pr/2005/December/05_civ_685.html.

FN21. U.S. ex rel. Fraklin v. Parke-Davis, 147 F. Supp. 2d 39 (D.Mass. 2001); U.S. ex rel. Hess v. Sanofi-Synthelabo, Inc., 2006 WL 1064127 (E.D. Mo. April 21, 2006).

FN22. U.S. ex rel. Rost v. Pfizer, Inc., 2007 WL 3379842 *5 (1st Cir. Nov. 15, 2007).

FN23. 31 U.S.C. §3729(a)(1)-(2); U.S. ex rel. Rost v. Pfizer, Inc., 2007 WL 3379842 *5 (1st Cir. Nov. 15, 2007).

FN24. Id. at *10.

FN25. U.S. ex rel. Rost v. Pfizer, Inc., 2007 WL 3379842 *10 (1st Cir. Nov. 15, 2007).

FN26. U.S. ex rel. Kennedy. v. Aventis Pharmaceuticals Inc., 2007 WL 2681701 (N.D. Ill. Sept. 13, 2007).

FN27. Id. at *5.

FN28. The False Claims Act Legal Center, Top 20 Cases, available at http:// www.taf.org/top20.htm.

FN29. Id.

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