IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

UNITED STATES OF AMERICA, *ex rel.* ELAINE BENNETT AND DONALD P. BOONE,	§	
Plaintiffs,	§	
V.	§	CIVIL ACTION NO. H-08-3408
MEDTRONIC, INC.,	§	
Defendant.	§	

MEMORANDUM AND OPINION

This case raises the question of when a manufacturer's promotion of a medical device for an "off-label" use may provide the basis for a *qui tam* action by private plaintiffs suing under the False Claims Act.[1] The relators, Elaine Bennett and Donald P. Boo4ne, allege that Medtronic, Inc. improperly promoted its Cardioblate system device for an off-label use and that the promotional activities caused physicians and hospitals to submit false claims for reimbursement from Medicare or Medicaid. The FDA has approved the Cardioblate system for the general uses of ablating tissue to control bleeding during general surgery and to coagulate cardiac tissue during general surgery. The relators allege that Medtronic has improperly promoted the use of the device for surgical ablation to treat atrial fibrillation, both in conjunction with other cardiac surgery and as a stand-alone procedure, which are off-label uses.

Medtronic has moved to dismiss under Rule 12(b)(6) and Rule 9(b) of the Federal Rules of Civil Procedure. Medtronic argues that the allegations of off-label promotional activities are

[1] (FCA), 31 U.S.C. § 3729, *et seq*.

insufficient to plead that it caused physicians or hospitals to submit false reimbursement claims to Medicare. (Docket Entry No. 30). The relators responded, (Docket Entry No. 41), and Medtronic replied, (Docket Entry No. 47).

Based on the pleadings, the motion, the responses, and applicable law, this court grants Medtronic's motion to dismiss, for the reasons explained in detail in this Memorandum and Opinion. Because there has been only one amendment, and because Rule 15 embodies a liberal amendment policy, the relators may amend no later than **October 29, 2010**, consistent with this Memorandum and Opinion.

I. Background

A. Procedural History

The relators filed their complaint on November 17, 2008, under seal, to allow the United States to decide whether it wanted to intervene.[2] This is one of five *qui tam* actions filed by one of the relators, Elaine Bennett, against medical-device manufacturers. (Docket Entry No. 4). Bennett also filed *qui tam* actions against Boston Scientific Corp. and Guidant Corp., *United States of America ex rel. Bennett v. Boston Sci. Corp.*, Civil Action No. H-07-2467; Atricure, Inc., *United States of America ex rel. Bennett v. Atricure, Inc.*, Civil Action No. H-07-2702; St. Jude's Medical, Inc. and Epicor Medical, Inc., *United States of America ex rel. Bennett v. St. Jude's Med. Inc.*, Civil Action No. H-07-2704; and Endoscopic Technologies, Inc., *United States ex rel. Bennett v. Endoscopic Tech., Inc.*, Civil Action No. H-07-2705. All these suits alleged off-label promotion of

[2] A private person may bring an FCA action in the name of the government. 31 U.S.C. § 3730(b). The complaint is served on the government under Federal Rule of Civil Procedure 4(d)(4) and filed *in camera* and under seal for at least sixty days. *Id.* at § 3730(b)(1). The government may elect to intervene and proceed with the action within sixty days after it receives both the complaint and the material evidence and information. *Id.* The relators did not file evidence or information beyond the complaint in this case.

surgical-ablation devices to treat atrial fibrillation. The *Boston Science* allegations involved a "microwave ablation device," (Civil Action No. H-07-2467, Docket Entry No. 58, at 3); the *Atricure* allegations involved a "bipolar ablation system," (Civil Action No. H-07-2702, Docket Entry No. 23, at 1); the *St. Jude* allegations involved "Epicor's cardiac ablation products," (Civil Action No. H-07-2704, Docket Entry No. 25, at 2); and the *Endoscopic Tech*. allegations involved "Cobra ablation products,"(Civil Action No. H-07-2705, Docket Entry No. 26, at 2). In each complaint,[3] the alleged unlawful promotional tactics included: encouraging sales representatives to promote the device for off-label use in treating atrial fibrillation; training doctors to use the device to treat atrial fibrillation; encouraging physicians and hospitals to "upcode" minimally invasive, stand-alone surgical ablations as open-chest procedures to obtain favorable Medicare reimbursement rates; marketing the high reimbursement-to-cost ratio of ablation devices compared to other atrial fibrillation treatments; encouraging the off-label use of the device by providing remuneration in forms that included (for physicians) referrals, free advertising, and direct payments, and (for hospitals) free products, volume discounts, and "lock-in" arrangements, all outside the antikickback statute's safe harbors.[4] On the government's motion, the cases were placed under joint

---

[3] *Boston Sci.*, Civil Action No. H-07-2467, Docket Entry No. 58, at 13–29; *Atricure*, H-07-2702, Docket Entry No. 23, at 19–29; *St. Jude*, Civil Action No. H-07-2704, Docket Entry No. 25, at 20–28; *Endoscopic Tech.*, Civil Action No. H-07-2705, Docket Entry No. 26, at 19–31.

[4] The precise features of each defendant's promotional tactics varied. Some of these cases involved additional tactics. In *Atricure*, the relators identified an individual who sat on the boards of both Atricure and a hospital and alleged that he caused that hospital to use Atricure's ablation device off-label and to submit upcoded claims for reimbursement. (H-07-2702, Docket Entry No. 23, at 28–29). The *Atricure* complaint also named individual doctors who allegedly upcoded. (*Id.* at 30). In *St. Jude*, the relator identified contracts that the defendants offered to hospitals under which they would establish "Atrial Fibrillation Centers" and "certify" physicians to perform surgical ablations, using the favorable reimbursement-to-cost ratio to market the profit opportunities from the centers. (Civil Action No. H-07-2704, Docket Entry No. 25, at 29–31).

administration. (Docket Entry Nos. 4, 6).[5] The United States declined to intervene in this suit against Medtronic on August 2009. The relators filed an amended complaint in July 2009, (Docket Entry No. 12), and an unredacted version of that complaint in December 2009, (Docket Entry No. 27).

B. The Parties

Medtronic develops, manufactures, and markets medical devices, including surgical devices. The relators, Elaine Bennett and Donald P. Boone, describe themselves as "industry insiders" who have never worked for Medtronic but have worked for other medical-device manufacturers. Bennett alleges that she worked for Boston Scientific for four months as a sales representative. She alleges that she has knowledge of Medtronic's "illegal billing and coding practices."[6] Boone alleges that he worked as a sales representative for Guidant, in a management position for St. Jude Medical, and most recently at Endoscopic Technologies, which manufactures devices that compete with Medtronic in treating atrial fibrillation. (*Id.* at ¶¶ 16–17). Boone alleges that he became familiar with the practices alleged in this complaint while working for Guidant and St. Jude.

---

[5] The complaint against Boston Scientific was unsealed on July 2, 2009. (Civil Action No. H-07-2467, Docket Entry No. 30). The United States has not intervened and Boston Scientific has moved to dismiss. (Docket Entry No. 68). The United States intervened in *Atricure*. (Civil Action No. H-07-2702, Docket Entry No. 41). That case settled and was dismissed with prejudice. (*Id.*, Docket Entry No. 43) St. Jude Medical and Epicor Medical settled with the relator and those claims were dismissed with prejudice. (Civil Action No. H-07-2704, Docket Entry No. 46). The United States did not make an election on whether to intervene and the dismissal was without prejudice to future claims by the United States. (*Id.*, Docket Entry No. 47). Endoscopic Technologies settled with both the relator and the United States, and that case was dismissed with prejudice. (Civil Action No. H-07-2705, Docket Entry No. 21, 28).

[6] Bennett also alleges that she has knowledge of "the improper practice of medicine undertaken by unlicensed Medtronic Representatives," (Docket Entry No. 27, ¶ 16), but such a practice is not alleged as a basis for relief in this case.

C. The False Claims Act

The False Claims Act prohibits the knowing submission of false or fraudulent claims for payment, or causing the submission of such claims, to the federal government, and prescribes fines and treble damages to penalize offenders. 31 U.S.C. § 3729(a). The FCA establishes liability for "[a]ny 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 to get a false or fraudulent claim paid or approved by the government." 31 U.S.C. § 3729(a)(1–2), *amended by* 31 U.S.C. § 3729(a)(1)(A–B).

When a *qui tam* suit is brought by a private relator and the government declines to intervene, the relator is entitled to between 25 and 30% of the recovery, § 3730(d)(2), as well as attorneys' fees. As has often been pointed out, the Act does not create a cause of action against all fraudulent conduct affecting the government. Rather, 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." 31 U.S.C. § 3729(a)(1)–(2), *amended by* 31 U.S.C. § 37299(a)(1)(A–B). "Evidence of an actual false claim is the '*sine qua non* of a False Claims Act violation.'" *United States ex rel. Clausen v. Lab. Corp. of Am., Inc*., 290 F.3d 1301, 1311 (11th Cir. 2002).

In this case, there are no specific allegations that Medtronic itself submitted false claims. Instead, the complaint alleges that Medtronic knowingly caused the submission of fraudulent claims by physicians and hospitals in the form of claims for reimbursement for off-label uses of a Medtronic device. The complaint does not identify any specific false claim presented by others to Medicare/Medicaid. Nor does the complaint identify any entity or person who actually submitted such a claim. Instead, the complaint alleges that as a result of Medtronic's marketing campaign and

illegal kickbacks, the Medtronic Cardioblate system has been widely used for the off-label purpose of treating atrial fibrillation by physicians and hospitals and that this use "would result in the submission of fraudulent claims." (Docket Entry No. 27, ¶ 136).

D. Off-Label Use of Medical Devices

The FDA approves products for specific indications, which are stated in the label. When a medical device is approved for one purpose or indication and used outside this approved purpose, that use is deemed "off label." Off-label promotion involves disseminating information about product uses not approved by the FDA. The FDA generally restricts a manufacturer from marketing for off-label purposes but does not restrict a hospital from purchasing or a doctor from prescribing or using a medical device for an off-label purpose. Off-label use of many products and drugs is an accepted medical practice.[7]

Courts recognize that off-label use of a drug or medical device is not the same as a medically unnecessary use of that drug or device. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 121 S. Ct. 1012, 1018 (2001) ("'[O]ff-label' usage of medical devices . . . is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine."); *Svidler v. United States Dep't of Health and Human Servs.*, No. C-03-3593 MJJ, 2004 WL 2005781, at *5 (N.D. Cal. Sept. 8, 2004) ("[T]he FDA can restrict a company from marketing off-label uses, but cannot prevent a doctor from prescribing a device for an off-label use for any purpose she deems medically necessary." (citing *Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998)); *United States ex rel. Polansky v. Pfizer*, No. 04-cv-0704 (ERK),

[7] *See generally*, Ralph F. Hall & Robert J. Berlin, *When You Have a Hammer Everything Looks Like a Nail*, 61 FOOD AND DRUG L.J. 653, 655–56 (2006)

2009 WL 1456582, at *6 (E.D.N.Y. May 22, 2009) ("[T]he FDA has acknowledged that 'accepted medical practice often includes drug use that is not reflected in approved drug labeling.'" (citing Food & Drug Admin., Use of Approved Drugs for Unlabeled Indications, 12 FDA Drug Bulletin 4, 5 (1982)); *United States ex rel. Stephens v. Tissue Sci. Labs., Inc.*, Civil Action No. 1:07-CV-2357-ODE, LEXIS 2009 DIST. 101601, at *20 (N.D. Ga. Aug. 13, 2009) (noting that DRG payment may be made for hernia care even if noncovered care—the use of the device at issue—was present).

Medicare reimbursements for off-label uses of medical devices are not addressed within the Medicare Act itself. *See generally Yale-New Haven Hosp. v. Leavitt*, 470 F.3d 71, 73 (2d Cir. 2006). Broad wording excludes from Medicare coverage "any expenses incurred for items or services . . . which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). The Secretary of the Department of Health and Human Services "is responsible for specifying those services that are covered under the 'reasonable and necessary' standard" and "has wide discretion in selecting the means for doing so." *Yale-New Haven Hosp.*, 470 F.3d at 74 (citing 42 U.S.C. § 1395ff(a); *Heckler v. Ringer*, 466 U.S. 602, 617 (1984)). Traditionally, the Secretary has acted through "formal regulations and (informal) instructional manuals and letters." *Id.* Before 1995, the Medicare Hospital Manual, the Medicare Carriers Manual, and the Intermediary Manual stated that payment could not be made for devices not approved by the FDA for commercial distribution because "they were not considered 'reasonable and necessary' under 42 U.S.C. § 1395y(a)(1)." *In re Cardiac Devices Qui Tam Litig.*, 221 F.R.D. 318, 323 (D. Conn. 2004) (citing Medicare Hospital Manual § 260.1(B) (effective July 15, 1986); Medicare Carriers Manual § 230.1; Intermediary

Manual § 3151.1); *see also Yale-New Haven Hosp.*, 470 F.3d at 74 (discussing the history of the manual provisions). In 1995, the Secretary of the United States Department of Health and Human Services published regulations superseding the manual provisions and allowing Medicare coverage for Category B investigational devices under the "reasonable and necessary" standard. *Yale-New Haven Hosp.*, 470 F.3d at 71. As one court has summarized:

> On September 19, 1995, after completing a formal notice-and-comment rule-making process regarding coverage for investigational devices under the statutory 'reasonable and necessary' standard, the Secretary of HHS published final regulations addressing the coverage of medical devices categorized by the FDA as 'investigational.' The new regulations provided Medicare coverage for those 'non-experimental/investigational' devices as to which the initial questions about the devices' safety and effectiveness had been resolved. *See* 42 C.F.R. §§ 405.201(b), 405.203, 405.211(b). In contrast to the total exclusion from coverage of such devices under the Manual provision, the new regulations classified such devices as either experimental/investigational ('Category A') for which there continued to be no coverage, or non-experimental investigational ('Category B') which are eligible for Medicare coverage. *See* C.F.R. §§ 405.201, 405.203(a), 405.205, 405.209, 405.211.

In re Cardiac Devices Qui Tam Litig., 221 F.R.D. 318, 325 (D. Conn. 2004).

The allegations in this case are that a Category B non-experimental/investigational medical device the FDA approved for a general use—to ablate tissue, including cardiac tissue, in surgical procedures—is being marketed for an off-label, specific use that the FDA has not approved—to ablate cardiac tissue to treat atrial fibrillation. Atrial fibrillation is a fast and irregular beating of the heart's atria. The first-line treatments for atrial fibrillation are nonsurgical and include using drugs. (Docket Entry No. 27, ¶ 47). According to the relators, a recognized surgical treatment is an open-heart procedure known as the "maze." In a maze procedure, a cardiothoracic surgeon makes strategic incisions in both atria and uses a "cut and sew" technique to repair the heart. The maze procedure is effective but also dangerous and difficult. (*Id.* at ¶ 48). As a result, the medical community has continued efforts to find less invasive, more effective methods of treatment.

Two newer forms of treatment for atrial fibrillation are catheter ablation and surgical ablation. In catheter ablation, an electrophysiologist—a specialized cardiologist—threads a catheter through the patient's leg and into the heart. The catheter is equipped with a device that delivers radiofrequency waves to ablate heart tissue. The relators allege that catheter ablation is often an outpatient procedure. (*Id.* at ¶¶ 50–52). The relators allege that a large number of studies and scientific organizations have recently recognized catheter ablation as an effective procedure to treat atrial fibrillation. In 2006, catheter ablation was included within the "Guidelines" for treating atrial fibrillation as a "third-tier treatment option, following drug therapy and cardioversion." (*Id.* at ¶¶ 52–53).

The relators allege that surgical ablation is a more recent ablation method. Surgical ablation treats atrial fibrillation by using radiofrequency waves to ablate heart tissue to disrupt the normal pathways for electrical impulses. (*Id.* at ¶¶ 46, 54–55). It is typically an inpatient procedure performed by cardiothoracic surgeons. It can be performed as an additional procedure during open-chest surgery for other cardiac conditions or as a stand-alone procedure. As part of other open-chest procedures, a surgeon uses the cardiac ablation device to create incisions on tissue similar to the incisions made in a "maze" procedure. In a stand-alone surgical ablation, sometimes referred to as a "mini maze" procedure, a surgeon makes three to four incisions on a patient's chest and directs an ablation device through those incisions to the heart. According to the relators, stand-alone surgical ablation "unlike traditional open heart surgery, does not require opening the thoracic cavity to expose the heart and lungs and does not require a heart-lung machine." (*Id.* at ¶ 65). It is an inpatient but minimally invasive surgery.

As the relators acknowledge, Cardioblate system devices are classified for Medicare reimbursement purposes as Class II devices. (*Id.* at ¶ 75); *see also* 21 C.F.R. § 878.4400 (identifying "electrosurgical cutting and coagulation device and accessories . . . intended to remove tissue and control bleeding by use of high-frequency electrical current" as a Class II device). Under Medicare regulations, a device "believed to be in . . . Class II" is a Category B—"non-experimental/investigational"—device. 42 C.F.R. § 405.201(b). Class II devices "require special controls, such as performance standards or postmarket surveillance, to provide reasonable assurance of safety and effectiveness." 42 C.F.R. § 405.201(b). Medicare contractors may approve coverage for Category B devices. *Id.* at § 405.211(b). The relators acknowledge that there is no "national coverage determination" for reimbursement for surgical ablation using radiofrequency devices. "Accordingly, the Medicare Carrier in each state or region determines the conditions for coverage and reimbursement of physician charges for surgical cardiac ablation." (Docket Entry No. 27, ¶ 67). While there is no FDA approval for using the Cardioblate system to treat atrial fibrillation, there is no identified statutory, regulatory, or other prohibition on reimbursement to physicians or hospitals for using the Cardioblate system for this purpose. While Medicare and Medicaid typically do not reimburse off-label prescriptions for drugs, *see United States ex rel. Franklin v. Parke–Davis*, 147 F. Supp. 2d 39, 44–45 (D. Mass. 2001); *United States ex rel. Hess v. Sanofi–Synthelabo Inc.*, No. 4;05CV570MLM, 2006 WL 1064127, at *10 (E.D. Mo. Apr. 21, 2006), the relators have not pointed to a similar categorical restriction on reimbursement for Category B medical devices.[8] For medical

[8] Under the FDCA, new pharmaceuticals cannot be distributed in interstate commerce unless the drug's sponsor satisfies the FDA that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a), (d). Once a drug is approved for a particular use, the FDA does not prevent doctors from prescribing the drugs for uses that are different than those approved by the FDA. *Parke–Davis*, 147 F. Supp. 2d 39, 44 (D. Mass. 2001) (citing *Buckman*, 121 S. Ct. at 1018). However, "[w]hether a drug is FDA-approved for a

devices, eligibility for reimbursement depends on whether the procedure performed is "medically necessary" or "reasonable and necessary."

E. The Medicare Billing System

The Medicare billing scheme is the context for this FCA suit. Under its "prospective payment system," Medicare prepays hospitals specific predetermined amounts based on codes for the diagnosis and procedure performed. (Docket Entry No. 27, ¶¶ 25, 29). The complex billing scheme includes a lengthy list of codes that reflect medical and administrative judgments.

The amounts hospitals receive for inpatient procedures depend on the Diagnosis Related Group ("DRG") code assigned to a patient. In addition to basic information about the patient and the diagnosis, the procedure performed on the patient is a factor in determining a patient's DRG. 42 C.F.R. § 412.60(c)(1) (stating that the DRG is based on "essential data extracted from the inpatient bill for that discharge" including "the patient's age, sex, principal diagnosis, . . . secondary diagnoses, procedures performed, and discharge status"). Hospitals enter a procedure code when they submit Form HCFA-1450 (UB-92) to obtain reimbursement for items and services provided

---

particular use will largely determine whether a prescription for that use of the drug will be reimbursed under the federal Medicaid program." *Id.* One court has summarized the drug-reimbursement criteria, as follows:

> Reimbursement under Medicaid is, in most circumstances, available only for "covered outpatient drugs." 42 U.S.C. § 1396b(i)(10). Covered outpatient drugs do not include drugs that are "used for a medical indication which is not a medically accepted indication." *Id*. § 1396r-8(k)(3). A medically accepted indication, in turn, includes a use "which is approved under the Federal Food Drug and Cosmetic Act" or which is included in specified drug compendia. *Id.* § 1396r-8(k)(6). *See also id.* § 1396r-8(g)(1)(B)(i) (identifying compendia to be consulted). Thus, unless a particular off-label use for a drug is included in one of the identified drug compendia, a prescription for the off-label use of that drug is not eligible for reimbursement under Medicaid.

United States ex rel. Franklin v. Parke–Davis, 147 F. Supp. 2d 39, 44–45 (D. Mass. 2001).

to a patient. *Cardiac Devices.*, 221 F.R.D. at 328–29; *United States ex rel. Smith v. Yale Univ.*, 415 F. Supp. 58, 91–92 (D. Conn. 2006). These codes are based on the International Classification of Diseases, Ninth Revision, Clinical Modification ("ICD-9-CM") system. (Docket Entry No. 27, ¶¶ 27). In addition to Forms UB-92, hospitals annually submit a Hospital Cost Report, Form HCFA-2552, which summarizes the amounts of interim payments received and the amounts the hospital claims from Medicare. *Cardiac Devices.*, 221 F.R.D. at 328–29

The amounts Medicare pays physicians for services provided in conjunction with a procedure performed at a hospital are based on Current Procedural Terminology ("CPT") codes published by the American Medical Association. Physicians typically provide the CPT code and submit claims for payment on Form CMS-1500. (Docket Entry No. 27, ¶¶ 29–33).

F. The Medical Device at Issue

The Medtronic Cardioblate system includes a radiofrequency-power generator, surgical probes to create lesions, and a MAPS device that evaluates the effectiveness of ablation. (*Id.* at ¶¶ 62–65). Medtronic's Cardioblate system can be used either in conjunction with other cardiac surgical procedures or for stand-alone surgical ablation. As noted, the FDA has approved Medtronic's Cardioblate system for the coagulation of cardiac tissue using radiofrequency [] energy during cardiac surgery"; for use "during general surgery to coagulate soft tissues; and "to remove tissue and control bleeding by use of high-frequency electrical current." (*Id.* at ¶ 76); *see also* 510(k) Premarket Submission—Medtronic—Cardioblate System (Jan. 25, 2002) (granting premarket approval for the Medtronic Cardioblate Radiofrequency Ablation System "to ablate cardiac tissue

during cardiac surgery using radiofrequency energy")[9]; 510(k) Summary of Safety and Effectiveness (May 5, 2008) (granting premarket approval for the Cardioblate Surgical Ablation System "to ablate cardiac tissue during cardiac surgery using radiofrequency energy").[10] The FDA has approved one

---

[9] This premarket notification letter was quoted in the relators' complaint, (Docket Entry No. 12, ¶ 76), and in Medtronic's Motion to Dismiss, (Docket Entry No. 30, at 5 n.4). The letter is available at http://www.accessdata.fda.gov/cdrh_docs/pdf/K013392.pdf. In deciding a motion to dismiss, a court may consider the pleadings and "documents attached to or incorporated into the complaint and matters of which judicial notice may be taken." *United States ex rel. Willard v. Humana Health Plan of Tex. Inc.*, 336 F.3d 375, 379 (5th Cir. 2003) (citing *Lovelace v. Software Spectrum Inc.*, 78 F.3d 1015, 1017-18 (5th Cir. 1996)); *Cinnel v. Connick*, 15 F.3d 1338, 1343 n. 6 (5th Cir.1994); *see also Funk v. Stryker Corp.*, 673 F. Supp. 2d 522, 530 (S.D. Tex. 2009) (taking judicial notice of FDA premarket-approval letters because they are in the "public record" (quoting *Norris v. Hearst Trust*, 500 F.3d 454, 461 n.9 (5th Cir. 2007)). This court also takes judicial notice of the following documents cited by the parties: Medtronic Cardioblate Gemini Surgical-Ablation Device 510(k) Premarket Notification, (Apr. 24, 2007), *available at* https://www.accessdata.fda.gov/cdrh_docs/pdf7/K070311.pdf (Docket Entry No. 30, at 5 n.4); FOOD AND DRUG ADMINISTRATION, GUIDANCE ON THE CDRH PREMARKET NOTIFICATION REVIEW PROGRAM 6/30/86 (K86-3), 510(K) MEMORANDUM #K86-3, *available* at http://www.fda.gov/MedicalDevices/ DeviceRegulationandGuidance/GuidanceDocuments/ucm081383.htm (Docket Entry No. 56 , at 5 n.4); and FOOD AND DRUG ADMINISTRATION, GUIDANCE FOR INDUSTRY: GENERAL/SPECIFIC INTENDED USE (Nov. 4, 1998), *available at* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ GuidanceDocuments/ucm073944.htm. (Docket Entry No. 45, at 5–6, n.4).

The parties dispute whether this court should take judicial notice of an FDA warning letter sent to St. Jude Medical, Inc. about its marketing of a different surgical-ablation device for treating atrial fibrillation. The relators filed a motion for this court to take judicial notice, (Docket Entry No. 48); Medtronic responded, (Docket Entry No. 49); and the relators replied, (Docket Entry Nos. 50–52). The FDA warning letter informs St. Jude that promotion of its surgical ablation device for the treatment of atrial fibrillation violates FDA regulations. (Docket Entry No. 48, Ex. A). Medtronic, citing *Lovelace*, argues that this court's notice is limited to the existence of the document, not the "veracity" of its contents. 78 F.3d at 1018. In *Lovelace*, the court stated,

> When deciding a motion to dismiss a claim for securities fraud on the pleadings, a court may consider the contents of relevant public disclosure documents which (1) are required to be filed with the SEC, and (2) are actually filed with the SEC. Such documents should be considered only for the purpose of determining what statements the documents contain, not to prove the truth of the documents' contents.

Id. The letter only informs St. Jude that its promotion of its surgical ablation device violated FDA regulations. The court may take judicial notice of this document without resolving whether its contents are true. The relators' motion for judicial notice, within this limit, is granted.

[10] This premarket notification letter is available at http://www.accessdata.fda.gov/cdrh_docs/pdf8/K080509.pdf.

Cardioblate system for a "minimally invasive, closed-chest" stand-alone surgical procedure. Medtronic Cardioblate Gemini Surgical-Ablation Device 510(k) Premarket Notification, (Apr. 24, 2007).[11] The FDA has denied general approval for the Cardioblate system as a treatment for atrial fibrillation three times. (Docket Entry No. 27, ¶ 81). The relators allege, and Medtronic accepts as true for the purpose of this motion, that because the FDA has approved the Cardioblate system for use during "open surgical procedures," and has not approved the Cardioblate system for treating atrial fibrillation, Medtronic may not market the Cardioblate devices for use in minimally invasive closed-chest surgical procedures for treating atrial fibrillation. (Docket Entry No. 27, ¶ 85); *see* 21 C.F.R. § 812.7(a).

The relators allege facts showing disagreement and uncertainty in the medical community about surgical ablation's efficacy in treating atrial fibrillation. The relators allege that at a May 2007 American Association of Thoracic Surgeons Society meeting, several surgeons reported the efficacy rate of surgical ablation to treat atrial fibrillation to be under 50% in some clinical studies. (Docket Entry No. 27, ¶ 59). The relators also cite a joint statement by the Heart Rhythm Society, European Heart Rhythm Association, and European Cardiac Arrhythmia Society that "prospective multicenter clinical trials are needed to better define the relative safety and efficacy of surgical [ablation] tools and techniques," and that "[t]he true success rates of these procedures are likely to be lower than reported. (*Id.* at ¶ 60).

The relators also allege facts showing competition among hospitals and physicians for atrial fibrillation patients. The competition is particularly acute between physicians who perform catheter ablations (electrophysiologists) and those who perform surgical ablations (cardiothoracic surgeons).

---

[11] This letter is available at https://www.accessdata.fda.gov/cdrh_docs/pdf7/K070311.pdf.

The relators unabashedly take the electrophysiologists' side in this competition. The relators accuse Medtronic of, among other things, seeking to change the referral patterns so that physicians will refer atrial fibrillation patients directly to cardiothoracic surgeons for treatment, rather than to cardiologists, who according to the relator are more likely to refer patients to electrophysiologists for treatment. (*Id.* at ¶¶ 90–91, 108).

G. The Alleged Improper Promotional Activities

The relators allege four categories of what they characterize as actionable conduct by Medtronic promoting off-label use of the Cardioblate systems.

- Medtronic sales representatives provided physicians and hospitals with patient-education brochures about the use of stand-alone surgical ablation to treat atrial fibrillation. These brochures included statements that: "[e]xperience to date indicates that Mini-Maze surgery eliminates afib in more than 85% of patients who undergo the procedure"; "[m]ost patients with afib are candidates for Mini-Maze. Together, you and your doctor can determine if this surgery is right for you."; "Mini-Maze surgery is the first treatment that can safely, easily and reliably eliminate afib, helping patients avoid lifelong drug therapy and reducing the high risk of stroke and other complications that are associated with afib."; "Catheter Ablation destroys the source of abnormal electrical signals, vs. Mini-Maze Surgery, which creates a 'zone of defense' to permanently eliminate afib"; and "Catheter Ablation procedures take hours to perform, may require a pacemaker, and can cause life-threatening damage to organs near the heart. As a result, they are reserved for the most severe cases of afib. The Mini-Maze experience to date indicates that the surgery corrects afib in

more than 85% of patients." (*Id.* at ¶¶ 88-91). The complaint alleges that these statements are misleading because there is no "safety and efficacy study submitted to the FDA" and no "conclusive consensus of clinical studies documenting 85% efficacy or cure rate" (although the brochures do not make such claims). The complaint alleges that the statements equate to a statement that stand-alone surgical ablation is recommended other than as a last resort, while acknowledging that in 2006, cardiology peer groups recommended that surgical ablation should be performed in conjunction with other open heart procedures taking place. The complaint alleges that the comparisons between surgical ablation and catheter ablation are misleading because the procedures are similar in effect and similar in the identified risks. (*Id.*). There is no allegation, however, that the patient brochures falsely identified the FDA-approval status of the Cardioblate system.

- Medtronic, like "other minimally invasive surgical ablation companies," on "information and belief" marketed its devices to hospitals by emphasizing the high reimbursement-to-cost ratio available through using surgical ablation to treat atrial fibrillation in minimally invasive procedures. This is part of the "upcoding" allegations set out below. The relators also allege that this promotion of the "high profit margin hospitals can expect to see" in using the Cardioblate system to treat atrial fibrillation "demonstrate[s] that Defendant intends off-label use of their product." (*Id.* at ¶¶ 93–95). The relators also allege that Medtronic's promotion activities included requiring its sales representatives to accompany new surgeons into the operating room to provide them with instructions on administering the

Cardioblate system to treat atrial fibrillation and using this "Experts in the OR" Program to provide direct training on using the Cardioblate system to treat atrial fibrillation. (*Id.* at ¶¶ 97, 112).

- Medtronic "coached" hospitals to "upcode" and overcharge Medicare for closed-chest stand-alone procedures by billing them with a DRG and procedure code for open-chest surgery.[12] The relators allege that Medtronic told its sales representatives to tell hospitals that they could bill Medicare for closed chest stand alone procedures using DRG 108 (excision or destruction of other lesion or tissue of heart, open approach), which is a code for "open chest" approaches, including the Maze procedure. The relators acknowledge that the DRG code associated with procedure code 37.33 is DRG 108. The relators allege that the ICD-9 procedure code and the DRG codes are incorrect for closed-chest procedures. The relators allege that because there is no procedure code that provides reimbursement for the closed-chest surgical ablation, "a more appropriate code . . . would be procedure code 37.99 (other operations on heart and pericardium)," and DRG 110 or 111 (respectively, major cardiovascular procedures with and without complications and comorbidities)." The relators allege that the average reimbursement for a hospital under DRG 108 is $30,289 and the average cost to the hospital for patients who require procedures qualifying under that DRG is $31, 074. In contrast, the average cost of a closed-

[12] The relators' upcoding allegations appear to be directed at hospitals. (Docket Entry No. 27, ¶ 122). In describing Medicare billing procedures, the amended complaint alleges that hospitals use ICD-9-CM codes for billing, (*Id.* at ¶ 27) and that physicians use CPT codes, (*Id.* at ¶¶ 33–36). The upcoding allegations appear to be focused on the upcoding of the ICD-9-CM code entered by the hospitals. (*Id.* at ¶¶ 121–29).

chest stand-alone surgical ablation is $10,650. The relators allege that by training sales representatives to tell hospitals that they could bill Medicare for closed-chest stand-alone procedures using DRG and procedure codes for open-chest procedures, Medtronic improperly promoted its Cardioblate surgical-ablation system. (*Id.* at ¶¶ 121–30). This category of alleged actionable promotion by Medtronic only applies to stand-alone procedures; the use of the Cardioblate in open-chest procedures that also treat other cardiac conditions is properly billed using the codes for such procedures.

- The relators also allege that Medtronic provided remuneration to physicians and hospitals to encourage them to use the Cardioblate system device, in violation of the antikickback statute, 42 U.S.C. § 1320a-7b(b). The relators allege that Medtronic provided in-kind services to physicians, particularly cardiothoracic surgeons, including referral services, marketing, and direct payments. (Docket Entry No. 27, ¶ 102). The relators allege that Medtronic sponsored meetings to screen candidates for surgical ablation and referred them to cardiothoracic surgeons who used the Cardioblate system. (*Id.* at ¶ 109). The relators allege that Medtronic "endow[ed] elaborate dinner programs" to present information about Cardioblate to physicians who could make referrals, paying Medtronic-trained surgeons to put on the programs. (*Id.* at ¶ 105). The relators allege that Medtronic also helped cardiothoracic surgeons advertise "minimally invasive" surgical ablation to treat atrial fibrillation. The relators allege that Medtronic provided cardiothoracic surgeons using the Cardioblate system free advertising by paying for brochures

> describing their use of the device. Finally, the relators allege that Medtronic provided direct payments to physicians in the form of grants to physicians who promoted the Cardioblate system to other physicians. (*Id.* at ¶¶ 102–04; 108–11). As to hospitals, the relators allege that Medtronic paid kickbacks in the forms of discounts for buying large amounts of the Cardioblate equipment, loans to purchase the equipment contingent on a minimum number, and free products. The relators allege that Medtronic offered these inducements on the condition that a hospital use the Cardioblate system for at least ninety percent of surgical ablation procedures. (*Id.* at ¶¶ 113–20). The relators allege that Medtronic's kickbacks caused false or fraudulent claims for payment to be submitted because certification of compliance with all applicable laws and regulations, including the antikickback statute, is a condition for payment under Medicare. (*Id.* at ¶ 141–43).

The relators allege that these promotional efforts "caused physicians and hospitals to perform an increased number of costly inpatient surgical ablation procedures in cases where less costly and less invasive treatments otherwise have been performed." (*Id.* at ¶ 140). The relators allege that Medtronic "knowingly made, used, and caused to be made and used false records and statements in order to obtain reimbursement from the United States for surgical ablation services performed with [Medtronic's] surgical ablation products." (*Id.* at ¶ 143).[13] To support its allegations, Medtronic does not allege specific instances of false claims. Instead, Medtronic points to the high number of

[13] The relators include an allegation that Medtronic "knowingly presented and caused to be presented . . . fraudulent claims, records, and statements in order to obtain reimbursement for surgical ablation services performed with [Medtronic's] ablation products" but appear to limit their allegations to causing hospitals and physicians to present false reimbursement claims. (Docket Entry No. 45, at 6–16).

surgical ablations performed at LDS Hospital in Salt Lake City, at Scott & White Healthcare in Central Texas, and by eight individual physicians. (*Id.* at ¶ 132–35).

In its motion to dismiss under Rule 12(b)(6), Medtronic argues that the relators have not alleged that it made or caused any false claim to be submitted to Medicare. Medtronic emphasizes both that the complaint does not link Medtronic's marketing practices to the submission of a false claim and that Medtronic's promotional tactics are not "material" to the government's decisions to pay Medicare claims for surgical ablations. Medtronic also argues that the relators did not allege sufficient facts to support a reasonable inference that hospitals or physicians falsely certified compliance with the antikickback statute. Finally, Medtronic argues that the relators have not met Federal Rule of Civil Procedure 9(b)'s heightened pleading requirements for fraud because they fail to identify the "who, what, when, where, and how of the alleged fraud." *See United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 903 (5th Cir. 1997).

The relators respond that Medtronic's promotional efforts caused physicians and hospitals to perform more surgical ablations to treat atrial fibrillation than would otherwise have been performed and, as a result, more that were not medically necessary. As a result, physicians and hospitals submitted claims for reimbursement for procedures that were not medically necessary and that would not have been submitted but for the off-label promotion. (Docket Entry No. 45, at 8); 42 U.S.C. § 1320c-5(a)(3) ("medically necessary"); 42 U.S.C. § 1395y(a)(1)(A) ("reasonable and necessary"). The relators argue that using the Cardioblate system in minimally invasive closed-chest procedures to treat atrial fibrillation is never medically necessary because the Cardioblate system is not FDA approved, is experimental, and is not a first-line treatment for this purpose. The relators also argue that by marketing hospitals' ability to upcode stand-alone ablation procedures using the

Cardioblate system, Medtronic was the "but for" cause of hospitals and doctors submitting claims for payment with three false statements: that the code used accurately represented the procedure performed; that the procedure was the most economical, as required by 42 U.S.C. § 1320c-5(a)(1), and that the procedure was "medically necessary," as required by 42 U.S.C. § 1320c-5(a)(3). The relators also argue that Medtronic's kickbacks caused physicians and hospitals to falsely certify—either implicitly in claims for payment, or expressly in annual compliance statements—compliance with the antikickback statute. The relators argue that Medtronic's promotional efforts were material because their "natural tendency" was to cause the submission of false claims. Finally, the relators respond that they have provided sufficient factual allegations to demonstrate a scheme to defraud.

In its reply, Medtronic argues that although the FDA has not specifically approved the Cardioblate system for surgically treating Atrial Fibrillation, such use can be and often is "medically necessary." Medtronic emphasizes that the decision whether to use its device in surgically treating atrial fibrillation is a medical decision, made by a physician, and that nothing in the complaint alleges that any physician made such a decision knowing that it was not a medically necessary treatment in the specific use. Medtronic argues that the relators' failure to plead any specific unnecessary procedure means that they cannot meet Rule 9(b)'s particularity requirement. For both relators' antikickback claims and upcoding claims, Medtronic argues that the relators have failed to meet Rule 9(b) because they fail to identify any physicians or hospitals who upcoded or submitted false certifications—implied or express—of compliance.

Each argument and response is analyzed below.

II. The Legal Standards for a Motion to Dismiss

Medtronic moves to dismiss the allegations based solely on the alleged off-label promotion of the Cardioblate surgical ablation devices and the allegations of the antikickback statute in connection with the sale of these devices under Rule 12(b)(6). Medtronic also moves to dismiss under Rule 9(b) because of the failure to plead fraud with the requisite particularity. Claims brought under the FCA are fraud claims that must comply with the requirements of Rule 9(b). *Hopper v. Solvay Pharms.*, 588 F.3d 1318, 1325 (11th Cir. 2009); *Thompson*, 125 F.3d at 903; *United States ex rel. Longhi v. Lithium Power Techs., Inc.*, 575 F.3d 458, 468 (5th Cir. 2009). The parties also analyze the application of 31 U.S.C. § 3729(a).

A. Rule 12(b)(6)

Rule 12(b)(6) allows dismissal if a plaintiff fails "to state a claim upon which relief can be granted." FED. R. CIV. P. 12(b)(6). In *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007), and *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009), the Supreme Court confirmed that Rule 12(b)(6) must be read in conjunction with Rule 8(a), which requires "a short and plain statement of the claim showing that the pleader is entitled to relief." FED. R. CIV. P. 8(a)(2). To withstand a Rule 12(b)(6) motion, a complaint must contain "enough facts to state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* (citing *Twombly*, 550 U.S. at 556). "To survive a Rule 12(b)(6) motion to dismiss, a complaint 'does not need detailed factual allegations,' but must provide the plaintiff's grounds for entitlement to relief—including factual allegations that when assumed to be true 'raise a right to

relief above the speculative level." *Cuvillier v. Taylor*, 503 F.3d 397, 401 (5th Cir. 2007) (footnote omitted) (quoting *Twombly*, 550 U.S. at 555); *see also S. Scrap Material Co. v. ABC Ins. Co.* (*In re S. Scrap Material Co.*), 541 F.3d 584, 587 (5th Cir. 2008) (quoting *Twombly*, 550 U.S. at 555), *cert. denied*, 129 S. Ct. 1669 (2009). "Conversely, 'when the allegations in a complaint, however true, could not raise a claim of entitlement to relief, this basic deficiency should . . . be exposed at the point of minimum expenditure of time and money by the parties and the court.'" *Cuvillier*, 503 F.3d at 401 (quoting *Twombly*, 550 U.S. at 558).

When a plaintiff's complaint fails to state a claim, the court should generally give the plaintiff at least one chance to amend under Rule 15(a) before dismissing with prejudice. *See Great Plains Trust Co. v. Morgan Stanley Dean Witter & Co.*, 313 F.3d 305, 329 (5th Cir. 2002) ("[D]istrict courts often afford plaintiffs at least one opportunity to cure pleading deficiencies before dismissing a case, unless it is clear that the defects are incurable or the plaintiffs advise the court that they are unwilling or unable to amend in a manner that will avoid dismissal."); *see also United States ex rel. Adrian v. Regents of the Univ. of Cal.*, 363 F.3d 398, 403 (5th Cir. 2004) ("Leave to amend should be freely given, and outright refusal to grant leave to amend without a justification . . . is considered an abuse of discretion." (internal citation omitted)). However, a plaintiff should be denied leave to amend a complaint if the court determines that "the proposed change clearly is frivolous or advances a claim or defense that is legally insufficient on its face . . . ." 6 CHARLES A. WRIGHT, ARTHUR R. MILLER & MARY KAY KANE, FEDERAL PRACTICE AND PROCEDURE § 1487 (2d ed. 1990); *see also Ayers v. Johnson*, 247 F. App'x 534, 535 (5th Cir. 2007) (unpublished) (per curiam) ("'[A] district court acts within its discretion when dismissing a motion to amend that is

frivolous or futile.'" (quoting *Martin's Herend Imports, Inc. v. Diamond & Gem Trading United States of Am. Co.*, 195 F.3d 765, 771 (5th Cir. 1999)).

B. Rule 9(b)

"In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." FED. R. CIV. P. 9(b). "At a minimum, Rule 9(b) requires that a plaintiff set forth the 'who, what, when, where, and how' of the alleged fraud." *Thompson*, 125 F.3d at 903 (quoting *Williams v. WMX Techs., Inc.*, 112 F.3d 175, 179 (5th Cir. 1997)). The pleader must "specify the statements contended to be fraudulent, identify the speaker, state when and where the statements were made, and explain why the statements were fraudulent." *Williams*, 112 F.3d at 177. "'Rule 9(b)'s ultimate meaning is context specific, and thus there is no single construction of Rule 9(b) that applies in all contexts.'" *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 188 (5th Cir. 2009) (quoting *Williams*, 112 F.3d at 178). In the context of the FCA, the parties dispute whether it is appropriate to relax the Rule 9(b) standard. The relators acknowledge that they have failed to identify a specific false claim but argue that this should not be required because the facts relating to the alleged fraud are "peculiarly within the perpetrator's knowledge" and the alleged fraud occurred over a multi-year period. (Docket Entry No. 45, at 20–22). Medtronic responds that, to the contrary, the relevant information on billing and reimbursements are in the hands of third parties, including physicians, hospitals, and Medicare, and that there is no basis in the case law to relax the Rule 9(b) requirements in such circumstances. (Docket Entry No. 47, at 13–15).

III. The False Claims Act

In *United States ex rel. Longhi v. Lithium Power Techs., Inc.*, the Fifth Circuit adopted a four-prong test for § 3729(a) claims. 575 F.3d 458 (5th Cir. 2009). The Fifth Circuit requires: "(1) a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that caused the government to pay out money or to forfeit moneys."[14] *Id.* at 467 (adopting the test stated in *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 376 (4th Cir. 2008)).

A. Which Version of the FCA Applies?

A threshold issue is whether the amended or earlier version of 31 U.S.C. § 3729 applies. The Fraud Enforcement Recovery Act of 2009 (FERA) amended sections of the False Claims Act, including two subsections implicated in this action, 31 U.S.C. § 3729(a)(1) and (2).[15] Pub. L. No. 111-21, § 386, 123 Stat. 1617 (2009). FERA became law on May 20, 2009. It contained a retroactivity provision stating as follows:

> The amendments made by this section shall take effect on the date of enactment of this Act and shall apply to conduct on or after the date of enactment, except that (1) subparagraph (B) of section 3729(a)(1) of title 31, United States Code, as added by

---

[14] In *Longhi*, the Fifth Circuit did not state whether this four-prong test applies to the version of the FCA amended by 31 U.S.C. § 3729(a)(1)(B), the "post-FERA version." For post-FERA claims, the fourth prong—that the statement "cause the government to pay out money or forfeit money"— may need alteration. The post-FERA FCA does not require that the government actually pay the false claim. *Compare* 31 U.S.C. § 3729(a)(2), *amended by* 31 U.S.C. § 3729(a)(1)(B) (establishing liability for "any person 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*.") (emphasis added); *with* 31 U.S.C. § 3729(a)(1)(B) (establishing liability for "any person who . . . knowingly makes, uses, or causes to be made or used, a false record or statement material to a false fraudulent claim"). The application of pre- and post-FERA versions of the FCA is analyzed below, but the elements of a false statement, scienter, and materiality are unaffected. 31 U.S.C. 3729(a)(1)(A–B).

[15] In the amended complaint, the relators alleged that Medtronic also violated 31 U.S.C. § 3729(a)(7), *amended by* 31 U.S.C. § 3729(a)(1)(G). (Docket Entry No. 12, ¶ 139). In their response to the motion to dismiss, the relators asked to amend the complaint to remove "any reference to § 3729(a)(7)." (Docket Entry No. 45, at 2 n.2). Medtronic has not objected. That claim is deleted.

> subsection (a)(1), shall take effect as if enacted on June 7, 2008, and apply to all claims under the False Claims Act (31 U.S.C. 3729 *et seq*.) that are pending on or after that date.

123 Stat. 1617 § 4(f). For the § 3729(a)(1) claim, this court must apply the pre-FERA version of § 3729(a)(1) because the relators filed this suit in November 2008, before the "date of [FERA's] enactment." Section 4(f)'s exception—"subparagraph (B) of section 3729(a)(1)"—applies to the § 3729(a)(2) claim. Section 4(f) states that the amended version of subsection (a)(2), now found at 31 U.S.C. § 3729(a)(1)(B), applies to all "claims" under the FCA pending on or after June 7, 2008. The pre- and post-FERA versions of the FCA define "claim" similarly. The pre-FERA FCA defines claim as

> [A]ny request or demand, whether under a contract or otherwise, for money or property which is made to a contractor, guarantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.

31 U.S.C. § 3729(c), *amended by* 31 U.S.C. § 3729(b)(2). The post-FERA amendments define "claim" as "any request or demand, whether under a contract or otherwise, for money or property . . . [that] is presented to an officer, employee, or agent of the United States . . . ." 31 U.S.C. § 3729(b)(2). Neither definition refers to *cases* or causes of action under the FCA. Instead, both definitions refer to claims "for money or property" from the government. Because "claim" is a defined term in the FCA, the reference to "claims" in FERA § 4(f)(1) must be read in accordance with that definition. *See United States ex rel. Gonzales v. Fresenius Med. Care N. Am.*, No. EP-07-CV-247-PRM, 2010 WL 1645971, at *9 (W.D. Tex. Mar. 31, 2010) (reaching the same conclusion). Under this approach, the post-FERA version of § 3729(a)(2), 31 U.S.C. § 3729(a)(1)(B), applies if the false claims alleged by the relators were pending on or after June 7, 2008.

Most of the district courts that have ruled on this issue have reached the same conclusion. *See, e.g.*, *United States ex rel. Compton v. Circle B Enters., Inc.*, No. 7:07-CV-32, 2010 WL 942293, at *2 n. 5 (M.D. Ga. Mar. 11, 2010) ("The revised version of section (a)(1)(B) does not apply to this case because none of Defendants' claims (the ... reimbursement claims) at issue here were pending on or after June 7, 2008."); *United States ex rel. Putnam v. E. Idaho Reg'l Med. Ctr.*, No. CIV. 4:07-192, 2010 WL 910751, at *4 (D. Idaho Mar. 10, 2010) ("[B]ecause the claims for Medicaid reimbursement at issue in this case were neither pending on nor filed after June 7, 2008, the pre-FERA version of § 3729(a)(2) governs . . . ."); *Mason v. Medline Indus., Inc.*, No. 07-C-5615, 2010 WL 653542, at *3 (N.D. Ill. Feb.18, 2010) ("The court interprets § 4(f)(1) to apply to 'claims' as defined in the FCA. Accordingly, FERA's amendment does not apply retroactively to this case."); *United States ex rel. Sanders v. Allison Engine Co., Inc.*, 667 F. Supp. 2d 747, 752 (S.D. Ohio 2009) ("[T]he clear indication from Congress is that the revised language at issue here is applicable to 'claims' pending on June 7, 2008, and not to 'cases' pending on June 7, 2008. Since the Defendants in this case had no 'claims' pending on June 7, 2008, the retroactivity clause does not apply to them . . . ."); *United States v. Sci. Applications Int'l Corp.*, 653 F. Supp. 2d 87, 107 (D. D.C. 2009) ("[S]ection 4(f)(1) will be interpreted to apply to 'claims' as defined in § 3729, that is, requests or demands for money or property. Thus, FERA has no impact on the present action.").

The relators' amended complaint does not appear to involve claims pending on or after June 7, 2008. The amended complaint refers to 31 U.S.C. § 3729(a)(2), not 31 U.S.C. § 3729(a)(1)(B). The relators' allegations of unlawful promotional tactics date back to 2001. (Docket Entry No. 12, ¶ 17). The relators' allegations of false or fraudulent claim submission refer to 1,000 claims submitted at various times before February 2008 by physicians at LDS Hospital in Salt Lake City.

(*Id.* at ¶ 132). Finally, the amended complaint contains no allegations of false claims pending after June 7, 2008. Medtronic has pointed out that the FCA has been amended, (Docket Entry No. 30, at 6 n.6). The relators have not argued whether the amended FCA or the prior version applies to their claims. Medtronic argues that the result is the same under either version and the relators have not addressed this issue. (Docket Entry No. 30, at 6 n.6).[16] In an abundance of caution, the analysis is conducted under both the pre- and post-FERA versions of the FCA because the amended complaint may cover claims pending on or after June 7, 2008.[17]

---

[16] Some courts have held that FERA's retroactivity clause is unconstitutional. *E.g., United States ex rel. Sanders v. Allison Engine Co., Inc.*, 667 F. Supp. 2d 747, 755 (S.D. Ohio 2009) (finding that application of the retroactivity clause violates the Constitution's Ex Post Facto Clause, U.S. CONST. art. 1, § 9, cl. 3). The Fifth Circuit has not ruled on this issue. *See United States ex rel. Longhi v. Lithium Power Techs., Inc.*, 575 F.3d 458, 470 (5th Cir. 2009) (declining to rule on whether FERA applies retroactively). Neither party raised this issue and it is not necessary to address because the result is the same under either the pre- or post-FERA version of the FCA.

[17] As the analysis makes clear, in this litigation, there is no material difference between pre- and post-FERA versions of § 3729(a)(1). FERA removed § 3729(a)(1)'s requirement that the claim be presented "to an officer or employer of the United States Government or a member of the Armed Forces of the United States." *Compare* 31 U.S.C. § 3729(a)(1), *amended by* 31 U.S.C. § 3729(a)(1)(A) (establishing liability for "any person who . . . knowingly presents or causes to be presented, *to an officer or employee of the United States government or a member of the Armed Forces of the United States*, a false or fraudulent claim for payment or approval." (deleted language italicized)); *with* 31 U.S.C. § 3729(a)(1)(A) (establishing liability for "any person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval"). Medtronic does not contest that the reimbursement claims were presented to the government. Similarly, the differences between the pre- and post-FERA versions of § 3729(a)(2) do not affect this litigation. FERA removed § 3729(a)(2)'s requirement that the alleged false claim be "paid or approved by the government." *Compare* 31 U.S.C. § 3729(a)(2), *amended by* 31 U.S.C. § 3729(a)(1)(B) (establishing liability for "any person 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."); *with* 31 U.S.C. § 3729(a)(1)(B) (establishing liability for "any person who . . . knowingly makes, uses, or causes to be made or used, a false record or statement material to a false fraudulent claim"). Medtronic does not dispute that the government paid or approved the reimbursement claims. FERA also added a materiality requirement to § 3729(a)(2). *See* 31 U.S.C. § 3729(a)(1)(B) (establishing liability for "any person who . . . knowingly makes, uses, or causes to be made or used, a false record or statement *material* to a false fraudulent claim") (emphasis added). This change does not affect this litigation because the Fifth Circuit required "material" false statements before the FERA amendments to § 3729(a)(2). *United States ex rel. Longhi v. Lithium Power Techs., Inc.*, 575 F.3d 458, 470 (5th Cir. 2009). And the post-FERA version of § 3729(a)(2) and the Fifth Circuit both use the same test for materiality. 31 U.S.C. § 3729(b)(4) ("[M]aterial means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."); *Longhi*, 575 F.3d at 470 (adopting the "natural tendency test," which only requires "that the false or fraudulent

B. The Elements of An FCA Claim

1. A False or Fraudulent Claim

The Supreme Court has cautioned that the FCA does not punish every type of fraud committed upon the government. *See United States v. McNinch*, 356 U.S. 595, 599 (1958). "The [FCA] attaches liability, not to the underlying fraudulent activity, but to the 'claim for payment.'" *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266–67 (9th Cir. 1996) (finding on summary judgment that violation of Individuals with Disabilities Education Act regulations is not also an FCA violation unless compliance certification is a prerequisite to receive federal funds); *see also United States ex rel. Siewick v. Jamieson Sci. And Eng., Inc.*, 214 F.3d 1372, 1376–77 (D.C. Cir. 2000) (upholding district court's determination on summary judgment that even if the defendants had violated 18 U.S.C. § 207, "a criminal statute aimed at 'revolving door' abuses by former government employees," there was no fact issue as to an FCA violation because defendants were not required to certify compliance with the statute); *United States ex rel. Willard v. Humana Health Plan of Tex Inc.*, 336 F.3d 375, 382–83 (5th Cir. 2003) (upholding district court's dismissal because the plaintiff only alleged violations of HMO enrollment antidiscrimination laws but did not allege that the United States "conditioned payment . . . on any implied certification of compliance with the anti-discriminatory provisions"); *United States ex rel. Roop v. Hypoguard USA, Inc.*, 559 F.3d 818, 824 (8th Cir. 2009) (upholding district court's dismissal because the plaintiff alleged violations of the FDA medical-device-reporting regulations by selling defective products but did not allege that certification with these regulations was a prerequisite to payment).

---

statements have the potential to influence the government's decisions," and noting the test's consistency with FERA).

In the specific context of reimbursement claims for using a drug or device in a way that violates the FDA, the courts have held that the "mere fact" of "violating FDA regulations does not translate into liability for causing a false claim to be filed." *United States ex rel. Polansky v. Pfizer*, No. 04-cv-0704 (ERK), 2009 WL 1456582, at *7 (E.D.N.Y. May 22, 2009); *see also United States ex rel. Rost*, 507 F.3d 729, 732 (1st Cir. 2007), *overruled on other grounds by Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662 (2008) (noting that the alleged marketing practices, "while illegal, are not a sufficient basis for an FCA action because they do not involve claims for government reimbursement"); *Thompson*, 125 F.3d at 902 ("[C]laims for services rendered in violation of a statute do not necessarily constitute false or fraudulent claims under the FCA.").

The courts have held that a claim may be false or fraudulent under the FCA because it includes a certification of compliance with a federal statute, regulation, or contract that is a prerequisite to obtaining the government benefit. *United States ex rel. Graves v. ITT Educ. Servs., Inc.*, 284 F. Supp. 2d 487, 497 (S.D. Tex. 2003), *aff'd*, 111 Fed. App'x 296 (5th Cir. Oct. 20, 2004). Such "legally false" certification differs from "factually false" certification, which involves an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided. *See Mikes v. Straus*, 274 F.3d 687 (2d Cir. 2001). The Fifth Circuit has held that a claim is "legally false" only when a party affirmatively and explicitly certifies compliance with a statute or regulation and the certification is a condition to receiving the government benefit. *See Thompson*, 125 F.3d at 902. In addition to express certifications of compliance, other circuits have found that FCA liability may exist under an "implied theory" of certification. *See Willard*, 336 F.3d at 82 (discussing cases). "The theory of implied certification rests on the notion that 'where the government pays funds to a party, and would not have paid those funds had it known of a violation of a law or regulation, the claim submitted for those funds

contained an implied certification of compliance with the law or regulation and was fraudulent.'" *United States ex rel. Foster v. Bristol–Myers Squibb Co.*, 587 F. Supp. 2d 805, 823 (E.D. Tex. 2008) (citing *United States ex rel. Barrett v. Columbia/HCA Healthcare Corp.*, 251 F. Supp. 2d 28, 33 (D.D.C. 2003)). For example, the Sixth Circuit has found that FCA liability "can attach if the claimant violates its continuing duty to comply with the regulations on which payment is conditioned." *Willard*, 336 F.3d at 82 (quoting *United States ex rel. Augustine v. Century Health Servs., Inc.*, 289 F.3d 409, 415 (6th Cir. 2002)). The Fifth Circuit has never adopted implied certification as a theory of FCA liability. *United States ex rel. Marcy v. Rowan Cos., Inc.*, 520 F.3d 384, 389 (5th Cir. 2008) (citing *Willard*, 336 F.3d at 381–82); *United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 679 (5th Cir. 2003) (en banc) (Jones, J. concurring). Instead, the Fifth Circuit has held that "[t]he violation of the statute or regulation does not create a cause of action under the False Claims Act; liability arises only if the defendant has made a false certification of compliance with the statute or regulation, when payment is conditioned on that certification." *Graves*, 284 F. Supp.2d at 497.

2. Materiality

Liability under both the pre- and post-FERA versions of the FCA requires that an actionable false statement be "material." *Longhi*, 575 F.3d at 467 (citing *Thompson*, 125 F.3d at 899); *see also Allison Engine Co., Inc. v. United States ex rel. Sanders*, 128 S. Ct. 2123, 2126 (2008) (explaining that a § 3729(a)(2) "plaintiff must prove that the defendant intended that the false statement be material to the Government's decision to pay or approve the false claim"). The Fifth Circuit applies the "natural tendency" test to determine materiality. *Longhi*, 575 F.3d at 470. This test asks whether "the false or fraudulent statements either (1) make the government prone to a particular impression, thereby producing some sort of effect, or (2) have the ability to effect the government's actions, even

if this is a result of indirect or intangible actions on the part of the Defendants." *Id.* "All that is required under the test for materiality, therefore, is that the false or fraudulent statements have the potential to influence the government's decisions." *Id.*

3. Knowingly

An FCA claim must allege that the false statements were "knowingly" made or caused to be made. The FCA defines "knowing or knowingly" to mean "that a person, with respect to information," (i) "has actual knowledge of the information"; (ii) "acts in deliberate ignorance of the truth or falsity of the information"; or (iii) "acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1–3). Because an FCA claim alleges a fraudulent or false statement knowingly made or caused to be made, *Longhi*, 575 F.3d at 468, "[c]laims brought under the FCA must comply with Rule 9(b)." *Thompson*, 125 F.3d at 903 (5th Cir. 1997); *see also Hopper v. Solvay Pharms.*, 588 F.3d 1318, 1325 (11th Cir. 2009). However, "[i]n contrast to common law fraud, the FCA "lacks the element of reliance and damages." *Grubbs*, 565 F.3d at 189. "It is adequate to allege that a false claim was knowingly presented regardless of its exact amount; the contents of the bill are less significant because a complaint need not allege that the Government relied on or was damaged by the false claim." *Id.* "To plead with particularity the circumstances constituting fraud for a FCA section [3729(a)(1)(A)] 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." *Id.* at 190. To plead with the requisite particularity a § 3729(a)(1)(B) claim, the complaint need not "allege details of fraudulent bills actually presented to the government." *Id.* at 192. The relators must, however, allege facts linking a scheme to submit false claims to the submission of false claims. *Solvay Pharms.*, 588 F.3d at 1325.

4. The Application of the Pleading Standards to FCA Claims

Although the parties' discussion of Rule 12(b)(6) cites *Twombly* and *Iqbal* as the most recent statements by the Supreme Court under the rule, the arguments do not turn on a claim that the analysis and result in this case are different under those decisions than they would have been earlier. The parties' briefs do not argue whether the facts alleged are sufficient to make the claim of an FCA violation "plausible." Rather, Medtronic argues that taking the facts alleged as true, as a matter of law, the FCA does not provide a basis for relief for the promotional activities and remuneration alleged. (Docket Entry No. 30, at 14, 22).

The relators do argue for a relaxed application of Rule 9(b). The cases are clear that Rule 9(b) applies in FCA cases. *Longhi*, 575 F.3d at 468, *Thompson*, 125 F.3d at 903; *Hopper*, 588 F.3d at 1325. The cases also recognize two exceptions that the relators urge. "It is possible that the pleading requirements of Rule 9(b) may be relaxed in certain circumstances—when, for instance, the facts relating to the fraud are 'peculiarly within the perpetrator's knowledge.'" *United States ex rel. Doe v. Dow Chem. Co.*, 343 F.3d 325, 330 (5th Cir. 2003) (quoting *United States ex rel. Russell v. Epic Healthcare Mgmt. Grp.*, 193 F.3d 304, 308 (5th Cir. 1999). "Fraud may be pleaded on information and belief under such circumstances." *United States ex rel. Willard v. Humana Health Plan of Texas Inc.*, 336 F.3d 375, 385 (5th Cir. 2003). But the Fifth Circuit has held that a plaintiff should not be relieved from complying with the Rule 9(b) requirements "where the documents containing the requisite information are in the possession of, and presumably available from, other sources." *United States ex rel. Rafizadeh v. Cont'l Common, Inc.*, 553 F.3d 869, 873 n.6 (5th Cir. 2008) (citing *Doe*, 343 F.3d at 330); *see also Polansky*, 2009 WL 1456582, at *8 ("The rationale for reducing the pleading burden when information is in the defendant's possession appears to spring from the fact that an adverse party would not willingly divulge incriminating information.

Where the information needed to fill out the complaint is in the hands of third parties, rather than defendants, this rationale for reducing the pleading burden does not apply.").

The Eleventh Circuit has held that the pleading standard should not be relaxed for *qui tam* plaintiffs who may only have access to information through discovery in suits where the government refuses to intervene, even though the government would have access to those documents without discovery. *Atkins*, 70 F.3d at 1360 & n.17. The court reasoned,

> The *qui tam* relator bring the action *on behalf of* the federal government. The relator stands in the government's shoes—in neither a better nor worse position than the government stands when it brings suit. Accordingly, we cannot furnish a *qui tam* relator with an easier burden than the government would bear if it intervened and assumed the prosecution of the case. Permitting a *qui tam* relator to go forward with his complaint, when we would not allow the government to proceed, might encourage the government to evade its burden by merely recruiting a willing relator to file a *qui tam* action.

United States ex. Rel. Atkins, 470 F.3d 1350, 1360 (11th Cir. 2006).

The relators argue that this court should relax the pleading standard because they do not have access to certain information. In the Fifth Circuit, the pleading standard is not relaxed when such information is available from third party entities and individuals. *Rafizadeh*, 553 F.3d at 873 n.6. Medtronic notes that it does not have billing or reimbursement information; doctors, hospitals, and government agencies do. There is no basis to relax the Rule 9(b) pleading standard in this case under the applicable precedents. *See Polansky*, 2009 WL 1456582, at *8 (refusing to relax the pleading the standard in off-label *qui tam* against drug manufacturer because the needed information available was in the hands of third parties).

Even under a relaxed pleading standard, the relators must still state a factual basis for their beliefs. *See United States ex rel. King v. Alcon Labs., Inc.*, 232 F. Supp. 2d 568, 572 (N.D. Tex. 2005) (finding that even under a relaxed pleading standard, the relators failed to plead fraud with

particularity because the relator did not identify a single person involved in the alleged fraud, did not did not identify specific fraudulent claims, and did not identify a single date on which fraudulent activity occurred); *United States ex rel. Lam v. Tenet Healthcare*, 481 F. Supp. 2d 673, 688 (W.D. Tex. 2006) (finding that even under a relaxed pleading standard, the relators failed to set forth a factual basis for their beliefs because they failed to name one physician who violated the anti-referral statute; did not specifically identify one fraudulent transaction; and failed to specifically allege the fraud's "when" by alleging only that the fraudulent events occurred "at some point in the 1980s, between 1995 and 2002, and in 1999). *Cf. Rost*, 507 F.3d at 732–33 (recognizing that Rule 9(b) may be satisfied where "although some questions remain unanswered, the complaint as a whole is sufficient to pass muster under the FCA," but upholding dismissal because the relator did not identify specific physicians who submitted claims for reimbursement for off-label prescriptions).

In addition, "some district courts in the Fifth Circuit [] relaxed Rule 9(b)'s pleading standard where the alleged fraud occurred over an extended period of time and consists of numerous acts." *Bristol–Myers Squibb Co.*, 587 F. Supp. 2d at 821 (listing cases). In such cases, courts have allowed the plaintiff to "plead the fraudulent scheme with particularity and provide representative examples of specific fraudulent acts conducted pursuant to that scheme." *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493, 509–10 (6th Cir. 2007); *see also Barrett*, 251 F. Supp. 2d at 35 ("While a complaint that covers a multi-year period may not be required by Rule 9(b) to contain a detailed allegation of all facts supporting each and every instance of submission of a false claim, some information on the false claims must be included." (citing *United States ex rel. Lee v. SmithKline Beecham, Inc.*, 245 F.3d 1048, 1051 (9th Cir. 2001)). The relators have not, however, provided a "representative sample" or even an "instance of submission." *Bledsoe*, 501 F.3d at

509–10; *Barrett*, 251 F. Supp. 2d at 35. Nor have the relators provided a factual basis to support a belief that a specific physician or hospital submitted a false claim. *Willard*, 336 F.3d at 385. Instead, the relators rely on their allegations that some physicians performed a high number of surgical ablations. There relators have identified no basis to relax the Rule 9(b) pleading standard under the applicable law.

C. The Case Law on Off-Label Marketing as an FDA Claim

Recently, a number of *qui tam* actions alleging FCA violations caused by off-label marketing by drug companies have been filed in federal courts.[18] Both parties discuss three such cases: *United States ex rel. Franklin v. Parke–Davis*, 147 F. Supp. 2d 39 (D. Mass. 2001); *United States ex rel. Hess v. Sanofi–Synthelabo Inc.*, No. 4;05CV570MLM, 2006 WL 1064127 (E.D. Mo. Apr. 21, 2006); *Hopper v. Solvay Pharms. Inc.*, 588 F.3d 1318 (11th Cir. 2009). In addition, both parties discuss *In re Cardiac Devices Qui Tam Litig.*, a *qui tam* case alleging FCA violations caused by unlawful use of medical devices by hospitals. 221 F.R.D. 318 (D. Conn. 2004).

In *Franklin v. Parke–Davis*, the relator, a doctor formerly employed by Parke–Davis to promote its drug Neurotonin, alleged that Parke–Davis engaged in a "fraudulent scheme to promote the sale of the drug Neurotonin for 'off-label uses' . . . and that this illegal marketing campaign caused the submission of false claims to the Veterans Administration and to the federal government for Medicaid reimbursement." 147 F. Supp. 2d at 43. The FDA approved Neurotonin "for use as an adjunctive treatment for epilepsy in doses from 900 to 1800 mg per day." *Id.* at 45. The relator alleged that Parke–Davis promoted Neurotonin for off-label use "as mono-therapy for epilepsy, for

---

[18] *See* Richard C. Ausness, *There's Danger Here, Cherie!: Liability for the Promotion and Marketing of Drugs and Medical Devices for Off-label Uses*, 73 BROOK. L. REV. 1253, 1275–96 (2008) (identifying the FCA as a source of liability for off-label promotion and discussing recent cases).

control of bipolar disease, and as treatment for attention deficit disorder." *Id.* Parke–Davis's alleged off-label promotional tactics included using medical liaisons such as the relator to make "exaggerated or false claims concerning the safety and efficacy of Parke–Davis drugs for off-label uses"; rewarding physicians who prescribed large quantities of Parke–Davis drugs with kickbacks; and paying physicians to create "sham" studies urging off-label uses that "had no scientific value." *Id.* at 45–46.

The relator also alleged that "when questions arose concerning the availability of reimbursement for prescriptions for off-label uses of Parke–Davis drugs" Parke–Davis made efforts to conceal the fraud. *Id.* at 46. Medical liasons "were instructed to coach doctors on how to conceal the off-label nature of the prescription" and Parke–Davis "shredd[ed] documents, falsif[ied] documents, and encourag[ed] medical liaisons to conduct their marketing activities without leaving a paper trail." *Id.*

Parke–Davis moved to dismiss. Unlike the medical device case in which there is FDA approval for general use related to the specific purpose being promoted, there was no dispute as to whether "an off-label prescription submitted for reimbursement is a false claim within the meaning of the FCA." *Id.* at 51. The court granted Parke–Davis's motion in part and denied it in part. *Id.* at 44.

The court found that the complaint met Rule 9(b)'s pleading requirements with respect to submissions to Medicaid because it sufficiently alleged fraudulent schemes to "increase the submission of off-label prescriptions for Neuortonin for payment by Medicaid" and "to induce off-label prescriptions for Neurotonin" by physicians. *Id.* at 48. It reasoned that the relator identified the fraud's "who" by naming Parke–Davis employees who instructed medical liaisons on how to fraudulently promote off-label use of Neurotonin, listing the medical liaisons by name, and

identifying the physicians contacted; identified the fraud's "what" by alleging that the off-label promotion resulted in the submission of ineligible claims for reimbursement for off-label use of Neurtonin; identified the fraud's "when" by alleging the term of the relator's employment; and the fraud's "how" by alleging a detailed description of the marketing scheme that included "misleading" materials *Id.* The relator also alleged eleven "specific examples of fraudulent statements which medical liaisons . . . were trained to give to physicians, and did give to physicians, to induce the purchase of Neurotonin for off-label uses." *Id.* In contrast, the court found that the complaint did not sufficiently allege a fraudulent scheme to cause false submissions to the Veterans Administration because it did not "specify which Parke–Davis personnel engaged in this conduct, where such conduct took place, which VA personnel were involved, or any specific fraudulent statements made to personnel at the [VA]." *Id.* at 50.

With respect to the Medicaid allegations, the court rejected Parke–Davis's causation challenges. Parke–Davis argued that the FCA does not impose liability for violating FDA regulations because such violations do not involve a claim or statement to the government. The court stated:

> It is true that the FCA cannot be used to enforce compliance with every law or regulation . . . the FCA can be used to create liability where failure to abide by a rule or regulation amounts to a material misrepresentation made to obtain a government benefit . . . . Thus, the failure of Congress to provide a cause of action for money damages against a pharmaceutical manufacturer for marketing off-label drugs does not preclude an FCA claim where the manufacturer has knowingly caused a false statement to be made to get a false claim paid or approved by the government in violation of 31 U.S.C. § 3729(a).

Id. at 51–52 (internal citations omitted). The court also rejected Parke–Davis's argument that off-label promotion does not always entail a false statements. Parke–Davis argued that off-label promotion may involve only the distribution of one physician's finding of new drug's use to another

physician. The court responded that the relator alleged "more than a mere technical violation of the FDA" by alleging that physicians distributed findings they knew to be false. The court also rejected Parke–Davis's argument that physicians' independent determinations that an off-label prescription provided the best treatment for a patient cut off Parke–Davis's liability because it was an intervening cause. The court responded that because the intervening cause was foreseeable to Parke–Davis, the chain of causation did not break. *Id.* at 51–53. Finally, the court rejected Parke–Davis's argument that its false statements were not "material" to the government's decision to pay because "[l]iability under the FCA . . . is not limited only to false statements or claims made directly by the Defendant to the government," noting also that the FCA "'reaches beyond claims which might be legally enforced, to all fraudulent attempts to cause the Government to pay out sums of money.'" *Id.* at 53 (citing *United States v. Neifert–White Co.*, 390 U.S. 228, 233 (1968)).

However, the *Parke–Davis* Court dismissed the relator's kickback allegations. The court rejected the relator's argument that a violation of the antikickback statute is a *per se* violation of the FCA. It reasoned that though an FCA violation might arise based on a theory of "'implied certification' [of compliance with the antikickback statute] by virtue of the defendant's participation in the federal program," the relator "failed to allege that physicians either expressly certified or, through their participation in a federally funded program, impliedly certified their compliance with the federal antikickback statute as a prerequisite to participating in the federal program." *Id.* The court reasoned further that "while Defendant's payment of kickbacks may well be illegal," the relator did not allege that "Parke–Davis caused or induced a doctor and/or pharmacist to file a false or fraudulent certification regarding compliance with the anti-kickback statute." *Id.* at 55.

In *Hess*, the relator alleged that Sanofi–Snythelabo's off-label promotion of its drugs Eloxatin—approved for "second line treatment of fourth stage colorectal cancer"—and

Elitek—approved for the treatment and prevention of tumor lyses syndrome—caused the submission of false claims for payment for off-label uses of the respective drugs. 2006 WL 1064127, at *2. The relator alleged that Sanofi–Synthelabo promoted Eloxatin for treatment in both "first-line" and "adjuvant" settings by training sales representatives to use off-label data when promoting Eloxatin to physicians, creating sales goals impossible to meet without off-label usage, and by providing sales representatives with monographs containing information on adjuvant and first-line trials for Eloxatin. *Id.* at *8. The relator further alleged that the data provided to physicians was "immature, unreliable, and misleading." *Id.* With respect to Elitek, the relator alleged that Sanofi–Synthelabo trained sales representatives to promote off-label uses and pressured sales representatives to derive a substantial number of sales from off-label use. *Id.* at *6. Sanofi–Synthelabo moved to dismiss arguing that the relator did not allege any false representations to physicians or the government, any improper prescriptions, or that doctors who prescribed the drugs also sought reimbursement from Medicare. Sanofi–Synthelabo also argued that the relator failed to alleged fraud with the required particularity. *Id.* at *4. Specifically as to Eloxatin, Sanofi–Synthelabo argued that because Medicare does not require a physician to specify the stage of cancer in submitting claims for reimbursement, physicians made no false statements in submitting claims for use of Eloxatin to treat colorectal cancer in first-line and adjuvant setting. *Id.* at *8. The court granted Sanofi–Synthelabo's motion to dismiss, addressing the allegations involving each drug separately.

The court dismissed the allegations related to Elitek under Rule 9(b) because the relator failed to allege the "who, what, when, where, and how of fraud." *Id* at *6. The court noted that the relator did not allege "the time or place of the allegedly false representations regarding Elitek," "the nature or content of claims made which were allegedly fraudulent," or "that doctors to whom Plaintiff promoted off-label use of Elitek actually submitted false claims to the Government for off-

label uses of this prescription drug." *Id.* The court deemed the relator's allegations "vague" and "conclusory" and dismissed for "lack of the requisite specificity to withstand a motion to dismiss pursuant to either Rule 12(b)(6) or Rule 9(b)." *Id.*

The court also dismissed the Eloxatim allegations because the relator did not allege a "material" misrepresentation. In *United States ex rel. Costner v. United States*, the 8th Circuit adopted a materiality requirement for FCA claims requiring that the misrepresentation have the natural tendency to influence an agency action, the same test adopted by the Fifth Circuit in *Longhi*. 317 F.3d 883, 887–88 (8th Cir. 2003). The court accepted Sanofi–Synthelabo's argument that the alleged false claims for reimbursement did not contain a material false statement because the reimbursement forms did not require that the physician indicate the stage of cancer, only that the patient has cancer. Thus the only statement material to Medicare reimbursement is that the patient has cancer; the government does not inquire further into whether the drug is approved for a particular cancer stage. *Id.* at *7.

Though the court's decision on the Eloxatim allegations rested on this ground, the court considered other arguments. It agreed with Sanofi–Synthelabo's argument that the relator did not sufficiently plead the FCA's knowledge requirement because the plaintiff did not allege that the "Defendant deliberately lied nor that the data provided by Defendant either to its sales representatives or to doctors was incorrect or false." *Id.* at *9. The court distinguished the alleged promotion tactics in *Parke–Davis* by noting that "none of the actions which Plaintiff alleges on the part of the Defendant . . . involve conduct which was designed to present *false* information; rather . . . the Defendant sought to disseminate date and information from trials and studies." *Id.* at *10. Further, the court found that the relator did not sufficiently allege any false statements to Medicare. The court noted that while typically Medicare reimburses only on-label prescriptions, "such

approval is not necessarily a requirement." *Id.* The court also noted that—unlike the facts in *Parke–Davis*—the relevant Medicare administrator chose to apply an exception allowing coverage for off-label prescriptions of Eloxatin and concluded that "because . . . the Medicare administrator included off-label uses of Eloxatin for reimbursement purposes, Plaintiff can prove no set of facts to establish that Defendant violated the FCA." *Id.* at *9. Finally, the court, applying *Parke–Davis*, found that the relator did not allege fraud with the particularity required by Rule 9(b). The court found that the complaint did not identify the fraud's "who" because it did not "identify doctors whom sales representatives allegedly contacted nor . . . doctors who allegedly made claims for Medicare reimbursement for off-label uses" or the fraud's "how" because it did not provide "examples of the allegedly false information which Defendant allegedly gave its sales representatives." *Id.*

In *Solvay*, the relators alleged that Solvay Pharmaceuticals's off-label promotion of Marinol caused the submission of false claims for reimbursement to Medicare. 588 F.3d at 1321. The FDA approved Marinol, a synthetic form of THC, a hallucinogenic compound found in marijuana, for use as an appetite stimulant for AIDS patients and for the treatment of nausea and vomiting associated with cancer chemotherapy. *Id.* at 1322. The relators alleged that Solvay promoted Marinol off-label for appetite loss in cancer patients and for treatment of nausea in HIV patients. The alleged off-label promotional activities included "a sophisticated marketing plan" and "kickbacks to physicians and other healthcare providers to induce them to prescribe Marinol for off-label purposes." *Id.* at 1323. The district court referred the case to a magistrate judge who recommended dismissal. The district court adopted the magistrate's recommendation in full and the relators appealed. *Id.* "The sole issue on appeal" was whether the Complaint, which did not include allegations of specific false claims or allege that Solvay intended for its statements to influence the government's decision to pay any

claims, satisfies the particularity requirements of Rule 9(b)." *Id.*

The Eleventh Circuit upheld the district court's dismissal. In reaching this conclusion, the Eleventh Circuit discussed its decisions in *United States ex rel. Clausen v. Lab Corp. of Am.*, 290 F.3d 1301 (11th Cir. 2002); *United States ex rel. Corsello v. Lincare, Inc.*, 428 F.3d 1008 (11th Cir. 2005); and *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350 (11th Cir. 2006). In *Clausen*, the court upheld the district court's dismissal of a complaint alleging the submission of claims for reimbursement for unnecessary laboratory tests even though the complaint "included detailed allegations of a scheme to overcharge, [] identified the patients who received tests, specified which tests were improper, and set forth the dates on which the tests were performed" because the complaint "failed to provide any information linking the testing schemes to the submission of false claims." *Solvay*, 588 F.3d at 1325 (citing *Clausen*, 290 F.3d at 1303). Absent an allegation linking the schemes to the submission of false claims, the Eleventh Circuit found that the allegations were conclusory. *Id.* (citing *id.*). In *Corsello*, the court upheld the district court's dismissal of a complaint alleging that medical equipment companies engaged in a "kickback and referral scheme to falsify certificates of medical necessity to submit false claims for Medicare payments" because "it did not allege that a specific fraudulent claim was in fact to submitted to the government." *Id.* (citing *Corsello*, 428 F.3d at 1013–14). In *Atkins*, the court upheld the district court's dismissal of a complaint alleging "an elaborate scheme for defrauding the government by submitting false claims" for payments from Medicare for psychiatric services that were not actually rendered. *Id.* (citing *Atkins*, 470 F.3d at 1354). The complaint cited "particular patients, dates and corresponding medical records for services" not eligible for reimbursement. *Id.* (citing *id.* at 1359). In upholding the dismissal, the *Atkins* court reasoned that the relator "failed to provide the next link in the [FCA] liability chin: showing that the defendant *actually submitted* reimbursement claims for the services

he described." *Id.* (quoting *id.*). The *Solvay* court noted that unlike *Clausen*, *Corsello*, and *Atkins*, the complaint contained "a highly-detailed compelling statistical analysis [that] rendered inescapable the conclusion that a huge number of claims for ineffective uses of Marinol resulted from [Solvay's illegal marketing] campaign." *Id.* at 1326. Nonetheless, the court upheld the dismissal because it did not "allege the existence of a single actual false claim." *Id.* Under these precedents, the *Solvay* court upheld the district court's dismissal because the relators did not allege "the actual presentment of a false claim." *Id.* at 1324.

The *Solvay* court also found the allegations insufficient under Rule 9(b) because they did not "identify specific persons or entities that participated in any step of the process. Nor [did] it allege dates, times, or amounts of individual false claims." *Id.* And, even assuming that "when a physician writes an off-label prescription with knowledge or intent that the cost of filling that prescription be borne by the federal government," the allegations were still insufficient because the complaint did not "identify a single physician who wrote a prescription with such knowledge; did not "identify a single pharmacist who filled such a prescription;" and did not "identify a single state healthcare program that submitted a claim for reimbursement to the federal government." *Id.* The court, summarizing its conclusion stated, "We cannot 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.* (citing *Clausen*, 290 F.3d at 1311 (emphasis removed)). Finally, the *Solvay* Court distinguished the allegations from those found sufficient in *United States ex rel. Walker v. R&F Properties of Lake Co., Inc.*, 433 F.3d 1349 (11th Cir. 2005). In *Walker*, the complaint "included allegations of first-hand knowledge that explained why [the relator] believed a specific defendant submitted false or fraudulent claims"; under the facts alleged in *Solvay*, by contrast, "the relators [did] not allege personal knowledge of the billing practices of

any person or entity." *Id.*

In re Cardiac Devices discussed an FCA claim based on off-label use of a medical device, but unlike the present suit, that case involved the pre-1995 Medicare regulations that prohibited reimbursement for devices the FDA did not approve for marketing. In *Cardiac Devices*, a sales representative for cardiovascular-device manufacturers alleged that 132 clinical-trial hospitals from thirty states submitted Medicare reimbursement claims for services involving "nearly sixty different investigational cardiac devices that had not been approved for marketing by the [FDA]" in direct contravention of the manual instructions.[19] *Id.* at 332. After receiving notice of the complaint, the Office of the Inspector General of HHS subpoenaed records from the hospitals, and ultimately elected to intervene. *Id.* at 327. The government and the relator moved to sever the action against each hospital and to transfer each to the federal district where the hospital was located. *Id.* at 327.

The separate complaints for each hospital generally alleged that the hospitals received cardiac devices the FDA had not pursuant to an "Investigation Device Exemption" that restricted their use to "carefully monitored clinical trials . . . to gather evidence of the safety and effectiveness of the devices." *Id.* at 329. The complaints alleged that the hospitals had submitted claims for reimbursement to Medicare and Medicaid for the use of the devices in treatment and received "millions of dollars in Medicare and Medicaid reimbursements." *Id.* at 330. The complaints broke "down the number of procedures performed involving each particular cardiac device." *Id.* For example, the complaint for one hospital stated "that it charged Medicare and/or Medicaid for at least thirty-seven procedures involving prosthetic heart valves manufactured by St. Jude that had not received marketing approval from the FDA." *Id.* The complaints also alleged that the defendant

---

[19] A number of the defendant hospitals settled before the court's decision on the motion to dismiss. *Cardiac Devices*, 221 F.R.D. at 326–27.

hospitals "were on notice . . . that Medicare considered medical procedures involving cardiac devices that had not been approved for marketing by the FDA . . . to be non-covered and non-reimbursable" and that the hospitals knowingly misrepresented the devices' approval in claims for reimbursement sent to their respective Medicare intermediaries. *Id.* The defendants filed two motions to dismiss all complaints. The first motion argued that the complaints did not allege fraud with sufficient particularity. Specifically, the defendants argued that:

> (1) The complaints merely allege a "per se" fraud theory, equating fraud with an alleged violation of the Medicare Hospital Manual and do not allege particular fraudulent misconduct.
>
> (2) The complaints do not identify specific claims submitted to the Government and do not allege the "who, what, when, where, and why" of the defendants' allegedly fraudulent misconduct.
>
> (3) The complaints do not allege facts giving rise to a strong inference of fraudulent intent.

Id. at 331.

In denying the defendant's motion to dismiss, the court first held that the plaintiffs were entitled to a relaxed pleading standard because the alleged fraud involved a "complex scheme" with numerous transactions and "the specific factual information" was peculiarly within the defendants' control. *Id.* at 333–34. By contrast, no such relaxation is warranted here under the Fifth Circuit case law. The court rejected the defendant's first argument—that violation of the manual provision's "reasonable and necessary" requirement is only a regulatory violation and not fraud *per se*—finding that a physician's certification that the use of the device was "reasonable and necessary" was an "underlying condition to payment." *Id.* at 335–36. The court also found that the complaints alleged both specific false submissions by the hospitals including the "who, what, where, when, and how"

of the alleged fraudulent statement.[20] The court cited the Eleventh Circuit's decision in *United States ex rel. Clausen v. Lab Corp. of Am.*, which upheld dismissal of an FCA complaint because the relator did not allege "an actual false claim." 290 F.3d at 1311. The *Cardiac Devices* court noted that the complaints "listed the number of claims" for each device and included "patient lists" provided by the defendant hospitals that, when read in conjunction, "identified the submission of specific claims." *Id.* at 337. The court distinguished *Clausen*, noting,

> This is not a situation where only a general scheme of fraud was alleged that might have resulted in the submission of false claims. Here, the fraudulent scheme was the submission of the claims themselves. This stands in sharp contrast to the complaints in Clausen, which "[a]t most, . . . raise[d] questions about [the defendant's] internal testing policies. But nowhere in the blur of facts and documents assembled by Clausen regarding six alleged testing schemes can one find any allegation, stated with particularity, of a false claim actually being submitted to the Government." 290 F.3d at 1312.

Id. Finally, the court found that the complaints alleged facts giving rise to a strong inference of fraudulent intent. Because the FCA only requires that a defendant act "knowingly," the complaints do not to allege "a specific intent to defraud." *Id.* at 339. Instead, complaints had to allege "'the knowing presentation of what is known to be false' as opposed negligence or innocent mistake." *Id.* (citing *Mikes v. Straus*, 274 F.3d 687, 703 (2d Cir. 2001) (citing *Hagood v. Sonoma County Water Agency*, 81 F.3d 1465, 1478 (9th Cir. 1996), *cert. denied*, 519 U.S. 865 (1996))).

The defendant's second motion to dismiss argued that the complaints failed to state a claim for relief under Federal Rule of Civil Procedure 12(b)(6) because they did not allege that the claims were "false or fraudulent." *Id.* at 342. The court first determined that hospitals requests for

---

[20] The complaints alleged "who" by identifying the specific hospitals; "what" by identifying the specific claims submitted; "where" as the place where the claims were filed; "when" by providing the "dates of the patients' hospitalizations" or the year annual cost reports were filed; and "how" by detailing the Medicare reimbursement scheme. *Clausen*, 209 F.3d at 337.

payments on form HCFA-1450 (UB-82[21] and UB-92) "clearly constituted the submission of a 'claim'" under the FCA. *Id.* at 343. The court also found that annual Cost Reports were claims because they were accompanied by certifications that the reports were "true, correct, and complete and prepared in accordance with applicable instructions." *Id.* at 344. The court held that the claims were alleged to be false under the Second Circuit's approach in *Mikes v. Straus*, 274 F.3d 687 (2d Cir. 2001). The court noted that *Mikes* discussed three theories for false claims:

> The Second Circuit in *Mikes* held that a claim may satisfy the falsity element of the FCA in one of three ways. It may be factually false if it "incorrectly describes the goods or services provided or a request for goods or services never provided," [274 F.3d] at 697, or it may be legally false because of an express false certification or an implied false certification. *Id.* at 697–98. In *Mikes*, the Second Circuit held an "expressly false claim is . . . a claim that falsely certifies compliance with a particular statute, regulation or contractual terms, where compliance is a prerequisite to payment." *Id.* at 698 (emphasis added). Under an implied false certification theory, the act of submitting a claim for reimbursement itself implies compliance with the governing federal rules that are a precondition to payment. *Id.* at 699 (emphasis added). The Court emphasized that "implied false certification is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies expressly states the provider must comply in order to be paid." *Id.* at 700 (emphasis in original). "Liability under the [FCA] may properly be found therefore when a defendant submits a claim for reimbursement while knowing–as that term is defined by the Act, see 31 U.S.C. § 3729(b)–that payment expressly is precluded because of some noncompliance by the defendant."

Cardiac Devices, 221 F.R.D. at 345. The court found that the claims were false under the "factually false" and "legally false/expressly false certification" theories. The claims were alleged to be factually false because the forms instructed hospitals "to enter any remarks not shown elsewhere on the bill but which were necessary for proper payment" and to list "[n]on-covered charges." *Id.* The hospitals' failure to state that experimental procedures, which were non-covered charges, were performed constituted a factually false claim. The court also found that as alleged the claims were

---

[21] UB-82 forms were used until 1994, when they were replaced by UB-92 forms. *See Cardiac Devices*, 221 F.R.D. at 345.

"legally false" because "42 U.S.C. § 1395y(a)(1)(A) contains an express condition of payment—'no payment may be made [under Medicare] for any expenses incurred for items or services which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury,'" and that it "'explicitly links each Medicare payment to the requirement that the particular item or service be 'reasonable and necessary.'" *Id.* (quoting *Mikes*, 274 F.3d at 700). The court found that the alleged claims falsely certified compliance and that the certification of compliance was a prerequisite for payment. *Id.* at 346. For the same reasons, the court found that hospitals' certifications on annual Cost Reports that the reports were "true, correct, and complete" falsely certified compliance where compliance was a prerequisite for payment." The court stated:

> The Medicare regulations imposed on defendants the obligation to provide the intermediaries with all information necessary to determine whether payment was due. Critical to this determination would be information concerning whether services were provided for a non-covered item . . .
>
> . . . [I]n submitting their claims, defendants were obligated to seek payment only for those services that were covered. To the extent that they sought payment for services that were not covered, the claims were legally false. The Government has alleged in its complaints that defendants knowingly submitted claims for payment of non-covered services provided in connection with investigational devices that were not reasonable and necessary. These FCA causes of action, as pled, set forth sufficient facts to satisfy the third element, that the claims were false or fraudulent.

Id. at 347.

IV. Analysis

A. The Allegations that Medtronic Violated the FCA by Marketing a Medical Device for Off-Label Use

The relators allege that Medtronic's off-label promotion of the Cardioblate system for the treatment of atrial fibrillation caused physicians and hospitals to submit claims to the government falsely stating that the use of Cardioblate was "reasonable and necessary" or "medically necessary." *See, e.g.*, *Mikes*, 254 F. 3d at 700–01 (finding that HCFA-1500 forms implicitly certify that requests

for reimbursement comply with 42 U.S.C. § 1395y(a)(1)(A)'s requirement that the items and services provided were "reasonable and necessary"). The relators' "central claim" is that the use of the Cardioblate system for treating atrial fibrillation cannot be medically necessary because "no element of the Cardioblate system has ever received approval *for the treatment of Atrial Fibrillation*." (Docket Entry No. 45, at 4) (emphasis in original).

Importantly, there is no allegation that Medtronic concealed or misstated the limits of the FDA's approval on the use of the Cardioblate system. *Compare Parke–Davis*, 147 F. Supp. 2d at 46 (describing Parke–Davis's efforts to conceal the lack of FDA approval). Unlike the Medicare coverage at issue in *Cardiac Devices*, Medicare may cover medically necessary uses of the Cardioblate system. Medicare contractors may approve coverage for Category B devices. 42 C.F.R. § 405.211(b). The decision on medical necessity is made by individual physicians exercising independent professional judgment based on the knowledge of their particular patients. The cases recognize that off-label use of a drug or medical device is distinct from a medically unnecessary use of that drug or device. *See Buckman*, 121 S. Ct. at 1018; *Polansky*, 2009 WL 1456582, at *6; *Svidler*, 2004 WL 2005781, at *5; *Stephens*, LEXIS 2009 DIST. 101601, at *20. For medical devices like the Cardioblate system, the relators must allege sufficient facts to support an inference that the use of the device is not "medically necessary" or "reasonable and necessary" under Medicare regulations. The relators acknowledge this in their brief. (Docket Entry No. 45, at 6–9).

The relators cite *United States ex rel. Riley v. St. Luke's Episcopal Hosp.*, 355 F.3d 370, 376 n.6 (5th Cir. 2004), in which the court stated that submitting a request for payment "certifies" that "the services shown on the [payment] form were medically indicated and necessary for the health of the patient." They also point to 42 U.S.C. § 1320c-5(a)(3)'s statement that:

> It shall be the obligation of any health care practitioner . . . who provides health care services for which payment may be made . . . to assure, to the extent of his authority that services or items ordered or provided by such practitioner or person to beneficiaries and recipients of this chapter . . . will be supported by evidence of medical necessity and quality in such form and fashion and at such time as may reasonably be required by a reviewing peer review organization in the exercise of its duties and responsibilities.

These authorities state that a procedure must be "medically necessary" but do not further define the term. The authorities cited by the relators do not provide a basis to infer that a reimbursement submission for using the Cardioblate system to treat atrial fibrillation, even as a stand-alone procedure, cannot be medically necessary or reasonable and necessary because it is not specifically approved for that purpose.

The relators argue that the use of the Cardioblate system for surgical treatment of atrial fibrillation is not medically necessary because it is viewed as experimental within the scientific community. (Docket Entry No. 45, at 11). But Medicare may cover Class II devices even though they "require special controls, such as performance standards or postmarket surveillance, to provide reasonable assurance of safety and effectiveness." 42 C.F.R. §§ 405.201(b), 405.211(b). The state's Medicare carrier determines "the conditions for coverage and reimbursement of physician charges for surgical cardiac ablation." (Docket Entry No. 27, ¶ 67). The relators do not allege that *any* state has denied coverage for surgical ablation to treat atrial fibrillation, whether as a stand-alone treatment or in connection with other cardiac procedures. Alleging that the use of the Cardioblate system to treat atrial fibrillation is "experimental" does not allege a basis for an inference that such use of the Cardioblate system is categorically medically unnecessary.

Nor do the relators allege specific false statements by Medtronic that the Cardioblate system is a first-line treatment for atrial fibrillation. The relators allege that the following statements are in Medtronic patient-education brochures: "[e]xperience to date indicates that Mini-Maze surgery

eliminates afib in more than 85% of patients who undergo the procedure"; "[m]ost patients with afib are candidates for Mini-Maze. Together, you and your doctor can determine if this surgery is right for you."; "Mini-Maze surgery is the first treatment that can safely, easily and reliably eliminate afib, helping patients avoid lifelong drug therapy and reducing the high risk of stroke and other complications that are associated with afib."; "Catheter Ablation destroys the source of abnormal electrical signals, vs. Mini-Maze Surgery, which creates a 'zone of defense' to permanently eliminate afib"; and "Catheter Ablation procedures take hours to perform, may require a pacemaker, and can cause life-threatening damage to organs near the heart. As a result, they are reserved for the most severe cases of afib. The Mini-Maze experience to date indicates that the surgery corrects afib in more than 85% of patients." (Docket Entry No. 27, ¶¶ 88–91). These are general statements about the safety and efficacy of closed-chest surgical ablation compared to catheter ablation. These are not statements that the Cardioblate system is a first-line treatment for atrial fibrillation and do not support an inference that Medtronic caused physicians and hospitals to submit reimbursement claims for using the Cardioblate system as a first-line treatment for atrial fibrillation.

In addition, the relators have failed to plead with sufficient particularity the alleged false claims. The relators have not identified any Medtronic employees who engaged in off-label promotion nor specific physicians or hospitals who received the promotions. They have not alleged the "who" or "where" of the alleged fraud. *See, e.g.*, *Thompson*, 125 F.3d at 903. Like the allegations involving false submissions to the Veterans Administration the *Parke–Davis* court dismissed, but unlike the allegations involving Medicaid submissions the court did not dismiss, the relators have identified neither specific Medtronic employees who engaged in off-label promotions nor specific doctors who received such promotion. *Parke–Davis*, 147 F. Supp. 2d at 48. Nor have the plaintiffs identified any physician to whom Medtronic promoted Cardioblate off-label and who

also "actually submitted false claims to the Government for off-label uses" of Cardioblate. *Hess*, 2006 WL 1064127, at *6; *see also Solvay*, 588 F.3d at 1326 (upholding the district court's dismissal because the relators "did not identify specific persons or entities that participated in any step of the process");[22] *Polansky*, 2009 WL 1456582 (E.D.N.Y. May 22, 2009) (dismissing *qui tam* involving off-label promotion of Lipitor because the plaintiff did not identify any false claims or physicians who were induced to write a prescription for an off-label use). *Compare Cardiac Devices*, 221 F.R.D. at 337 (denying a motion to dismiss where the complaint identified specific hospitals and specific fraudulent claims). These allegations do not plead fraud with the particularity required by the Fifth Circuit's decision in *Thompson*.

The relators have alleged a number of unlawful promotional tactics. The relators have alleged that physicians and hospitals used the Cardioblate system to treat atrial fibrillation. The cases recognize that even if a drug or device manufacturer's marketing or promotion activities violate FDA regulations, that is insufficient to plead that the manufacturer caused physicians or hospitals to submit false claims for reimbursement. *See Rost*, 507 F.3d at 732; *Hess*, 2006 WL 1064127, at *6; *Polansky*, 2009 WL 1456582, at *7. In *Parke–Davis*, the relator identified Parke–Davis's unlawful promotional tactics, including using medical liaisons such as the relator to make "exaggerated or false claims concerning the safety and efficacy of Parke–Davis drugs for off-label uses"; rewarding physicians who prescribed large quantities of Parke–Davis drugs with kickbacks; and paying physicians to create "sham" studies urging off-label uses that "had no

[22] The relators argue that the Eleventh Circuit's decision in *Solvay* is inconsistent with the Fifth Circuit's decision in *Grubbs* because the Fifth Circuit explicitly rejected *Clausen*'s holding that "the minimum indicia of reliability required to satisfy the particularity standard are the specific contents of actually submitted claims." *Grubbs*, 565 F.3d at 186 (citing *Clausen*, 290 F.3d at 1311). The *Solvay* court did not apply this rule. In *Grubbs*, the court recognized that the Eleventh Circuit has "moved away from *Clausen*'s most exacting language, accepting less billing in a case where particular allegations of a scheme offered indicia of reliability that bills were presented." *Id.* at 187 (citing *Walker*, 433 F.3d at 1360).

scientific value." 147 F. Supp. 2d at 45–46. The relator also provided eleven "specific examples of fraudulent statements which medical liaisons . . . were trained to give physicians, and did give to physicians." *Id.* at 48. The court still dismissed the relator's allegations covering the submission of claims to the Veterans Administration for failure to identify "which Parke–Davis personnel engaged in this conduct, where such conduct took place, which VA personnel were involved, or any specific fraudulent statements made to personnel at the VA." *Id.* at 50. Similarly, in *Rost*, the relator alleged that Pharmacia promoted Genotropin off-label through cash payments for off-label studies, rebates and other kickbacks for off-label prescriptions, and off-label marketing materials. 507 F.3d at 723–24. The relator also alleged statistical data demonstrating a likelihood of high volume off-label prescription-writing. *Id.* at 732. The appellate court nonetheless upheld the dismissal:

> It may well be that doctors who prescribed Genotropin for off-label uses as a result of Pharmacia's illegal marketing of the drug withstood the temptation and did not seek federal reimbursement, and neither did their patients. It may be that physicians prescribed Genotropin for off-label uses only where the patients paid for it themselves or when the patients' private insurers paid for it. Rost did not plead enough to satisfy the concerns behind Rule 9(b).

Id.

The relators argue that *Grubbs* relaxed the pleading standard for pleading fraud under the FCA. In *Grubbs*, the Fifth Circuit reversed the district court's dismissal of a *qui tam* suit alleging that psychiatrists billed Medicare and Medicaid for services not performed. 565 F.3d at 195. *Grubbs* analyzed the Eleventh Circuit's decision in *Clausen* requiring allegations of the "specific contents of actually submitted claims, such as billing numbers, dates, and amounts." *Id.* at 186. rejecting this requirement, the court stated as follows:

> [T]he "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 Claim 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 § 3729(a)(1) 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.

Id. at 190.

The relators' complaint is not deficient because it fails to allege the specific contents of fraudulent submissions. The relators have not alleged the type of information that the *Grubbs* relator did. As the Fifth Circuit explained in *Grubbs*:

> The complaint sets out the particular workings of a scheme that was communicated directly to the relator by those perpetrating the fraud. Grubbs describes in detail, including the date, place, and participants, the dinner meeting at which two doctors in his section attempted to bring him into the fold of their on-going fraudulent plot. He alleges his first-hand experience of the scheme unfolding as it related to him, describing how the weekend on-call nursing staff attempted to assist him in recording face-to-face physician visits that had not occurred. Also alleged are specific dates that each doctor falsely claimed to have provided services to patients and often the type of medical service or its Current Procedural Terminology code that would have been used in the bill.

Id. at 191–92. Under *Grubbs*, *Thompson*, and other precedents, the relators' complaint does not sufficiently allege that by promoting off-label use, Medtronic caused the submission of false claims and is liable under the FCA.

B. The Allegations on Upcoding

The relators allege that Medtronic instructed hospitals and physicians to "upcode" stand-alone surgical ablations—minimally invasive, closed-chest procedures—by entering the code associated with open-chest procedures, ICD-9 procedure code 37.33, in reimbursement claims. The relators allege that physicians and hospitals should have entered procedure code 37.99, which is more appropriate for such minimally invasive procedures. The relators allege that entering code

37.33 instead of code 37.99 generates a significantly higher Medicare reimbursement and that Medtronic sales representatives were instructed to inform physicians and hospitals that they "could make great profit by over-billing Medicare." (Docket Entry No. 27, ¶ 122). The relators allege that Medtronic marketing materials identified code 37.33 as the appropriate code for stand-alone surgical ablations, not code 37.99. Because there was an economic incentive to "upcode," because Medtronic pointed out the opportunity to do so, and because stand-alone ablation procedures were performed, the relators argue that they have alleged a sufficient basis to support an inference that Medtronic caused hospitals to "upcode" and submit false claims to Medicare.

Under the applicable case law authority, the relators have not pleaded this scheme to defraud with sufficient particularity to withstand dismissal. The relators have not identified any Medtronic sales representative or employee who encouraged hospitals or physicians to "upcode" improperly or any hospital or physician who did in fact "upcode" improperly in a Medicare reimbursement submission. These allegations fail to allege information about the "who, what, when, where, and how of the alleged fraud." *Thompson*, 125 F.3d at 903.

The cases involving FCA upcoding allegations against physicians support this result. In *United States ex rel. Bledsoe v. Cmty. Health Sys.*, a district court dismissed a relator's allegations that a hospital submitted numerous false claims for reimbursement to Medicare and Medicaid. 501 F.3d 493 (6th Cir. 2007). The appellate court upheld the dismissal even though the relator identified the CPT codes incorrectly entered in reimbursement submissions because the allegations did "not meet the minimum standard of the 'time, place and content of the alleged misrepresentation on which [the injured party] relied.'" *Id.* at 513 (citing *United States ex rel. Bledsoe v. Cmty. Health Sys.*, 342 F.3d 634, 643(6th Cir. 2003)). Although the Fifth Circuit backed away from the "time, place, and contents" standard in *Grubbs*, the relators' complaint in this case is still deficient. While

the relators in this case have alleged codes physicians and hospitals should use in submitting claims for reimbursement for minimally invasive, stand-alone surgical ablation procedures, the relators have not identified any physicians or hospitals that put the incorrect code on a Medicare reimbursement claim. These allegations are insufficient under the applicable case law.

In *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350 (11th Cir.2006), the allegations included upcoding. The relator alleged that the defendants submitted claims for, and received, Medicare reimbursement for psychiatric services that were: "(1) not rendered, (2) not medically necessary, (3) the result of improper 'upcoding,' (4) grounded in psychiatric evaluations provided by unqualified staff personnel, (5) based upon 'pre-formed,' predetermined sets of patient evaluations, diagnostic codes, and treatment plans, and (6) provided with substandard levels of care." *Id.* at 1354. The Eleventh Circuit affirmed the district court's dismissal, stating that "the complaint fails rule 9(b) for want of sufficient indicia of reliability to support the assertion that the defendants submitted false claims." *Id.* at 1358–59. Even though the relator cited particular patients, dates, and corresponding medical records for services he contended were not eligible for government reimbursement, his claim failed because he did not allege facts showing that the defendants actually submitted reimbursement claims for the services he described. "Instead, he portrays the scheme and then summarily concludes that the defendants submitted false claims to the government for reimbursement." *Id.* at 1359; *see also United States ex rel. Barrett v. Columbia/HCA Healthcare Corp.*, 251 F. Supp. 2d 28, 35 (D.D.C. 2003) (dismissing FCA upcoding allegations because the complaint did not sufficiently "link" the upcoding allegations "with the submission of claims to Medicare"); *United States v. Aggarwal*, No. 6:03-cv-117-Orl-31KRS, 2005 WL 6011259, at *6 (M.D. Fla. Feb. 10, 2005) (dismissing FCA upcoding allegations against a physician because the United States failed to allege that claims were filed in connection with a

specific procedure performed and also failed to allege "the names of the patients in whose name claims were filed, claim numbers, the dates of such claims, to whom the claims were made, and what any of the Defendants received as a result"). *Compare United States ex rel. Harris v. Bernard*, 275 F. Supp. 2d 1, 6 (D. D.C. 2003) (denying a motion to dismiss because the relator identified the employees who caused the submission of false claims; pleaded that the fraud began in 1993 and continued to the time of lawsuit; pleaded that the fraud occurred in the defendant's offices; pleaded twelve "sample patients" whose claims did not correspond with their treatment; and pleaded that the defendants provided treating physicians with fee tickets allowing physicians to select only high paying codes). In the complaint filed in the present case, the relators have not cited "particular patients, dates, and corresponding medical records" for the alleged upcoding. Nor have the relators alleged with particularity that any physician or hospital submitted a false claim for reimbursement. These allegations do not plead fraud with the particularity required by Rule 9(b).

One other point is worth noting. Procedure codes and DRGs are part of Medicare's Prospective Payment System (PPS). One court has explained PPS as follows:

> Under PPS, hospitals are reimbursed based on a pre-determined rate for each Medicare admission. The rate depends on each patient's particular diagnosis and other clinical information. Each patient is classified into a Diagnosis Related Group (DRG) that determines the amount of payment. The DRG payment amounts were derived based on average costs incurred in treating particular conditions. By paying a flat rate based on the patient diagnosis, the PPS system gives providers a financial incentive to provide cost-efficient care.

United States ex rel. Digiovanni v. St. Joseph's/Candler Health Sys., 2008 WL 395012, at *6 (S.D. Ga. Feb. 8, 2008) (citing 42 C.F.R. § 412.2(f); Health Care Financing Administration, 65 Fed. Reg. 18434-01 (April 7, 2000); American Hospital Directory, Medicare Prospective Payment System, http://www.ahd.com/pps.html (last visited Nov. 19, 2007)). The PPS is designed to provide an incentive to hospitals to use lower-cost procedures to treat the diagnosis identified in the PPS code.

The allegation that Medtronic encouraged hospitals to use the Cardioblate system in part because of the opportunity to profit by performing a lower-cost procedure to treat the diagnosis does not create a reasonable inference that physicians and hospitals knowingly submitted false claims. There must be an allegation that Medtronic and the hospitals and physicians knew that using the DRG code 37.33 for stand-alone minimally invasive surgical ablations was always incorrect and that code 37.99 was the only correct code. The complaint fails to state a claim for relief.

C. The Allegations that Medtronic Paid Kickbacks

The relators allege that Medtronic provided remuneration in various forms to hospitals and physicians to induce them to purchase and use the Cardioblate system, in violation of the antikickback statute, 42 U.S.C. § 1320a-7b(b)(1–2). The relators allege that compliance with the antikickback statute is a prerequisite to seeking reimbursement under Medicare and that a false certification of compliance is a basis for a claim under the FCA. *See Thompson*, 125 F.3d at 902; *Graves*, 284 F. Supp. 2d at 497. The Fifth Circuit has held that payment of Medicare claims may be "conditioned upon certification of compliance with laws and regulations including the anti-kickback statute." *Id.*; *see also United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 20 F. Supp. 2d 1017, 1041–42 (S.D. Tex. 1998) (finding on remand that allegations that the defendant expressly certified compliance with the antikickback statute in annual cost reports sufficiently states a claim under the FCA because the certifications were a condition of retaining Medicare payments made during the prior year and a condition of continued eligibility for the Medicare program).

The antikickback statute provides:

> (1) whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind--

> (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.
>
> (2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person–
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b)(1–2).

The facts alleged by the relators are insufficient under the applicable case law to state a claim under the certification theory of FCA liability. The cases demonstrate that the basis of liability is the certification of compliance, not the payment or acceptance of remuneration. *See Siewick*, 214 F.3d at 1376–77 (upholding district court's determination on summary judgment that even if the defendants had violated 18 U.S.C. § 207, "a criminal statute aimed at 'revolving door' abuses by former government employees," there was no fact issue as to an FCA violation because defendants were not required to certify compliance with the statute); *Willard*, 336 F.3d at 382–83 (upholding district court's dismissal because the plaintiff only alleged violations of HMO enrollment

antidiscrimination laws but did not allege that the United States "conditioned payment . . . on any implied certification of compliance with the anti-discriminatory provisions"); *Roop*, 559 F.3d at 824 (upholding district court's dismissal because the plaintiff alleged only violation of FDA medical-device-reporting regulations by selling defective products but did not allege that certification with these regulations was a prerequisite to payment).

The relators allege that Medtronic paid unlawful remuneration to hospitals and physicians for their use of the Cardioblate system, that physicians and hospitals accepted the remuneration, and that physicians and hospitals made reimbursement claims to Medicare. However, the relators have not alleged that Medtronic caused any physicians or hospital to make false certifications of compliance. In *Parke–Davis*, the relator's failure to make this allegation warranted dismissal. *See* 147 F. Supp. 2d at 55 (noting that the relator did not allege that "Parke–Davis caused or induced a doctor and/or pharmacist to file a false or fraudulent certification regarding compliance with the anti-kickback statute"). Because the relators have not alleged that Medtronic caused any hospital or physician to certify compliance with the antikickback statute, these allegations are dismissed.[23]

Even if the relators sufficiently alleged that Medtronic's kickbacks caused false certifications, the relators have not provided reliable indicia that physicians or hospitals falsely

---

[23] As noted, the Fifth Circuit has never adopted implied certification as a theory of FCA liability. *Marcy*, 520 F.3d at 389 (5th Cir. 2008) (citing *Willard*, 336 F.3d at 381–82); *Southland Mgmt. Corp.*, 326 F.3d at 679 (Jones, J. concurring). The relators can state a claim that "the defendant has made a false certification of compliance with the statute or regulation, when payment is conditioned on that certification." *Graves*, 284 F. Supp. 2d at 497. Whether the relators allege that Medtronic expressly or impliedly certified compliance with the antikickback statute is unclear. The relators allege: "Either pursuant to provider agreements, claims forms, or other manner, hospitals and physicians who participate in a federal health care program generally must certify that they have complied with the applicable federal rules and regulations." (Docket Entry No. 27, ¶ 44). The relators do allege that violation of the antikickback statute can cause exclusion from Medicare, but they do not allege any specific certification of compliance. (*Id.* at ¶ 43). *Compare Cardiac Devices*, 221 F.R.D. at 345 (identifying the forms on which the compliance certifications were made, where the forms required certification, and the false statements of certification).

certified compliance. They have not identified the "'who, what, when, where, and how'" of the alleged false certifications. *See Lam*, 481 F. Supp. 2d at (citing *Thompson*, 125 F.3d at 903). The relators have not identified a physician or hospital falsely certifying compliance with the antikickback statute in applying for Medicare reimbursement for surgical ablation using a Cardioblate system; when such a false certification was made; or how such a false certification was made. Instead, the relators have alleged different types of remuneration provided by Medtronic and identified certain hospitals and doctors performing stand-alone surgical ablations. These allegations do not provide reliable indicia of a scheme to defraud. *See id.* at 687 (dismissing FCA action alleging false certification of compliance with antikickback statute even though the relators named the "who" because the relators did not allege "even one specific illegal referral" or the specific times of the fraud); *United States ex rel. Kennedy v. Aventis Pharms.*, 610 F. Supp. 2d 938, 945 (2009) (the relators "identified a number of hospitals to which Aventis allegedly gave kickbacks disguised as unrestricted grants to induce their continued use and/or promotion of Lovenox for unapproved indications," but failed to allege "that one or more of the hospitals falsely certified, in connection with a Medicare claim, that it had complied with the anti-kickback statute; the failure to identify "any certification by a hospital," caused dismissal). The relators fail to identify any hospitals or physicians who certified compliance with the antikickback statute. These allegations are dismissed.

D. Leave to Amend

The relators requested leave to amend should this court dismiss their complaint. (Docket Entry No. 45, at 25). The relators have only amended once, (Docket Entry No. 12), before the filing of Medtronic's motion to dismiss. Medtronic does not argue that the relators' complaint is frivolous. S*ee Ayers*, 247 F. App'x at 535. This court grants the relators leave to amend. *See Great Plains*

Trust Co., 313 F.3d at 329; *Adrian*, 363 F.3d at 403. An amended complaint must be filed by **October 29, 2010**.

V. Conclusion

Medtronic's motion to dismiss is granted, without prejudice. The relators may amend their complaint by **October 29, 2010**.

SIGNED on September 30, 2010, at Houston, Texas.

Lee H. Rosenthal
United States District Judge