Legal Opinion Letter

WLF Washington Legal Foundation

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Vol. 20 No. 3 February 11, 2011

ABSENT PROOF OF CAUSATION, FEDERAL COURT DISMISSES *QUI TAM* SUIT ON OFF-LABEL SPEECH

by
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There can be no doubt that the False Claims Act ("FCA") has never been more popular as a healthcare fraud enforcement tool, particularly as applied to pharmaceutical and medical device manufacturers. Tony West, Assistant Attorney General for the Civil Division, noted that the most recent fiscal year, which ended September 20, 2010, "marked the largest healthcare fraud recovery under the False Claims Act in a single year ever – $2.5 billion."[1] And given that the FCA provides successful private plaintiffs, ("relators"), with up to 30% of the total recovery, there are potentially tens of millions of reasons for relators and their attorneys to allege that pharmaceutical and medical device manufacturers are engaged in conduct that violates the FCA, irrespective of whether those allegations are supported by facts.

In this environment, decisions like *United States ex. rel. Bennett v. Medtronic Inc.*, 2010 U.S. Dist. LEXIS 105018 (S.D. Tex. Sept. 30, 2010) from a federal district court in Texas importantly underscore that allegations made pursuant to the FCA must be plead with particularity. This ruling also reflects that the FCA should not be applied to alleged violations of regulations promulgated by the Food and Drug Administration ("FDA") where plaintiffs cannot demonstrate that those violations caused the actual submission of false claims.

Bennett was one of five *qui tam* actions filed by Elaine Bennett against seven medical device manufacturers, each alleging that the defendant had engaged in off-label promotion of certain surgical ablation devices to treat atrial fibrillation. *Bennett*, 2010 U.S. Dist LEXIS, at *1. Having never worked for Medtronic, Bennett and her fellow relator, Donald Boone, alleged that they were "industry insiders" and became aware of Medtronic's alleged improper practices while employed at competing medical device companies. *Id*. at *2.

The device at issue in *Bennett* was Medtronic's Cardioblate system, which the FDA had approved for ablating tissue to control bleeding and to coagulate cardiac tissue during general surgery. Despite relators' status as "industry insiders," the complaint did not allege that Medtronic submitted false claims to the government or that it concealed or misstated the limits of FDA approval for the Cardioblate System. Nor did relators provide details of any particular claim submitted to the Medicare or Medicaid program or the identity of any individual or entity that submitted such claims. Rather, relators highlighted three categories of what they characterized as actionable conduct by Medtronic in promoting the off-label use, or use not specifically approved by FDA, of Cardioblate systems: (1) providing physicians and hospitals with patient-education

[1] *See* November 22, 2010 Remarks as Prepared for Delivery by Assistant Attorney General for the Civil Division Tony West at the Pen and Pad Briefing on Civil Fraud Recoveries, last accessed at: http://www.mainjustice.com/2010/11/22/assistant-attorney-general-tony-wests-remarks-on-fy-2010-false-claims-act-recoveries/ on December 3, 2010.

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brochures about the use of the device to treat atrial fibrillation; (2) emphasizing the high reimbursement-to-cost ratio for using the device and coaching hospitals to "upcode" and overcharge Medicare by billing the procedure as an open-chest surgery instead of a closed-chest procedure; and (3) providing remuneration to hospitals and physicians to encourage them to use the device in violation of the anti-kickback statute. As a result of these actions, relators alleged that the Cardioblate system has been widely used for atrial fibrillation, and that a natural result of this increased utilization would include the submission of false claims to Medicare.

Citing two fundamental flaws in relators' complaint, the court granted Medtronic's motion to dismiss. First, the court held that in the absence of allegations identifying any Medtronic employee who engaged in off-label promotion or any physician or hospital that received off-label promotions or submitted false claims for off-label uses, relators failed to satisfy the pleading standard under FRCP 9(b). Rule 9(b) requires relators to allege the "who, what, when, where, and how" of the fraudulent scheme. Although relators argued that a relaxed pleading standard should be applied to their claims because either (1) the documents and information related to the alleged fraud were within Medtronic's knowledge and control or (2) the alleged fraud included a large number of claims over a long period of time, the court rejected these arguments. It noted that "even under a relaxed pleading standard, the relators must still state a factual basis for their claims" that a specific physician or hospital submitted a false claim. *Id*. at *17. Having failed to provide *any* factual basis to support their claims, the court concluded that relators' conclusory allegations of improper promotional activity coupled with independent allegations of increased utilization for an allegedly off-label use could not withstand scrutiny under Rule 9(b).

For the same reasons, the court dismissed relators' allegations of improper "upcoding" and violations of the anti-kickback statute. The complaint did not identify any Medtronic employee who encouraged upcoding, nor any physician or hospital that knowingly used an incorrect code on a Medicare reimbursement form. More fundamentally, relators failed to establish that the alleged proper code was the "only correct code." And relators' claim that Medtronic paid unlawful remuneration to hospitals and physicians for use of the Cardioblate system faltered as they did not allege that Medtronic caused such parties to falsely certify compliance with the anti-kickback statute in connection with submission of reimbursement forms to Medicare, or provide any reliable indicia that physicians or hospitals falsely certified compliance with the anti-kickback statute.

In addition to its failure to satisfy Rule 9(b)'s pleading requirements, the court dismissed relators' claim that Medtronic's alleged off-label promotion of the Cardioblate system for the treatment of atrial fibrillation resulted in the submission of false claims. The court noted that "[w]hile Medicare and Medicaid do not typically reimburse off-label prescriptions for drugs … for medical devices, eligibility for reimbursement depends on whether the procedure performed is "medically necessary" or "reasonable and necessary." *Id*. at *4. Accordingly, the court reasoned, claims for the use of the Cardioblate system in atrial fibrillation would be appropriately reimbursable, provided they are "medically necessary" or "reasonable and necessary," as determined "by independent physicians exercising independent professional judgment based on the knowledge of their particular patients." *Id*. at *26. The court rejected relators' argument that off-label uses were *per se* medically unnecessary simply because they had not been approved by the FDA. Without an independent basis to conclude that reimbursement claims were for non-medically necessary uses, or an allegation that Medtronic concealed or misstated the limits of the FDA's approval on use of the Cardioblate system, the court held there was no basis to presume that false claims had in fact been submitted. Significantly, the court concluded by noting that "even if a drug or device manufacturer's marketing or promotional activities violate FDA regulations, that is insufficient to plead that the manufacturer caused physicians or hospitals to submit false claims for reimbursement." *Id*. at *28.

In the wake of the government's announcement of record healthcare fraud recoveries under the FCA, and the recent publicity surrounding the $97 million award to the relator in *U.S. ex rel. Cheryl Eckard v. GlaxoSmithKline, et al.*, it is likely that FCA actions pursued against pharmaceutical and medical device companies will continue to increase. The *Bennett* decision provides other courts with an important framework for using Rule 9(b) to evaluate whether alleged regulatory violations by pharmaceutical and medical device manufacturers are appropriately subject to redress under the FCA.