Legal Backgrounder

WLF Washington Legal Foundation

Advocate for freedom and justice®
2009 Massachusetts Avenue, NW
Washington, DC 20036
202.588.0302

Vol. 25 No. 14 April 23, 2010

FIGHTING OFF-LABEL *QUI TAM* SUITS: HAVE FEDERAL COURTS ENCOURAGED FILING OF SPECULATIVE FCA CLAIMS?

by

Robert A. Salerno and Dimitra Doufekias

Pharmaceutical and medical device companies that would like to discuss off-label uses of their FDA-approved products with health care professionals face a treacherous path paved with substantial uncertainty, including the threat of criminal enforcement and civil lawsuits under the False Claims Act (FCA), 31 U.S.C. §§ 3729-33. This LEGAL BACKGROUNDER will focus on recent judicial decisions on the application of Federal Rule of Civil Procedure 9(b) to FCA lawsuits against health care companies, and their potential impact on the important gatekeeper function that Rule 9(b) serves to screen out speculative complaints in cases alleging fraud.

Background. "Off-label" use of a drug or device is a use other than the use(s) for which the product was approved by the Food and Drug Administration ("FDA"). The FDA does not regulate the practice of medicine, and nothing prohibits physicians from prescribing drugs and devices off-label. In fact, physicians widely employ off-label uses, particularly in specialties such as oncology and pediatrics. In order to balance the risks and benefits of off-label uses, physicians need reliable and up-to-date scientific information concerning such uses, and drug and device manufacturers are normally the most informed source for such information. The FDA, however, resists manufacturers' efforts to disseminate information about off-label uses to health care professionals. The agency fears that allowing the free flow of such information will encourage companies to bypass the regulatory approval process and undermine the FDA's mission to ensure the safety and efficacy of drugs and devices. Although the FDA has issued guidance to the industry addressing the distribution of articles and publications, precisely what manufacturers can and cannot say regarding off-label uses for their products remains unclear.[1] Moreover, the extent to which truthful, non-misleading communications regarding off-label uses are entitled to the free speech protections of the First Amendment is not resolved,[2] and litigation attempting to define the boundaries of permissible communications about off-label uses continues to this day.[3]

---

[1] *See* http://www.fda.gov/oc/op/goodreprint.html.

[2] *Washington Legal Found. v. Henney*, 128 F. Supp. 2d 11, 15 (D.D.C. 2000).

[3] *See, e.g., Allergan Inc. v. United States*, 1:09-cv-01879-JDB (filed October 1, 2009) (seeking an injunction against enforcement of regulations prohibiting communication of safety information regarding off-label uses).

Robert A. Salerno is a partner in the Washington, D.C. office of the law firm Morrison & Foerster LLP. **Dimitra Doufekias** is an associate in the firm's Washington office.

The FDA's longstanding position is that a manufacturer's promotion of a drug or device for an unapproved use violates the Food, Drug and Cosmetic Act ("FDCA"). The FDA considers a drug that is promoted for an unapproved use to be an unapproved new drug with respect to that use. 21 U.S.C. §§ 331(d), 355(a). Similarly, a medical device promoted for an off-label use without the requisite clearance for that use is considered to be misbranded or adulterated. 21 U.S.C. §§ 331(a), 351(f), and 352(o). The FDA also considers drugs and devices marketed for an unapproved use to be misbranded because the labeling of such drugs and devices cannot include "adequate directions for use" for the off-label use. 21 U.S.C. §§ 331(a), 352(f).

Although the legal theories by which off-label promotion becomes a criminal violation of the FDCA are somewhat attenuated and have received little judicial scrutiny, a steady stream of criminal prosecutions have been based on the premise that off-label promotion violates the FDCA. Violations of these FDCA provisions are criminal offenses, even without specific intent to defraud or mislead. 21 U.S.C. § 333. Moreover, convicted companies can face exclusion from participation in the Medicare and Medicaid programs, which means that the use of their products will not be reimbursed. This provides the government with extraordinary leverage. To avoid such devastating collateral consequences, most criminal prosecutions are resolved through negotiated settlements. This reality helps explain why there is such little case law addressing the applicability of the FDCA to off-label promotion.

The Civil False Claims Act. Settlements of off-label prosecutions typically include a civil damages component under the False Claims Act. The statute provides for civil liability for any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;" or "knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729 (a)(1)(A) and (B).[4] Individual plaintiffs, known as *qui tam* relators, may file a False Claims Act complaint on behalf of the government and share in a portion of any settlement or judgment, whether the United States intervenes in the lawsuit or not. As a result, "the qui tam mechanism has historically been susceptible to abuse . . . " Congress has recognized that there is "a fine line between encouraging whistle-blowing and discouraging opportunistic behavior." *United States ex rel Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 16 (1st Cir. 2009).

While there is no private right of action to enforce the FDCA, the *qui tam* provisions of the False Claims Act and the enormous settlements extracted by the government in off-label prosecutions have encouraged plaintiffs to try to use the FCA to address off-label promotion.

The first reported district court case to address the off-label theory of FCA liability was *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39 (D. Mass. 2001), in which a *qui tam* relator alleged that Parke-Davis misled doctors into believing that clinical trials supported the safety and efficacy of various off-label uses of the drug Neurontin, and that the company violated the False Claims Act by causing doctors to submit claims for Neurontin that were not eligible for reimbursement. The court noted that although the relator's theory of FCA liability "takes the parties into territory that is not well charted," the language of the statute "supports Relator's somewhat expansive claim." *Id.* at 53. In particular, the court noted that under the prior 31 U.S.C. § 3729(a)(1), so long as the defendant caused a claim for ineligible reimbursement to be filed, no false statements or otherwise unlawful conduct was necessary. Although plaintiff alleged that Parke-Davis made false statements as part of a fraudulent scheme, the court's analysis would permit even truthful, non-misleading promotional activities to be used as a basis for civil False Claims Act liability. The court also held that the prescribing doctors were not an intervening force that broke the causal connection

[4]The False Claims Act was amended in May 2009. Former sections 3729(a)(1) and (a)(2) were amended and renumbered as 3729(a)(1)(A) and (a)(1)(B). The cases discussed below interpret the version of the statute in effect prior to the May 2009 amendment. With respect to the issues discussed herein, the differences between the prior and current version of the statute are immaterial.

because the submission of false claims was not only foreseeable, it was an intended consequence of the alleged scheme to defraud.

Federal Rule of Civil Procedure 9(b). A claim brought under the False Claims Act must meet the heightened pleading standards of Federal Rule of Civil Procedure 9(b), which requires that the circumstances constituting an alleged fraud must be pled with particularity. This typically means that a complaint must set forth "facts as to time, place, and substance of the defendant's alleged fraud, specifically the details of the defendants' allegedly fraudulent acts, when they occurred, and who engaged in them." *Hopper v. Solvay Pharms., Inc.*, 588 F.3d 1318, 1324 (11th Cir. 2009) (citations and quotations omitted). Some courts have relaxed this pleading standard where the alleged False Claims Act violations occurred over a long period of time or where details of the alleged fraud are exclusively in the possession of the defendant. Notwithstanding, Rule 9(b) has proved to be a useful tool to combat efforts to apply the False Claims Act to off-label promotion, especially in lawsuits where the plaintiff is not an "insider." Unlike the whistleblower employee who has direct and independent knowledge of the alleged fraudulent conduct, a non-insider may never be able to allege the kind of detailed facts required by Rule 9(b).

United States ex rel. Clausen v. Lab. Corp. of Am. is widely cited for its holding that "Rule 9(b) … does not permit a False Claims Act plaintiff merely to describe a private scheme in detail but then to allege simply and without any stated reason for his belief that claims requesting illegal payments must have been submitted, were likely submitted, or should have been submitted to the Government." 290 F.3d 1301, 1311 (11th Cir. 2002). Although *Clausen* involved allegations of unauthorized, unnecessary, and/or excessive medical tests, its reasoning applies equally to the off-label promotion context. The court described presentment of a false claim as the "sin qua non" of an FCA violation and dismissed the complaint because it could not "find any allegation, stated with particularity, of a false claim actually being submitted to the Government." *Id.* at 1312. Although the court was not "unsympathetic" to the relator's position as a corporate outsider, it nonetheless rejected the argument that a more lenient pleading standard should apply. *Id*. at 1314 n.25 & 26.

Rule 9(b) has been used to stop False Claims Act cases alleging off-label promotion at the complaint stage. For example, in *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 726 (1st Cir. 2007), the First Circuit affirmed dismissal of the complaint based on Rule 9(b). Although the complaint in *Rost* alleged that Pfizer's subsidiary, Pharmacia, had significant information regarding the off-label use of Genotropin sales (including the percentage of off-label uses, the identities of the prescribing doctors, the primary and secondary diagnoses, and the dosages prescribed), such allegations merely suggested that it was "possible but not a necessary or even strong inference that doctors, persuaded by Pharmacia's financial and other incentives to prescribe Genotropin for off-label uses, [had] written such prescriptions even if the patient was federally insured." *Id.* at 732. Accordingly, "the complaint [did] not sufficiently establish that false claims were submitted for government payment in a way that satisfie[d] the particularity requirement [of Rule 9(b)]." *Id*. at 733.

A Widening Crack in Rule 9(b) in Off-Label Promotion Cases? Two recent appellate court decisions in False Claims Act cases involving allegations of off-label promotion – *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13 (1st Cir. 2009) and *United States ex rel. Hopper v. Solvay Pharma., Inc.*, 588 F.3d 1318 (11th Cir. 2009) – suggest that courts may be warming to the idea that a relaxed Rule 9(b) pleading standard should sometimes apply to False Claims Act allegations, thus increasing the number of off-label promotion cases capable of surviving a motion to dismiss.

Although the First Circuit affirmed the dismissal of the complaint in *Rost*, it noted that "Rule 9(b) may be satisfied where, although some questions remain unanswered, the complaint as a whole is sufficiently particular to pass muster under the FCA." *Rost,* 507 F.3d at 732 (citation omitted). This dicta was recently applied in *Duxbury* to sustain a broadly pled theory of FCA liability. The *qui tam* relator, a

former sales representative employed by the defendant company, did not identify a single allegedly false claim. Regardless, the First Circuit held that generally identifying "eight medical providers (the who), the illegal kickbacks (the what), the rough time periods and locations (the where and when), and the filing of the false claims themselves," was sufficient. 579 F.3d at 30. The *Duxbury* court held that even though the allegations at issue were "a close call," they satisfied Rule 9(b) "under this more flexible standard."

Less than two months ago, the Eleventh Circuit decided *Hopper*, which suggests that further loosening of Rule 9(b) may be taking hold. The *Hopper* court dismissed the *qui tam* complaint for failing to meet Rule 9(b)'s heightened standard precisely because "[t]he Complaint piles inference upon inference to suggest that Solvay's marketing campaign influenced some unknown third parties to file false claims." 588 F.3d at 1326. Thus, the court could not "conclude that the Complaint satisfies the particularity requirements of Rule 9(b) by offering 'some indicia of reliability . . . of *an actual false claim* for payment being made to the Government.'" *Id.* at 1326 (quoting *Clausen*, 290 F.3d at 1311). Despite that outcome, the Eleventh Circuit, citing *Duxbury*, stated that "in the appropriate case, we may consider whether the particularity requirements of Rule 9(b), . . . are more relaxed for [certain] claims" under the False Claims Act. *Id*. at 1329. In analyzing the differences between the prior 31 U.S.C. §§ 3729(a)(1) and (a)(2), the *Hopper* court specifically noted that *Clausen* – a case that undoubtedly stresses the stringent requirements of Rule 9(b) in False Claims Act cases – did not "necessarily foreclose the possibility that, for claims under subsection (a)(2), general allegations of improper government payments to third parties, supported by factual or statistical evidence to strengthen the inference of fraud . . . could satisfy the particularity requirements of Rule 9(b)." *Id.*

These two recent cases – along with another recent False Claims Act applying Rule 9(b) to allegations of the Medicaid and Medicare billing fraud[5] – may open the door to additional efforts to enforce the unspecified and largely untested FDCA prohibition of off-label promotion through the False Claims Act.[6] The defendant company in *Duxbury* has filed a petition for *certiorari* to the United States Supreme Court, asking the Court to review the new "flexible" Rule 9(b) standard applied by the First Circuit. On February 22, 2010, the U.S. Supreme Court invited the views of the Solicitor General of the United States on whether the Court should grant *certiorari.* This step is often an indication that the Court is inclined to grant review but first wants the federal government's views regarding the broader implications of the case. The broader implications here include whether Rule 9(b) will be applied in a way that encourages or discourages off-label promotion cases by non-insiders, whether the False Claims Act should reward such plaintiffs, and the relationship between a relaxed Rule 9(b) and recent Supreme Court cases tightening the general pleading standards under Federal Rule of Civil Procedure 8.[7]

---

[5]*See United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009) ("the time, place, contents, and identity standard is not a straitjacket for Rule 9(b). Rather, the rule is context specific and flexible and must remain so to achieve the remedial purpose of the False Claims Act. We reach for a workable construction of Rule 9(b) with complaints under the False Claims Act; that is, one that effectuates Rule 9(b) without stymieing legitimate efforts to expose fraud. We hold that to plead with particularity the circumstances constituting fraud for a False Claims Act [] claim, a relator's complaint, if it cannot allege the details of an actually submitted false claim, may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.").

[6]Within days after the Eleventh Circuit's decision in *Hopper*, a district court upholding a *qui tam* complaint alleging off-label promotion stated that although no specific claims for reimbursement were identified in the complaint at issue, "allegations of that nature *are by no means necessary*" as long as defendants are fully apprised of what is alleged to constitute the fraud charged. *United States ex rel. Strom v. Scios, Inc.*, 2009 WL 5062323, *9-10 (N.D. Cal. Dec. 23, 2009) (emphasis added). Indeed, the court held, "the specifics of the claims themselves are somewhat less important," a statement which seems exactly at odds with the plain language of Rule 9(b) and its well-established heightened pleading standard. *Id*. at *9.

[7]*Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009); *Bell Atlantic v. Twombly*, 550 U.S. 544 (2007).