UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

UNITED STATES OF AMERICA *ex rel.* KEVIN N. COLQUITT,	§	
Plaintiff,	§	
v.	§	No. 3:06-cv-1769-M
ABBOTT LABORATORIES f/k/a Guidant Corporation, ABBOTT VASCULAR SOLUTIONS, INC., BOSTON SCIENTIFIC CORPORATION, JOHNSON & JOHNSON, CORDIS CORPORATION,	§	
Defendants.	§	

MEMORANDUM OPINION AND ORDER

Before the Court are Motions to Dismiss filed by Boston Scientific Corporation [Docket Entry #110], Cordis Corporation and Johnson & Johnson (collectively, "Cordis") [Docket Entry #112], and Abbott Laboratories and Abbott Vascular Solutions, Inc. (collectively, "Abbott") [Docket Entry #115]. For the reasons stated below, the Motions to Dismiss filed by Boston Scientific and Cordis are **GRANTED**, and the Motion to Dismiss filed by Abbott is **GRANTED** in part and **DENIED** in part. As explained below, the Relator is granted leave to amend some of the dismissed claims.

I. BACKGROUND

Relator Kevin Colquitt brings this qui tam action, under the federal False Claims Act ("FCA") and several analogous state false claims statutes, against the Defendants, who are medical device manufacturers. The crux of Colquitt's suit is that the Defendants engaged in a scheme to thwart the FDA approval process for vascular stents by fraudulently obtaining FDA clearance for their devices as biliary stents, when in fact the Defendants intended to and did market and promote them as vascular stents. Colquitt argues that this scheme led or was material to false claims for reimbursement submitted to federal payer programs, such as Medicare and Medicaid. The Defendants move to dismiss Colquitt's claims under Rules 12(b)(1) and 12(b)(6), arguing that the FCA's public disclosure jurisdictional bar deprives the Court of jurisdiction over Colquitt's claims, *see* 31 U.S.C. § 3730(e)(4), that Colquitt has failed to state a plausible claim for relief as required by Rule 8, and that Colquitt has not pleaded fraud with particularity as required by Rule 9(b).

A. The Parties

Defendants are medical device manufacturers who make and sell biliary stents. Colquitt held the position of Territory Manager for Abbott, successor-in-interest to Guidant Corporation, from February 2004 to July 2006. Colquitt alleges that during this period he witnessed and participated in a scheme through which Abbott promoted the off-label use of its biliary stents, and induced physicians and hospitals to seek reimbursement from federal payer programs for such off-label use. Although Colquitt never worked for Boston Scientific or Cordis, he alleges that through his employment with Abbott he witnessed similar off-label promotion by them as well.

B. Colquitt's Allegations

The allegations in the Third Amended Complaint ("TAC") can be divided into four categories: (1) allegations concerning false statements allegedly made by the Defendants to the FDA in obtaining market clearance for their stents; (2) allegations that the Defendants promoted and marketed their biliary stents for off-label, vascular applications; (3) allegations that the Defendants induced healthcare providers to seek reimbursement from federal payer programs for the off-label use of their biliary stents; and (4) allegations of illegal kickbacks provided by the Defendants to physicians and hospitals to use their stents for off-label uses.

1. False Statements to the FDA

a. FDA Regulation of Medical Devices

Under the Federal Food, Drug, and Cosmetic Act ("FDCA") and the amendments thereto, medical devices are classified as Class I, Class II, or Class III. 21 U.S.C. § 360c(a)(1) (2006). Which class a particular device is placed in is determined by the level of regulatory review necessary to provide assurance of the device's "safety and effectiveness." *Id.* § 360c(a)(1)(A)(i), (B), (C)(i). Class I devices, such as tongue depressors and elastic bandages, are those that present no unreasonable risk of illness and injury and therefore require only general manufacturing controls. *Id.* § 360c(a)(1)(A); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344 (2001). Class II devices are those that require "special controls" to provide assurance of their safety and effectiveness. 21 U.S.C. § 360c(a)(1)(B); *see Buckman*, 531 U.S. at 344. Finally, Class III devices are those whose uses are purported or represented to support or sustain human life, are of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury. 21 U.S.C. § 360c(a)(1)(C). Therefore, Class III devices receive the FDA's strictest regulation. *Buckman*, 531 U.S. at 344.

Generally, all new devices introduced into interstate commerce for commercial distribution after May 28, 1976, are classified as Class III devices. 21 U.S.C. § 360c(f)(1). However, a new device is not classified as Class III if it is "substantially equivalent" to a type of device that has previously been classified in Class I or II. *Id.* § 360c(f)(1)(A). In that case, the device is placed in the same class as the substantially equivalent device type. *Id.*

The difference in the level of regulatory review required for Class II and Class III devices is substantial. Class III devices are subject to a premarket approval process, which is the most stringent level of device regulation imposed by the FDA, usually requiring the manufacturer to conduct costly clinical studies to demonstrate the safety and effectiveness of the device. *See id.* § 360e. Class II devices, on the other hand, are subject to a less arduous process, commonly known as § 510(k) certification. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 (1996).

Under the § 510(k) certification process, a manufacturer must submit to the FDA a premarket notification submission, commonly known as a 510(k) notice, before a device may be introduced into interstate commerce. 21 U.S.C. § 360(k); 21 C.F.R. § 807.81 (2010). The 510(k) notice must include, among other things, proposed labeling sufficient to describe the device, its intended use, and the directions for its use; a statement indicating the device is similar to or different from other products of comparable type in commercial distribution; and a statement that the submitter believes, to the best of the submitter's knowledge, that all information in the 510(k) notice is truthful and accurate, and that no material fact has been omitted. 21 C.F.R. § 807.87(e)–(h), (k).

Along with the 510(k) notice, a manufacturer must submit a "510(k) summary,"[1] which "shall be in sufficient detail to provide an understanding of the basis for a determination of substantial equivalence [to previously cleared devices]." *Id.* § 807.92(a). Among the information that must be contained in a 510(k) summary is "[a] description of the device . . . , including . . . the significant physical and performance characteristics of the device, such as device design, material used, and physical properties." *Id.* § 807.92(a)(4). The 510(k) summary must also include "[a] statement of the intended use of the device . . . including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate." *Id.* § 807.92(a)(5).

Biliary stents are Class II devices intended for use in the bile ducts of patients with biliary cancer. *See* 21 C.F.R. § 876.5010. Patients with biliary cancer can develop cancerous growths that restrict the flow of bile through the bile ducts, so the stents are used to keep the bile ducts open, allowing bile to drain freely from the liver and gallbladder. Biliary stents are classified as Class II devices, partly because of the short life expectancy of patients who use them. *See* Dorothy B. Abel, *Off-Label Medical Device Use*, Endovascular Today, March 2003, at 60 ("Given the terminal status of . . . patients [requiring biliary stenting due to malignant biliary cancer], any long-term risks associated with these devices are not a significant concern."); *see also* 21 U.S.C. § 360c(a)(2) ("[T]he safety and effectiveness of a device are to be determined . . . weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.").

[1] As an alternative to submitting a 510(k) summary, a manufacturer may submit a "510(k) statement" as described in 21 C.F.R. § 807.93. The TAC does not allege any facts with respect to a 510(k) statement.

Vascular stents are Class III devices. (Relator's Third Am. Compl. ¶ 64, ECF No. 68 [hereinafter TAC].) A vascular stent is used to treat peripheral vascular disease by providing structural support to the blood vessel in which it is implanted. (*Id.*) Unlike biliary stents, vascular stents are implanted in patients with long life expectancies, and thus, the stents are considered permanent implants. (TAC ¶ 65.) Vascular stents must undergo the premarket approval process in order to establish their safety and effectiveness, and cannot be cleared for marketing through the 510(k) certification process. (TAC ¶ 66.)

b. Alleged False Statements

Colquitt alleges the Defendants falsely represented in their 510(k) notices that their stents were intended for use in the biliary system when in fact they were intended for use in the vascular system. In other words, Colquitt charges that the Defendants misrepresented their stents as biliary stents in order to circumvent the costly premarket approval process, and instead to take advantage of the less stringent § 510(k) certification process. In particular, the TAC alleges that the Defendants made false statements and omitted material information regarding the stents' classification, type, predicate devices, substantial equivalence, intended use, appropriate labels, and risk to patients. (TAC ¶ 77.)

In support of these allegations, Colquitt points to the physical dimensions of the stents, asserting that 99% of the Defendants' devices "are too large or too small to fit the biliary tree and/or are marketed and sold to healthcare providers premounted on delivery catheters that are incorrectly sized to place the stents in the biliary tree." (TAC ¶ 72.) The devices were, Colquitt alleges, appropriately sized for use in vasculature. To demonstrate this argument, Colquitt attached as Exhibit 1 to the TAC a table that lists the Defendants' stents and a variety of physical characteristics of each. (TAC, Ex. 1.) Additionally, the table contains a column labeled "Biliary Use Probability," which for each device states, "Y," N," or "Y/N." (*Id.*)

Colquitt also relies on the significant increase in the number of biliary stents cleared for marketing in recent years in comparison to the steady and relatively small number of patients requiring stenting of the biliary tree. (*Id.*) Colquitt alleges that "[t]he obvious explanation is that Defendants intended the devices to be used for vascular procedures, which is a vastly larger market." (*Id.*)

In summary, Colquitt alleges that the dimensions of the devices the Defendants submitted for 510(k) clearance, and the quantity produced, demonstrates that the stents were intended to be used as vascular stents, despite the statements in the 510(k) notices. Had the Defendants been truthful about the stents' intended use, Colquitt asserts, they would have been required to complete the premarket approval process for Class III devices. Thus, according to Colquitt, the Defendants obtained market clearance of their stents through fraud.

2. Off-Label Promotion and Marketing

The bulk of Colquitt's factual allegations relate to the Defendants' alleged off-label promotion and marketing of biliary stents for vascular use.

a. Colquitt's Experiences as an Abbott Territory Manager

Colquitt worked for Abbott from February 2004 to July 2006. Colquitt alleges that he was trained to promote the off-label vascular use of several of Abbott's devices that had been cleared by the FDA only as biliary stents. His initial training sessions in Abbott's endovascular headquarters were allegedly centered on increasing Abbott's share of the vascular stent market, although Abbott had no FDA-approved vascular stents. Colquitt alleges that he and other attendees at the training sessions practiced deploying Abbott's biliary stents in anatomic models of the vascular system, under the supervision of Abbott instructors. Colquitt alleges that this training was provided so that he and other sales representatives could demonstrate to physicians how to use Abbott's biliary stents in the vascular system. According to Colquitt, the anatomic

models did not include biliary anatomy, and no laboratory training was provided for placement of stents in the biliary tree.

Colquitt also alleges that the other Defendants utilized similar training methods. According to the TAC, shortly after Colquitt completed his training with Abbott in the spring of 2004, he learned from a Cordis sales representative that Cordis's representatives were trained in a vascular laboratory where a physician taught them how to read vascular angiograms and let them watch live "peripheral vascular cases." The TAC does not contain any similar specific allegations about the training of Boston Scientific employees.

Colquitt alleges that he was trained on Abbott's Peripheral Preceptorship Program (the "Program"), the objective of which was to build a stent market share by soliciting interventional cardiologists and vascular surgeons to perform peripheral vascular stenting procedures using Abbott's bilary stents thereby promoting off-label usage. Abbott funded and sponsored the Program's courses through grants to Medical Media Communications ("MMC"), a for-profit company financed by the Defendants. According to Colquitt, Abbott established the timing and location of the Program courses, selected the vascular physician instructors, selected other vascular specialists to be trained, and negotiated payment to the instructors. In connection with these courses, Colquitt alleges that he was tasked with identifying cardiologists and vascular surgeons who were likely to prescribe large numbers of Abbott's biliary stents for vascular use. Once identified, these "target" physicians would be invited by Abbott's training department, through MMC, to attend one of the courses, which were conducted in the catheterization lab of the hospitals where the vascular specialists worked.

Colquitt alleges that Cordis and Boston Scientific also sponsored peripheral endovascular stenting courses to instruct physicians how to utilize Cordis's and Boston Scientific's biliary

stents for off-label vascular uses. According to Colquitt, the Defendants "conducted dozens of these courses annually, each of which promoted and marketed biliary stents for vascular procedures," and thus, "Defendants have sponsored the training of thousands of vascular specialist physicians on the off-label use of biliary stents for vascular purposes." (TAC ¶ 131.)

Furthermore, Colquitt alleges that Abbott induced off-label use of its stents through its "practice building program." As part of this program, Abbott allegedly compiled a package of information for distribution to vascular specialists that contained letters to physicians, patient questionnaires, and patient "advisory" letters. Colquitt claims that the patient advisory letters were prepared for the vascular specialist to send to his or her own patients to warn them of serious health risks of undiagnosed and untreated peripheral vascular disease, and that the physician letters provided information about the design specifications of Abbott's biliary stents. The TAC also states that Abbott coordinated and funded dinners for "referring physicians." Additionally, Colquitt alleges that as part of the practice building program, he accompanied another Abbott territory manager, who was also the "field sales trainer," on visits to healthcare providers. During the visits, Colquitt allegedly witnessed numerous vascular procedures involving the placement of biliary stents in the vascular anatomy, but never witnessed any procedures in which biliary stents were implanted in the biliary tree. The Abbott field sales trainer also allegedly trained Colquitt on how to market Abbott's stents against the biliary stents of Cordis and Boston Scientific, which Colquitt alleges also were marketed for vascular purposes.

Colquitt claims that during his time as a territory manager for Abbott, his entire focus was on promoting the off-label use of Abbott's biliary stents in the vascular system. He alleges that he was never instructed or trained to market the devices to gastroenterologists—the

physicians who would actually use stents in the biliary tree. According to the TAC, Colquitt and his managers participated in sales presentations that focused exclusively on soliciting vascular physicians for off-label use of Abbott's devices. Further, Colquitt alleges that he attended trade shows on peripheral vascular disease, where he witnessed identified sales representatives from Cordis and Boston Scientific promote their employers' biliary stents to vascular specialists for vascular procedures.

The trade shows are not the only occasion at which Colquitt claims to have witnessed sales representatives from Cordis and Boston Scientific promoting their biliary stents for vascular use. According to the TAC, Colquitt witnessed a Cordis sales representative attend live vascular stenting where off-label use of Cordis's stents was "successfully promoted." (TAC ¶ 142.) The TAC contains similar allegations regarding Boston Scientific, stating that Colquitt witnessed one of Boston Scientific's sales representatives promote the off-label use of its biliary stents to identified physicians in the hospital's catheterization lab.

According to the TAC, Abbott further induced off-label use of its stents by providing Abbott territory managers with compensation incentives to reward off-label promotion. Colquitt claims that the majority of his earnings came from commissions for off-label sales of Abbott's biliary stents, and that Abbott established biliary-stent sales quotas that "greatly exceeded" the number of potential on-label biliary uses. (TAC ¶ 153.) Colquitt thus asserts that Abbott's compensation structure "created a culture . . . that rewarded representatives for illegally promoting and marketing the biliary stents off-label." (TAC ¶ 154.) As for Cordis and Boston Scientific, the TAC alleges that they "similarly instituted compensation structures, quotas, and bonuses that rewarded and incentivized sales representatives to promote and sell the biliary stent

systems to vascular specialists and required representatives to promote the devices off-label." (TAC ¶ 156.)

Colquitt alleges that the Defendants also used consignments to promote and induce off-label use. According to Colquitt, the Defendants stocked hospitals with their biliary stents but did not charge the hospital for any stent until it was actually used, and that the majority of consigned stents were allocated to hospital departments where biliary procedures were not performed, but vascular surgery was. Colquitt estimates that at least half of all biliary stents are sold through consignment to hospital departments that do not perform biliary procedures. According to the TAC, Abbott also kept records and collected data concerning these consigned devices to measure off-label usage by physicians and overall vascular market share. Colquitt alleges that Cordis's recordkeeping involved a sophisticated system of handheld scanners, which he allegedly witnessed a Cordis representative use in departments that did not perform biliary procedures. Colquitt further claims to have witnessed Boston Scientific and Cordis sales representatives manage their consignment inventories in the catheterization labs of various hospitals.

Finally, the TAC contains allegations that the Defendants' sales representatives performed laboratory demonstrations of off-label use of the Defendants' biliary stents. According to the TAC, sales representatives of each Defendant were assigned exclusive days in catheterization labs during which they would attend live vascular cases, demonstrate the off-label use of biliary stents, and provide technical advice on how to prepare and deploy the biliary stents for use in the vascular system. Colquitt alleges that these live demonstrations were important because they allowed the Defendants' sales representatives to give instructions and advice that

they were prohibited from putting in writing due to labeling restrictions and the risk of misbranding the devices.

b. Off-Label Marketing in Vascular Journals and on the Internet

Outside of the activities and duties of the Defendants' sales teams, Colquitt alleges that the Defendants marketed their devices for off-label use on their websites, in press releases, and in journals focused on vascular medicine. Colquitt alleges that Cordis's website represented that its biliary stents were used for "endovascular interventional procedures." (TAC ¶ 166.) Likewise, Boston Scientific allegedly promoted its biliary stents as part of a treatment option for addressing peripheral artery disease, and on its website promoted one biliary stent in particular as a vascular stent, though that stent had not been approved by the FDA for vascular indications. Furthermore, the TAC alleges that Cordis twice issued press releases promoting the effectiveness of its biliary stents in treating vascular disease.

Finally, the TAC contains numerous allegations regarding the Defendants' placement of advertisements in vascular journals to promote their biliary stents. The TAC identifies the specific journals and dates for three ads announcing the launch of Boston Scientific devices, four announcing Cordis products, and one announcing an Abbott product. Colquitt alleges that in contrast to the Defendants' advertising in vascular journals, the Defendants did "little to no" advertising of their biliary stents in publications directed to biliary clinicians. (TAC ¶ 180.)

3. Inducement of Claims for Reimbursement

Colquitt claims that the Defendants not only induced the off-label use of their biliary stents, but also induced physicians to seek reimbursement for that off-label use from federal payer programs. Professional services rendered by physicians are reimbursed by Medicare and Medicaid on a fee-for-service basis, using a system of Current Procedural Terminology ("CPT") codes. (Pl.'s Br. Opp'n 76.) There are four CPT codes associated with the placement of a

vascular stent. Colquitt alleges that the Defendants distributed to healthcare providers "reimbursement guides" containing instructions to use these four CPT codes when seeking reimbursement from Medicare and Medicaid for off-label placement of biliary stents in the vascular system. Colquitt claims that these guides did not disclose that the safety and effectiveness of using biliary stents in the vasculature was not established, and that the Defendants expressly, or impliedly, made false representations that the biliary stents would safely and effectively treat peripheral vascular disease.

Specifically, Colquitt alleges that Cordis prepared and disseminated to healthcare providers "Endovascular Payment and Reimbursement Guidelines" that purported to "assist [healthcare providers] in obtaining the appropriate hospital reimbursement for services rendered to patients having peripheral vascular disease." (TAC ¶ 195.) The Guidelines allegedly instructed physicians to use the CPT code for "transcatheter placement of intravascular stent (non-coronary)." (*Id.*) Colquitt further alleges that Cordis gave healthcare providers a catalog that identified its biliary stent systems as endovascular stents.

The TAC contains similar allegations regarding Abbott. Colquitt alleges that Abbott also distributed guides to healthcare providers, instructing them to use vascular-procedure CPT codes to obtain reimbursement for procedures using Abbott's stents, when Abbott had no stents that were FDA-approved for such procedures. The TAC contains no similar allegations specific to Boston Scientific, although some of Colquitt's allegations apply generally to "Defendants."

4. Kickback Allegations

The TAC also alleges that the Defendants paid certain healthcare providers kickbacks, to induce them to use the Defendants' biliary stents for off-label, vascular applications. Colquitt names certain hospitals to which Abbott allegedly granted rebates based on specific market share criteria, such as the percentage of the hospital's stents purchased from Abbott in a given quarter.

According to Colquitt, these percentages were so high that the small number of biliary stenting procedures performed by the providers would not justify them. Colquitt further alleges that Abbott paid for dinners for physicians to encourage them to refer patients to vascular specialists who used Abbott's stents.

As for the other Defendants, the TAC alleges that Cordis and Boston Scientific offered similar discounts on their stents, and paid an identified doctor, $80,000 for a vascular fellowship program, and $15,000 per peripheral training course he taught, to induce him to recommend and prescribe off-label use of their biliary stents.

C. Colquitt's Legal Theories

The FCA creates liability for any person who knowingly presents, or causes to be presented to the United States government, a false or fraudulent claim for payment or approval. 31 U.S.C. § 3729(a)(1) (2006). Claims under this provision are often termed "presentment claims," because they require proof that a false claim was presented to the government. The FCA also creates liability for any person who knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim. 31 U.S.C. § 3729(a)(1)(B) (Supp. III 2009).[2] Claims seeking to impose this type of liability are often referred to as "false-statement claims."

[2] Section 2729(a) of the FCA was amended in 2009. Fraud Enforcement & Recovery Act (FERA) of 2009, Pub. L. No. 111-21, § 4(a)(1), 123 Stat. 1617, 1621–22 (2009). Although FERA's amendments generally apply only to conduct on or after May 20, 2009, the changes to former § 3729(a)(2) apply retroactively to "all claims under the [FCA] pending on or after [June 7, 2008]." *Id.* § 4(f)(1). The Fifth Circuit interpreted this retroactivity provision to mean that the amended version of former § 3729(a)(2) applies in cases where the plaintiff's complaint was pending on or after June 7, 2008. *United States ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 267 n.1 (5th Cir. 2010). The Relator's TAC was pending after June 7, 2008, and the Court therefore applies the post-FERA version of former § 3729(a)(2).

Relying on the factual allegations summarized above, Colquitt asserts three theories of liability under the FCA. First, Colquitt asserts a fraudulent inducement theory of liability. This theory is properly characterized as a false-statement claim. Colquitt alleges that the Defendants' false statements to the FDA were material to false or fraudulent claims because those statements induced the government to clear the stents for introduction into interstate commerce, which is a prerequisite for reimbursement by the healthcare payer programs. Importantly, the underlying principle of the fraudulent inducement theory is that the initial fraud taints all future claims presented, whether or not they are literally false or fraudulent. *United States ex rel. Longhi v. Lithium Power Techs., Inc.*, 575 F.3d 458, 467–68 (5th Cir. 2009). Thus, in the classic example of a government contractor who procures a government contract by fraud, the fact that the contract itself was procured by fraud creates FCA liability for every claim for payment made under the contract, even if all of the claims the contractor makes are otherwise free of falsity or fraud. *United States ex rel. Laird v. Lockheed Martin Eng'g & Sci. Servs. Co. (Laird II)*, 491 F.3d 254, 259 (5th Cir. 2007) (citing *United States ex rel. Marcus v. Hess*, 317 U.S. 537 (1943)).

Colquitt's second theory of liability, which he terms his "off-label promotion theory," focuses on the Defendants' alleged activities in promoting off-label use of their biliary stents in the vascular system. Colquitt frames this theory as both a presentment claim and a false-statement claim. As a presentment claim, Colquitt alleges that the Defendants knowingly caused the submission of false or fraudulent claims by promoting their stents for off-label use by healthcare providers, who in turn used the stents off-label and sought reimbursement from the government for such use. According to Colquitt, the requests for reimbursement were false claims because the off-label use caused by the Defendants' promotional activities was not properly reimbursable. Additionally, Colquitt alleges that some of the Defendants' promotional

activities—the distribution of reimbursement guides in particular—misrepresented to healthcare providers that the Defendants' biliary stents were approved for vascular use and that such use was thus reimbursable by the government. Thus, under the rubric of false-statement liability, Colquitt alleges that these promotional activities constituted knowingly false statements that were material to false or fraudulent claims.

Colquitt's third theory of liability relies on the federal Anti-Kickback Statute (AKS). Colquitt alleges that the Defendants paid kickbacks to healthcare providers in exchange for those providers using the Defendants' biliary stents off-label. According to Colquitt, these providers falsely certified their compliance with the AKS to be eligible to receive reimbursement from Medicare and other healthcare payer programs, and therefore, claims for reimbursement made by these providers were false or fraudulent.

D. Procedural Posture

Colquitt initiated this suit on September 26, 2006, by filing the Complaint ex parte and under seal pursuant to 31 U.S.C. § 3730(b)(2). On motion of the Government, the Court extended the time for the Government to elect to intervene, giving the Government until January 21, 2008 to do so. On October 25, 2007, Colquitt filed his First Amended Complaint, and on December 5, 2007, after obtaining leave of Court, filed his Second Amended Complaint. Through a series of extensions sought by the Government and granted by the Court, the case remained under seal until January 11, 2010, while the Government considered whether to intervene. On January 11, the Government filed notice that it was not intervening at that time. Shortly thereafter, the States of Florida, Louisiana, Tennessee, California, Illinois,[3] and Texas[4]

[3] The Court does not have on file a Notice of Election to Decline Intervention from the State of Illinois, but assumes that Relator Kevin N. Colquitt's Certificate of Service for a Certain Document [Docket Entry #88], which certifies service of such a Notice, is correct.

also filed notices of their decisions not to intervene. On May 6, 2010, after receiving leave of Court, Colquitt filed the TAC, which is the subject of the Motions to Dismiss before the Court.

II. ANALYSIS

The Defendants' Motions to Dismiss attack Colquitt's federal FCA claims on essentially two grounds: (1) lack of subject matter jurisdiction under the FCA's public disclosure bar; and (2) failure to state a claim. The Defendants further argue that Colquitt's claims under state false claims statutes should be dismissed, both on jurisdictional grounds and on the merits. Both the Government and the State of Texas have filed Statements of Interest opposing the Defendants' Motions.

A. Lack of Subject Matter Jurisdiction—Public Disclosure Bar

Congress has limited the subject matter jurisdiction of federal courts over qui tam actions under the FCA:

> No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

31 U.S.C. § 3730(e)(4)(A). An "original source" is "an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information." *Id.* Thus, if this qui tam action is based upon publicly disclosed allegations or transactions, the Court has subject matter jurisdiction only if Colquitt has direct and independent knowledge of the information on which his allegations are based.

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[4] Although the Motion to Dismiss filed by Cordis states that the State of Texas has not filed a notice declining to intervene, the Court has on file a Notice of Non-Intervention from the State of Texas [Docket Entry #59].

The Supreme Court held in *Rockwell International Corp. v. United States*, 549 U.S. 457 (2007), that when determining if a relator is an original source of the "information on which the allegations are based," the "allegations" courts are to examine are those in the relator's complaint, *as amended*. *Id.* at 473. Noting that an amended complaint that withdraws jurisdiction-giving allegations will defeat jurisdiction unless those allegations are replaced by others that establish jurisdiction, the Court stated that "when a plaintiff files a complaint in federal court and then voluntarily amends the complaint, courts look to the amended complaint to determine jurisdiction." *Id.* at 473–74.

However, on August 5, 2011, as this Court was finalizing and preparing to issue this Opinion, the Fifth Circuit decided *United States ex rel. Jamison v. McKesson Corp.*, 649 F.3d 322 (5th Cir. 2011). In *Jamison*, the Fifth Circuit held that the district court lacked jurisdiction under the FCA's public disclosure bar because the allegations in the relator's *original* complaint were based on publicly disclosed allegations or transactions. *Id.* at 330–32. Relying on *Rockwell*, the relator argued that the court should look instead to his amended complaint to determine the scope of his claims and whether they were based on publicly disclosed allegations or transactions. *Id.* at 327–28. Rejecting that argument, the Fifth Circuit interpreted *Rockwell* as holding only that "the court can lose jurisdiction over an otherwise sound action if the relator amends his complaint to remove the basis of the jurisdiction." *Id.* at 328. As the Fifth Circuit interpreted it, *Rockwell* does "not hold . . . that the original complaint is irrelevant to jurisdiction," nor does it "speak to the question whether a relator can use an amended complaint to establish jurisdiction when the original complaint is lacking." *Id.* Relying on "the longstanding rule that the amendment process cannot 'be used to create jurisdiction retroactively where it did not previously exist,'" the court concluded that if the relator's original complaint did

not establish jurisdiction, the amended complaint could not save it. *Id.* (quoting *Aetna Cas. & Sur. Co. v. Hillman*, 796 F.2d 770, 775 (5th Cir. 1986)).

Here, the Defendants have directed their jurisdictional arguments to the TAC, rather than Colquitt's original Complaint. In other words, the Defendants' Motions to Dismiss contend that the allegations in the TAC are such that this Court lacks jurisdiction, regardless of whether the original Complaint fails to provide a basis for jurisdiction in the first instance. Nothing in either *Rockwell* or *Jamison* precludes this argument. To the extent that the allegations in the original Complaint generate jurisdictional impediments not present in the TAC, the Defendants are not precluded from later raising jurisdictional arguments based on the original Complaint, as such arguments are not resolved here and cannot be waived. At this juncture, the Court focuses only on the TAC, to which the Motions to Dismiss are directed, to analyze whether it has jurisdiction under the FCA's public disclosure bar.

1. Alleged Public Disclosures

The Defendants have filed a Joint Defense Appendix containing 929 pages of documents that allegedly demonstrate the public disclosure of the allegations or transactions on which Colquitt's claims are based. (Joint Defense Appendix (JDA), ECF No. 114.) The forty-nine documents in the Appendix fall into three basic categories: (1) 510(k) summaries filed with the FDA; (2) articles published in medical journals and trade publications; and (3) letters sent to the Defendants from the FDA. The Defendants also rely on advertisements for their biliary stents published in medical journals and trade publications that are described in the TAC.

Regarding the first category, the Defendants argue that the 510(k) summaries publicly disclose the misstatements Colquitt alleges were made to the FDA during the clearance process for their biliary stents. These summaries are prepared and submitted by device manufacturers as part of the 510(k) clearance process, and are later made public by the FDA. 21 C.F.R. §

807.95(d) (2010). The 510(k) summaries contain a variety of information, including "the significant physical and performance characteristics of the device, such as device design, material used, and physical properties." *Id.* § 807.92(a)(4). Although the Joint Defense Appendix contains copies of only three 510(k) summaries, all of which relate to stents manufactured by Abbott, federal regulations require that these summaries be submitted as part of a manufacturer's 510(k) premarket notification submission to obtain Class II clearance. Colquitt has alleged that the Defendants obtained Class II certification for all of the stents underlying his claims; therefore, the Court can and does assume, and Colquitt does not dispute, that similar summaries were submitted and made public by the FDA for each of the Defendants' biliary stents.

Various articles published in medical journals and trade publications make up the second type of evidence provided by the Defendants. Some of these are scholarly articles published in medical journals, and others are non-scholarly articles published in trade journals focused on vascular medicine or on medical device regulation. For the most part, the Defendants cite these articles to argue that off-label use of biliary stents has been widely reported and was known to the public before Colquitt filed this suit.

The third type of evidence the Defendants rely on consists of two letters from the FDA. One of these letters is a "warning letter" sent to Cordis by the FDA in April 1999. An FDA warning letter "is a correspondence that notifies regulated industry about violations that [the] FDA has documented during its inspections or investigations." (Pl.'s Br. Opp'n App. 7.) The April 1999 warning letter sent to Cordis involved an advertisement placed for Cordis's S.M.A.R.T. stent, which was cleared only for biliary use. (JDA 392.) The ad in question appeared in an issue of *Endovascular Surgery*, an interdisciplinary journal for vascular

specialists, and referred to the S.M.A.R.T. stent as being from "Cordis Endovascular." (*Id.*) The FDA warning letter states that "the ad makes an implied claim for vascular use for the stent because it appears in a journal intended for vascular specialists." (*Id.*) The letter also states that the implied claim for vascular use demonstrated the device was not intended for biliary use, as Cordis had stated during the clearance process, but was instead "a class III [vascular stent] for which there [was] not in effect an approved premarket approval application, as required by [the FDCA]." (*Id.*)

The other FDA letter that the Defendants rely on is known as an "untitled letter." An untitled letter "cites [regulatory] violations that do not meet the threshold of regulatory significance for a Warning Letter." Food and Drug Administration, *Regulatory Procedures Manual*, "Untitled Letters," § 4-2 (March 2010). The warning letter in this case was received by Abbott and Boston Scientific, as well as other biliary stent manufacturers, and outlines the FDA's concerns about off-label marketing of biliary stents for vascular uses. (JDA Exs. EE & FF.) The letter does not identify any particular manufacturer, instead stating generally, "[I]t has come to our attention that many expandable metal biliary stents continue to be marketed for vascular use." (JDA 404, 406.) The letter continues, "It is clear that many more of these stents are used in the vasculature, for which they are not indicated, than the biliary tree, for which they are indicated." (*Id.*) The letter also states that biliary stents are approved through the 510(k) process, rather than the premarket approval process required for vascular stents, and that many of the characteristics of recently cleared biliary stents "appear to be made to optimize performance in vasculature." (*Id.*) Among the characteristics mentioned in the letter are the dimensions of the stents and the length of the attached catheters.

In addition to the three types of evidence included in the Joint Defense Appendix, the Defendants rely on allegations in the TAC to argue that the public disclosure bar applies. The TAC alleges that the Defendants "routinely marketed their biliary stent systems for vascular use in vascular journals," and identifies several specific advertisements admittedly placed by each of the Defendants in such journals. (*See* TAC ¶¶ 169–80.) The Defendants argue that these allegations, if true, publicly disclose their alleged off-label marketing efforts.

2. Legal Standard

Usually, when a Court is confronted with a motion to dismiss for lack of subject matter jurisdiction, it "may evaluate '(1) the complaint alone; (2) the complaint supplemented by the undisputed facts in the record; or (3) the complaint supplemented by undisputed facts plus the court's resolution of disputed facts.'" *United States ex rel. Barrett v. Johnson Controls, Inc.*, No. 3:01-cv-1641-M, 2003 WL 21500400, at *3 (N.D. Tex. Apr. 9, 2003) (Lynn, J.) (quoting *Williamson v. Tucker*, 645 F.2d 404, 413 (5th Cir. 1981)). However, the Fifth Circuit has held that a challenge to jurisdiction under the public disclosure bar is "'necessarily intertwined with the merits' [sic] and is, therefore, properly treated as a motion for summary judgment." *Jamison*, 649 F.3d at 326 (quoting *United States ex rel. Reagan v. E. Tex. Med. Cent. Reg'l Healthcare Sys.*, 384 F.3d 168, 173–74 (5th Cir. 2004)). Therefore, in deciding whether the Court has jurisdiction, the Court must view the evidence and inferences drawn from that evidence in the light most favorable to the non-moving party, and find the absence of jurisdiction only if there is no genuine issue of material fact. *Reagan*, 384 F.3d at 173–74. In the context of an FCA claim, a defendant asserting a jurisdictional argument under the public disclosure bar must "first point to documents plausibly containing allegations or transactions on which [the relator's] complaint is based." *Jamison*, 649 F.3d at 327. "Then, to survive summary judgment, [the relator] must produce evidence sufficient to show that there is a genuine issue of material fact as to whether

his action was based on those disclosures," or that he is an original source of the complaint's allegations. *Id.* As with any summary judgment motion, in deciding jurisdiction under the public disclosure bar, the Court may not weigh the evidence or evaluate the credibility of witnesses, and all justifiable inferences will be made in the non-moving party's favor. *Id.*

Here, Colquitt does not challenge any of the facts asserted by the Defendants in support of their jurisdictional-bar argument; that is, Colquitt does not dispute the authenticity of the evidence in the Joint Defense Appendix. Rather, Colquitt argues that the evidence is insufficient to trigger the jurisdictional bar. In other words, Colquitt argues that Defendants' evidence does not plausibly disclose allegations or transactions on which the TAC is based. Similarly, he argues that none of the evidence offered by the Defendants speaks to the truth of the factual allegations Colquitt relies on in arguing that he is an original source.[5] Defendants argue that those allegations, even if true, are insufficient to confer original source status on Colquitt. Therefore, the Court's task here is to determine whether, drawing all justifiable inferences in Colquitt's favor, the evidence in the Joint Defense Appendix and the assumed-as-true allegations in the TAC show as a matter of law that Colquitt's claims are based on publicly disclosed allegations and transactions, and if so, whether Colquitt was as an original source of the allegations in the TAC.

3. Analysis

The Fifth Circuit has adopted the following three-part test for analyzing whether a court has subject matter jurisdiction under the public disclosure bar: "(1) whether there has been a 'public disclosure' of allegations or transactions, (2) whether the qui tam action is 'based upon' such publicly disclosed allegations, and (3) if so, whether the relator is the 'original source' of

[5] Attached to Colquitt's Response is an affidavit swearing to all of the TAC's allegations regarding events he witnessed as an Abbott employee.

the information." *United States ex rel. Reagan v. E. Tex. Med. Cent. Reg'l Healthcare Sys.*, 384 F.3d 168, 173–74 (5th Cir. 2004); *accord United States ex rel. Barrett v. Johnson Controls, Inc.*, No. 3:01-cv-1641-M, 2003 WL 21500400, at *4 (N.D. Tex. Apr. 9, 2003) (Lynn, J.).

a. Public disclosure of allegations or transactions

The first element of the jurisdictional bar asks whether there has been a public disclosure of allegations or transactions. As this Court has recognized, the plain language of the statute suggests three sub-parts to this element: (1) public disclosure; (2) in a particular form specified in the statute; and (3) of allegations or transactions. *Barrett*, 2003 WL 21500400, at *4. The Defendants argue that the documents in the Joint Defense Appendix satisfy these requirements. Because only an analysis of the second and third sub-parts is necessary to the Court's conclusion, the Court does not discuss the first sub-part.[6]

i. Statutorily specified form

The public disclosure bar is triggered only by public disclosures "in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media." 31 U.S.C. § 3730(e)(4)(A). Colquitt argues that the 510(k) summaries and the stent advertisements are not in one of these specified forms.[7] The Defendants respond that the 510(k) summaries are "administrative reports" and that the stent advertisements are "from the news media."

[6] Colquitt challenges just one of the documents under the first sub-part—the untitled letter from the FDA. However, as explained further below, the Court concludes that the untitled letter, even if public, does not disclose allegations or transactions, and therefore, the Court need not decide whether the untitled letter is "public." Since Colquitt does not contend that any of the other documents are not public, the Court proceeds to examine the second and third sub-parts of the public disclosure bar's first element.

[7] Colquitt also contends that two internet-based articles included in the Joint Defense Exhibit are not in one of the forms specified in the statute. (*See* JDA Exs. N, U.) However, none of the Defendants cite Exhibit U in their briefing, and only Cordis cites Exhibit N, which is duplicative

The Defendants argue that the 510(k) summaries constitute administrative reports. In *United States ex rel. Reagan v. East Texas Medical Center Regional Health Care System*, the Fifth Circuit held that the contents of an agency's response to a Freedom of Information Act ("FOIA") request is an administrative report because "the response (1) 'constitute[s] official government action'—i.e., it is administrative—and (2) 'provides information and notification regarding the results of the agency's search for the requested documents.'—i.e., it is a report." *Reagan*, 384 F.3d 168, 176 (5th Cir. 2004) (quoting *United States ex rel. Mistick v. Hous. Auth.*, 186 F.3d 376, 383 (3d Cir. 1999)). The Supreme Court recently confirmed this view in *Schindler Elevator Corp. v. United States ex rel. Kirk*, defining a report as "'something that gives information' or a 'notification,'" and the Court thus holds that a response to a FOIA request is an administrative report under the FCA. 131 S. Ct. 1885, 1891 (2011). Thus, *Reagan* and *Schindler* suggest that, to be an administrative report within the meaning of the FCA, a document must (1) constitute official government action and (2) provide information.

The 510(k) summaries are published by a government agency. *See* 21 C.F.R. § 807.95 (stating that "*FDA* shall make a 510(k) summary . . . available to the public" (emphasis added)). Furthermore, they provide information in the government's possession that is collected as part of a government administrative procedure.

Colquitt argues, however, that the summaries are not administrative reports because they are prepared by the manufacturers, and are only *released* by the FDA. The focus of the Fifth Circuit's analysis in *Reagan* is not on who created the information, but on the fact that the information is made public through official government action. Whether the information is collected from medical device manufacturers or some other third party, the important factor is

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of other documents that are in one of the proper forms. Thus, the Court does not consider Cordis's arguments regarding Exhibit N.

that it is released by the FDA as part of its administrative clearance process for medical devices. That the 510(k) summaries are initially provided to the FDA by medical device manufacturers, then, does not detract from their status as administrative reports under the FCA.

Colquitt also argues that the stent advertisements described in the TAC cannot trigger the public disclosure bar because paid advertisements in specialty journals do not fall into any of the FCA's statutorily identified categories of disclosures. The Defendants' contention that the ads are disclosures "from the news media" presents two questions: (1) whether specialty medical journals such as *Endovascular Today* are "news media" under the FCA; and (2) if so, whether paid advertisements in those publications are "from" the news media.

The Fifth Circuit has not set out a specific test for determining what constitutes news media, but at least two courts have held that scholarly or technical periodicals constitute news media. *United States ex rel. Radcliffe v. Purdue Pharma L.P.*, 582 F. Supp. 2d 766, 770 (W.D. Va. 2008); *United States ex rel. Alcohol Found., Inc. v. Kalmanovitz Charitable Found.*, 186 F. Supp. 2d 458, 463 (S.D.N.Y. 2002), *aff'd*, 53 Fed. App'x 153 (2d Cir. 2002). Both district courts held that "[t]he term 'news media' includes scholarly, scientific, and technical periodicals, including trade journals, because, like newspapers, those sources disseminate information to the public in a periodic manner." *Radcliffe*, 582 F. Supp. 2d at 770 (citing *Alcohol Found.*, 186 F. Supp. 2d at 463).

Although this Court is not inclined to conclude that in the age of basement blogging and ease of publishing, *any* medium that disseminates information to the public in a periodic manner is part of the "news media," the Court agrees that "[n]o principle of statutory construction or public policy would compel a cramped reading of the term 'news media' or the imposition of a judicially created limit of 'news media' to encompass *only* the newspaper context." *Alcohol*

Found., 186 F. Supp. 2d at 463 (emphasis added). The Court agrees that scholarly periodicals are sufficiently similar to newspapers to constitute news media.

However, whether advertisements in such periodicals are, like articles, "from" the news media presents a much closer question. Nevertheless, the Court concludes that, like articles, advertisements in periodicals are "from the news media." In two recent opinions interpreting the public disclosure bar, the Supreme Court of the United States has emphasized the "broad scope" of the statutorily specified forms of disclosure generally, and "news media" in particular. *Schindler Elevator Corp. v. United States ex rel. Kirk*, 131 S. Ct. 1885, 1887 (2011); *Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 130 S. Ct. 1396, 1404 (2010) ("The 'news media' referenced in Category 3 plainly have a broader sweep."). The only other case this Court has located which has addressed this issue found no distinction between advertisements and articles, holding that the public disclosure bar requires only that the information be "from" the news media; "[i]t does not require that the information appear in any particular form or section of a [publication]." *United States ex rel. Ondis v. City of Woonsocket, R.I.*, 582 F. Supp. 2d 212, 217 (D.R.I. 2008). A person who picks up a copy of *Endovascular Today* has just as much access to the advertisements as the edited content. Thus, the advertisements that are described in the TAC are "from the news media," within the meaning of the FCA's public disclosure bar.

ii. Allegations or transactions

Having concluded that the 510(k) summaries and the stent advertisements are within one of the statutorily specified forms, the Court turns next to whether the Defendants' evidence discloses "allegations or transactions."

As this Court has stated before, "the key for determining whether allegations or transactions have been publicly disclosed is whether 'the critical elements of the fraudulent

transaction were in the public domain.'" *United States ex rel. Heath v. Dall./Fort Worth Int'l Airport Bd.*, No. 3:99-cv-100-M, 2004 WL 1197483, at *5 (N.D. Tex. May 28, 2004) (Lynn, J.) (quoting *United States ex rel. Springfield Terminal Ry. V. Quinn*, 14 F.3d 645, 654 (D.C. Cir. 1994)). "The critical elements have been sufficiently disclosed if the disclosures, taken together, would enable the government to draw an inference of fraud." *Id.* As the D.C. Circuit explained in *Springfield Terminal*, "if $X + Y = Z$, Z represents the *allegation* of fraud and X and Y represent its essential elements." *Springfield Terminal*, 14 F.3d at 654. "In order to disclose the fraudulent *transaction* publicly, the combination of X and Y must be revealed, from which readers or listeners may infer Z, i.e., the conclusion that fraud has been committed." *Id.* Furthermore, the FCA is concerned with fraud *on the government*, and thus, public disclosure of a predicate allegation of fraud—one that does not by itself lead to an inference of a false or fraudulent claim on the government—does not disclose "allegations or transactions" for purposes of the FCA. *See United States ex rel. Smart v. Christus Health*, 626 F. Supp. 2d 647, 653–54 (S.D. Tex. 2009).

Here, the Defendants argue that the alleged false statements to the FDA and their alleged off-label promotion have been publicly disclosed, and that such disclosure constitutes allegations or transactions of fraud from which the government could draw an inference of FCA liability.

(1) False statements to FDA

The 510(k) summaries disclose the Defendants' alleged misstatements to the FDA because they disclose the alleged false statements and the alleged true state of affairs. First, the 510(k) summaries unambiguously contain the alleged false statements because the FDA requires that each summary contain "[a] statement of the intended use of the device . . . including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate." 21 C.F.R. § 807.92(a)(5). Second, the summaries also contain information

that, according to the TAC, demonstrates that those statements were false when made: the sizes and dimensions of the stents.

The TAC relies heavily on the sizes of the stents in alleging that the statements of their intended use were false. Specifically, Exhibit 1 to the TAC is a table that lists the stents manufactured by each Defendant. The chart has columns for "Manufacturer," "Stent," "Balloon Expandable / Self Expanding," "Wire Size," "Stent Diameter," "Stent Length," "Shaft Length," and "Biliary Use Probability." Commenting on Exhibit 1, the TAC states,

> Based on accepted sizing for the biliary tree and vascular anatomy, as compared to the length and diameter of Defendants' stents and the length of the premounted delivery catheters, Exhibit 1 demonstrates that more than 99 percent of Defendants' devices are too large or too small to fit the biliary tree and/or are marketed and sold to healthcare providers premounted on delivery catheters that are incorrectly sized to place the stents on the biliary tree in compliance with medical standards and CGMP requirements.

(TAC ¶ 72.) Furthermore, the TAC states that "[t]he size and design of the stents and delivery catheters, which are sold only as premounted systems, are intended for placement in the blood-filled, pressurized vascular system, not the bloodless bile duct." (*Id.* ¶ 11.)

The same size information on which the TAC relies is disclosed in the 510(k) summaries. FDA regulations require that 510(k) summaries include "[a] description of the device . . . , including . . . the significant physical and performance characteristics of the device, such as device design, material used, and physical properties." 21 C.F.R. § 807.92(a)(4). Thus, not only do the summaries disclose the alleged false statements—that the stents were intended for biliary use—but they also disclose the alleged true state of affairs—that the stents were actually intended for vascular use—because the summaries disclose size information that, according to Colquitt, "demonstrates that more than 99 percent of Defendants' devices are too large or too small to fit the biliary."

Colquitt responds that the Defendants "cannot have it both ways," arguing that the Defendants cannot maintain that the stents' dimensions do not indicate the falsity of their stated intended use and simultaneously contend that the dimensions publicly disclose that alleged falsity:

> Abbott "denies that the design characteristics of these biliary stents are actually probative of intent to promote them for off-label use." This statement eviscerates Abbott's X + Y = Z equation by removing a public "Y". Abbott tells the Court that the falsehood (X) is "that the stents were intended for biliary use" and the publicly disclosed truth (Y) is "the configurations" and "stent system design factors" allegedly disclosed in 510(k) summaries. Irreconcilably, Abbott then denies that Y (configuration and design) is "probative" in contradicting X (intended use). If Abbott denies that Y is probative in disproving X, then according to Abbott the Government had no reason to conclude Z, that Abbott was committing fraud.

(Pl.'s Br. Opp'n 35–36 (citations omitted).)

The Court does not share Colquitt's interpretation of the Defendants' argument. The Defendants can deny that the stent dimensions make the stents inappropriate for biliary use, while at the same time arguing that even if the dimensions did, as Colquitt alleges, make them appropriate only for vascular use, those dimensions were publicly disclosed in administrative reports. It is the posture of almost every motion to dismiss that the defendant denies the alleged facts, but argues that those facts, even if true, do not create liability. Although the public disclosure bar highlights the unusual rhetorical dynamics of that posture, it does not make the Defendants' argument inappropriate or unfair.

Colquitt further argues that the Defendants overstate the TAC's reliance on the size of the stents, contending that size is only one piece of evidence of the Defendants' false statements. Specifically, Colquitt urges that "the fraud on the FDA allegation is based on the design sizes *and* the intent to promote and market off-label as described in the TAC—not design alone." (Pl.'s Br. Opp'n 36.) That the TAC relies on more than one piece of evidence to allege the

falsity of the Defendants' statements does not mean that one piece of evidence alone is insufficient to publicly disclose that falsity. Colquitt has alleged that, due to their size, 99% of the stents listed in the TAC are too large or too small to be used as biliary stents. Assumed as true, that allegation is sufficient on its own to support an inference that the Defendants did not intend to market their stents for biliary use, regardless of whether other allegations could also support such an inference.

Furthermore, the information in the 510(k) summaries is sufficient on its own to disclose "allegations or transactions," because it allows the government to draw an inference of FCA liability. According to Colquitt, the Defendants' alleged misrepresentations to the FDA, without more, support an FCA claim under a theory of fraudulent inducement. Without deciding whether Colquitt's fraudulent inducement theory is legally sound, the Court can conclude that, if it is, the information in the 510(k) summaries supports an inference of liability pursuant to that theory.

(2) Evidence of off-label promotion

The Defendants point to a variety of evidence to argue that information regarding off-label promotion was publicly disclosed and that such information constitutes "allegations or transactions" sufficient to trigger the public disclosure bar.

First, the Defendants cite several documents, including reports in medical journals and other media, demonstrating disclosure of off-label *use* of biliary stents. (*E.g.*, JDA Exs. A, C–D, I–L.) Abbott argues that "the pervasive (and exhaustively documented) off-label *use* of biliary stents from the late 1990s onward was more than sufficient to put the government on notice of the likelihood of the off-label *promotion* alleged by Relator." (Abbott Reply 3.) The Court does not agree. These documents do not disclose allegations or transactions, alone or in combination with the 510(k) summaries. Colquitt and the Defendants agree that off-label use of biliary stents

is lawful, so public disclosure of such use, even if widespread, does not disclose a fraudulent transaction or allegation of fraud.

The Defendants also argue that their alleged off-label promotion efforts were publicly disclosed in the FDA warning letter sent to Cordis in April 1999. (JDA Ex. BB.) The FDA's warning letter clearly contains an allegation of a regulatory violation concerning Cordis's S.M.A.R.T. stent, because it plainly alleges that Cordis violated FDA regulations by promoting the device for an off-label use. These allegations are sufficient to raise an inference of FCA liability because, according to Colquitt, off-label use of the Defendants' stents in the vascular system is not covered by government payer programs.

Colquitt argues that fraud cannot be inferred from the warning letter because Cordis responded to the letter by publicly stating that the challenged advertisement was placed by accident. The jurisdictional bar would essentially be read out of the statute if it never applied to allegations of fraud that were quickly followed by denials from the alleged wrongdoers. Thus, despite Cordis's public denial, the FDA warning letter publicly disclosed allegations of off-label marketing and promotion of Cordis's S.M.A.R.T. stent, which are sufficient to support an inference of FCA liability.

The Defendants next argue that the untitled letter sent by the FDA to biliary stent manufacturers in October 2002 discloses allegations of off-label promotion. However, the untitled letter does not disclose allegations or transactions because it does not identify any of the Defendants. In order to constitute allegations or transactions, a disclosure or group of disclosures must allow the Government to identify the defendant as the alleged wrongdoer. *Jamison,* 649 F.3d 322 at 329; *see United States ex rel. Gear v. Emergency Med. Assoc. of Ill., Inc.,* 436 F.3d 726, 729 (7th Cir. 2006). This does not mean that the wrongdoer must necessarily

be identified by name. *See id.* For instance, if publicly available information discloses that every member of an identifiable group or industry committed the alleged wrongdoing, and the defendant is a member of that group, then the disclosures constitute allegations or transactions regarding the defendant. *See Gear*, 436 F.3d at 729. On the other hand, information that discloses alleged wrongdoing by only a portion of a group or industry does not disclose allegations or transactions concerning every member of that group or industry. *See United States ex. rel. Baltazar v. Warden et al.*, 635 F.3d 866, 869 (7th Cir. 2011).

In arguing that the untitled letter discloses allegations against them, the Defendants rely on the Seventh Circuit's reasoning in *United States ex rel. Gear v. Emergency Medical Associates of Illinois, Inc.*, 436 F.3d 726 (7th Cir. 2006). *Gear* holds that "[i]ndustry-wide public disclosures bar qui tam actions against any defendant who is directly identifiable from the public disclosures." *Id.* at 729. In that case, the GAO issued a report stating that the University of Pennsylvania agreed to pay $30 million to settle allegations of improper billing for services provided by medical residents. *Id.* at 728. The Department of Health and Human Services then instituted a nationwide initiative to investigate how the nation's 125 medical schools, including Midwestern University, the focus of the relator's suit, billed Medicare for services provided by residents. *Id.* Several articles appeared in publications such as *American Medical News* and *Physician's Weekly* about the congressional interest in the audits. *Id.* at 729. Approximately two years after the investigation began, the relator, a resident at Midwestern, filed suit. The Seventh Circuit upheld the district court's dismissal of the suit, apparently unpersuaded by the relator's argument that the disclosures did not expose transactions from which the government could infer fraudulent billing by any particular school: "The disclosures at issue here were of industry-wide

abuses and investigations. Defendants were implicated. Industry-wide public disclosures bar qui tam actions against any defendant who is directly identifiable from the public disclosures." *Id.*

However, the Seventh Circuit has since made clear that *Gear*, properly interpreted, stands for the proposition that industry-wide allegations of fraud identify industry members only when they implicate every member of the industry: "Defendants rely heavily on *Gear*, but to say that a report identifying a *uniform* practice activates [the jurisdictional bar] does not imply anything about the effect of a report disclosing that some but not all of the firms use a practice." *United States ex. rel. Baltazar v. Warden et al.*, 635 F.3d 866, 869 (7th Cir. 2011). As the court in *Baltazar* further explained, "A statement such as 'half of all chiropractors' claims are bogus' does not reveal which half and therefore does not permit suit against any particular medical provider." *Id.* at 867–68.

Here, the untitled letter does not contain allegations against *all* manufacturers of biliary stents, but states that "*many* expandable metal biliary stents continue to be marketed for vascular use." (JDA 404, 406 (emphasis added).) Just like the example provided in *Baltazar*, the untitled letter does not disclose which biliary stent manufacturers are among the "many" marketing stents for vascular use. This is not a case like *Gear*, where the defendant is directly identifiable from industry-wide allegations. Therefore, the untitled letter sent to Cordis and Boston Scientific, among others, does not contain allegations or transactions triggering the FCA's public disclosure bar.

Nevertheless, allegations of off-label promotion by Abbott and Boston Scientific, as well as Cordis, were publicly disclosed by the advertisements described in the TAC. The advertisements, combined with the 510(k) summaries, disclose the critical elements of the allegation of off-label promotion: (1) that the Defendants advertised stents for vascular use, and

(2) that those stents were approved only for biliary use. Therefore, the advertisements disclose transactions raising the inference that the Defendants promoted the stents identified in the ads for off-label use in the vascular system.

iii. Conclusion—Public disclosure of allegations or transactions

In summary, the evidence in the Joint Defense Appendix and allegations in the TAC show that allegations of false statements to the FDA and of off-label promotion of the Defendants' biliary stents were publicly disclosed. The 510(k) summaries disclosed the critical elements of the Defendants' alleged false statements to the FDA regarding every stent that the TAC identifies as inappropriate for biliary use. The FDA warning letter to Cordis publicly disclosed allegations of off-label promotion of Cordis's S.M.A.R.T. stent, and the advertisements described in the TAC publicly disclosed the critical elements of off-label promotion allegations regarding the stents identified in those ads.

b. "Based upon" public disclosure of allegations

The second element of the jurisdictional bar asks whether Colquitt's case is "based upon the public disclosure of allegations or transactions." 31 U.S.C. § 3730. The "based upon" requirement is satisfied when the relator's suit is supported by the *allegations or transactions* that have been publicly disclosed; the suit need not be actually derived from the earlier public *disclosure* itself. *See United States ex rel. Smart v. Christus Health*, 626 F. Supp. 2d 647, 651 (S.D. Tex. 2009); *United States ex rel. Branch Consultants, L.L.C. v. Allstate Ins. Co.*, 668 F. Supp. 2d 780, 795–96 (E. D. La. 2009). Furthermore, "[a]n FCA qui tam action even partially based upon public allegations or transactions is nonetheless 'based upon' such allegations or transactions." *United States ex rel. Reagan v. E. Tex. Med. Ctr.*, 384 F.3d 168, 176 (5th Cir. 2004). "Stated another way, [a relator] cannot avoid the jurisdictional bar simply by adding other claims that are substantively identical to those previously disclosed." *Fed. Recovery*

Servs., Inc. v. Cresent City E.M.S., 72 F.3d 447, 451 (5th Cir. 1995). A claim is substantively identical when it merely alleges additional instances of fraud by a defendant when other instances of that defendant's fraudulent conduct have been publicly disclosed. *Id.*
The Defendants do not contend that Colquitt's anti-kickback theory is subject to the public disclosure bar, and thus, the Court analyzes only whether the fraudulent inducement and off-label promotion theories are based upon the publicly disclosed allegations.

Colquitt's fraudulent inducement theory is based upon the allegations disclosed in the 510(k) summaries. Although the TAC relies on non-public 510(k) notices as the source for the Defendants' alleged false statements and the stent size information, the publicly disclosed 510(k) summaries contain the same information. Because the TAC specifically cites this information, there is no doubt that the fraudulent inducement theory is supported by and, therefore, based upon, that information.

Similarly, Colquitt's off-label promotion theory is based on publicly disclosed allegations or transactions. The FDA warning letter disclosed allegations of off-label promotion regarding Cordis's S.M.A.R.T. stent, and the advertisements in the TAC, combined with the 510(k) summaries, disclosed the critical elements of the off-label promotion theory regarding the stents that were the subject of those ads. Clearly, Colquitt's claims regarding those stents are based upon those allegations and transactions.

Furthermore, although the warning letter and advertisements only expressly mention a handful of the Defendants' stents, Colquitt's off-label promotion claims regarding the Defendants' other stents are partially based upon the allegations disclosed, because the claims regarding the other stents are substantively identical to those concerning the stents named in the

advertisements and warning letter; that is, they allege new instances of the same fraudulent conduct already disclosed.

For those reasons, Colquitt's fraudulent inducement and off-label promotion claims are based upon publicly disclosed allegations and transactions. Thus, the Court has jurisdiction over those claims only if Colquitt is an "original source."

c. Original Source

Where an FCA action is based on publicly disclosed allegations or transactions, the court does not have jurisdiction unless the relator is "an original source of the information." 31 U.S.C. § 3730(e)(4)(A). An "original source" is "an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information." *Id.* The Supreme Court has held that "the information" of which a relator must have direct and independent knowledge is the information on which the allegations *in the complaint* are based, not the information on which the publicly disclosed allegations are based. *Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 472–73 (2007).

"In order to be 'direct,' the information must be firsthand knowledge." *United States ex rel. Fried v. W. Indep. Sch. Dist.*, 527 F.3d 439, 442–43 (5th Cir. 2008). In other words, the information must be "derived from the source without interruption or gained by the relator's own efforts rather than learned second-hand through the efforts of others." *United States ex rel. Laird v. Lockheed Martin Eng'g & Sci. Servs. Co. (Laird I)*, 336 F.3d 346, 355 (5th Cir. 2003), *overruled on other grounds by Rockwell*, 549 U.S. at 472–73. "In order to be 'independent,' the information known by the relator cannot depend or rely on the public disclosures." *United States ex rel. Fried*, 527 F.3d at 442–43.

Although a relator need not be the original source of every element of his claims, a relator must do more than apply his expertise to publicly disclosed information. *Id.* at 443. "'[S]econd hand information may not be converted into "direct independent knowledge" simply because the plaintiff discovered through investigation or experience what the public already knew.'" *Id.* (quoting *Reagan*, 384 F.3d at 179). "'Instead, the investigation or experience of the relator either must translate into some additional compelling fact, or must demonstrate a new and undisclosed relationship between disclosed facts, that puts a governmental agency on the trail of the fraud, where that fraud might otherwise go unnoticed.'" *Id.* (quoting *Reagan*, 384 F.3d at 179.)

Here, Colquitt argues that he is an original source of the information underlying both his fraudulent inducement claims and his off-label promotion claims. Colquitt argues that he is an original source of the fraudulent inducement claims because his expertise as a former sales manager allowed him to discover the relationship between the stent sizes and their intended use. Regarding the off-label promotion claims, Colquitt alleges that during his employment with Abbott he witnessed each of the Defendants promote their biliary stents for off-label uses.

Colquitt is not an original source of the fraudulent inducement claims because his knowledge is not independent of public disclosures. The dimensions and physical characteristics of the Defendants' biliary stents were available to any member of the public who wanted to find them, and they appeared on the same documents as the alleged false statements of the stents' intended use. Moreover, this information regarding the stents' dimensions is the very basis of Colquitt's fraudulent inducement claims, as shown by the TAC's claim that the "length and diameter of Defendants' stents and the length of the premounted delivery catheters . . . demonstrates that more than 99 percent of Defendants' devices are too large or too small to fit

the biliary tree." The information underlying Colquitt's fraudulent inducement claims depends and relies on public disclosures, and Colquitt therefore is not an independent source of that information. However, Colquitt is an original source of the information underlying his off-label promotion allegations because he has direct and independent knowledge of the information on which the TAC's off-label promotion allegations are based. Colquitt alleges that he was trained to and did promote Abbott's biliary stents for off-label use in the vascular system. According to the TAC, Colquitt was trained to teach physicians how to implant biliary stents in the vasculature, was required to solicit vascular surgeons to perform demonstrations of vascular off-label use, and received compensation incentives that rewarded off-label promotion. Colquitt further alleges that Abbott compiled packages of information for distribution to vascular specialists, which included "patient advisory letters" intended to be sent by the vascular specialists to their patients, warning them of the health risks of untreated peripheral artery disease. Additionally, Colquitt alleges that he observed sales representatives from Cordis and Boston Scientific promote their employers' biliary stents for vascular use at trade shows and manage their consignment inventories of biliary stents in the catheterization labs of various hospitals.

Colquitt's knowledge of this information is "independent" because the information was not publicly disclosed in the FDA warning letter to Cordis or the advertisements allegedly placed in vascular journals, and therefore, none of the information can be said to depend or rely on those public disclosures. This conclusion is not in conflict with the Court's determination that Colquitt's off-label promotion allegations were based on those disclosures. The Fifth Circuit's interpretation of the jurisdictional bar's "based upon" element makes clear that a relator's allegations are "based upon" public disclosures even when they are partly based on those

disclosures. *See Reagan*, 72 F.3d at 452. By the same token, a relator's information is that "on which the allegations [in the complaint] are based" even when the allegations are only partly based on that information. Thus, Colquitt's off-label promotion allegations are based on the disclosures *and* the information that Colquitt learned during his employment at Abbott.

Colquitt's knowledge is also "direct" because it was gained first hand from his experience as an Abbott employee. Colquitt not only observed Abbott's efforts to promote use of its biliary stents in the vascular system, but as an Abbott regional sales manager, he was an instrument of those efforts. It is difficult to imagine whose knowledge of those efforts could be more direct than that of an employee who carried them out. As for Cordis and Boston Scientific, Colquitt's knowledge of their off-label promotion efforts, although certainly not as thorough as his knowledge regarding Abbott, is still direct. According to the TAC, Colquitt learned through conversations with Cordis employees that Cordis trained its sales force to demonstrate implantation of biliary stents in the vascular system and also that he witnessed specific Cordis employees promoting biliary stents for off-label use.[8] Likewise, the TAC alleges that Colquitt witnessed Boston Scientific employees solicit off-label use of biliary stents for vascular purposes and saw Boston Scientific employees consign biliary stents for off-label use. These allegations sufficiently allege Colquitt's direct and independent knowledge of information on which his off-label promotion claims against all the Defendants are based.

Cordis and Boston Scientific argue that Colquitt's knowledge is not direct because his allegations recount information learned through hearsay and passive observation. In the Court's view, this argument misunderstands the requirement that direct knowledge be that which the

[8] This is similar to the example of direct knowledge described by the Fifth Circuit in *Laird*. *Laird I*, 336 F.3d at 356 (describing direct knowledge as firsthand communications and observations).

relator learned "firsthand." All that is required is that the information be "derived from the source without interruption or gained by the relator's own efforts rather than learned second-hand through the efforts of others." That Colquitt learned some of this information about the promotional efforts of Cordis and Boston Scientific through conversations with or observation of their employees does not make his knowledge second-hand. Even those who passively observe activity learn of that activity firsthand. If it were otherwise, an eyewitness to a car accident would only have "secondhand" knowledge of the crash, with the drivers and passengers possessing the only "firsthand" accounts. To adopt such a rule would unduly restrict the definition of "original source" to exclude many legitimate whistleblowers and allow only those who actually commit wrongdoing to benefit from sounding the alarm.

Likewise, the information a relator brings to the government need not be nonhearsay in order for the relator's knowledge to be direct. The Fifth Circuit, in describing cases where a relator's knowledge is direct, cited as an example a case in which a "nurse association [was found to have] had 'direct' knowledge that anesthesiologists routinely submitted fraudulent bills to Medicare . . . because the nurses had personal knowledge of the defendants' false claims by virtue of communications with the defendants themselves and had seen the hospital records containing false claims." *Laird I*, 336 F.3d at 356 (describing the holding in *Minn. Ass'n of Nurse Anesthetists v. Allina Health Sys. Corp.*, 276 F.3d 1032, 1050 (8th Cir. 2002)). The alleged conversations between Colquitt and sales representatives of Cordis and Boston Scientific, along with Colquitt's observations of those sales representatives' activities, demonstrate Colquitt's direct knowledge of information on which his off-label promotion claims are based.

The Defendants also suggest that even if Colquitt had direct and independent knowledge of their alleged promotional activities, he is not an original source because he did not have

similar knowledge of information underlying other elements of his off-label promotion theory—namely, the submission of false claims and the Defendant's intent to submit false claims. This argument ignores the distinction between (a) the *allegations or transactions* that must be disclosed in order to trigger the public disclosure bar, and (b) the *information* of which a relator must be an original source in order to overcome that bar. While there can be no disclosure of "allegations or transactions" unless all the critical elements of an alleged fraud are disclosed, a relator need not be the source of information underlying every element of *the complaint's* allegations in order to be an original source of information on which those allegations are based. *See Minn. Ass'n of Nurse Anesthetists*, 276 F.3d at 1050 (citing *United States ex rel. Springfield Terminal Ry. V. Quinn*, 14 F.3d 645, 656–57 (D.C. Cir. 1994)) ("[T]o qualify as an original source, a relator does not have to have personal knowledge of all elements of a cause of action."); *see also Reagan*, 384 F.3d at 179 (holding that the original source requirement is satisfied where a relator's investigation or experience "translate[s] into some *additional* compelling fact, or . . . demonstrate[s] a new and undisclosed relationship *between disclosed facts*." (emphasis added)). Colquitt's allegations, assumed as true, demonstrate that he had direct and independent knowledge of one critical element of his off-label promotion claims: the Defendant's off-label promotion of their biliary stents. More is not required.

The Defendants also argue that Colquitt is not an original source because he provided his information to the government after the public disclosure of the allegations and transactions underlying his off-label promotion claims. In so arguing, the Defendants urge this Court to impose a rule, adopted by at least two circuits, that requires a relator, to be an original source, to provide his information to the government before the alleged fraud is publicly disclosed. *See United States ex rel. McKenzie v. BellSouth Telecomms., Inc.*, 123 F.3d 935, 942–43 (6th Cir.

1997); *United States ex rel. Findley v. FPC-Boron Emps.' Club*, 105 F.3d 675, 691 (D.C. Cir. 1997). The Fifth Circuit has reserved decision on this issue, *Reagan*, 384 F.3d at 178 n.13, and more recently, other circuits have rejected it outright, *United States ex rel. Duxberry v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 28 (1st Cir. 2009); *Minn. Ass'n of Nurse Anesthetists v. Allina Health Sys. Corp.*, 276 F.3d 1032, 1050 (8th Cir. 2002).

Courts that have adopted the rule have relied on two primary justifications. First, they have reasoned that requiring relators to report fraud before it is publicly disclosed, even where the relator learns of the fraud independently of the disclosure, incentivizes early reporting by whistleblowers. *See McKenzie*, 123 F.3d at 943; *Findley*, 105 F.3d at 690–91. Second, they have found that the rule serves Congress's goal of preventing "parasitic qui tam actions in which relators, rather than bringing to light independently discovered information of fraud, simply feed off of previous disclosures of government fraud." *McKenzie*, 123 F.3d at 943 (citations and internal quotation marks omitted); *see Findley*, 105 F.3d at 690–91.

The First and Eighth Circuits have rejected this approach, concluding that it has no textual basis. *Duxberry*, 579 F.3d at 28; *Minn. Ass'n of Nurse Anesthetists*, 276 F.3d at 1051. Those courts have noted that the only temporal requirement of the original source element relates not to when public disclosure was made but to when the suit was filed: "'[O]riginal source means an individual who . . . has voluntarily provided the information to the Government before filing an action under this section which is based on the information." 31 U.S.C. § 3730. The First Circuit sharply criticized the emphasis placed on congressional intent by those courts that have adopted the rule urged by the Defendants:

> "It strikes us as especially inappropriate (not to mention frighteningly treacherous) to attempt, as these courts have done, to distill from such broad, generalized objectives, the answers to the kind of specific statutory questions that we herein address; fine calibrations are just not possible through the use of such

> crude instruments. This is particularly so in this context, given that, although we can perhaps divine from these abstract purposes a congressional intention to balance the need to encourage qui tam actions against the need to prevent parasitic suits, we can discern virtually nothing as to precisely how Congress ultimately believed it achieved that balance. If the language of law is to have any meaning at all, then surely it must prevail over the kind of speculation that is entailed in such an enterprise as these courts have undertaken."

Duxberry, 579 F.3d at 27 (quoting *United States ex rel. Siller v. Becton Dickinson & Co.*, 21 F.3d 1339, 1354–55 (4th Cir. 1994)).

Beyond the text of the statute, courts rejecting the rule have argued that the first-to-file rule already provides an incentive for potential relators to report fraud early, as the first whistleblower to the courthouse generally wins the qui tam prize. *Id.* at 24. As for the goal of preventing parasitic suits, the First Circuit noted that the legislative history of the current original source requirement suggests that an equally, if not more important, goal of the provision was to encourage more private enforcement suits, as the prior "government knowledge" regime barred all suits based on information already available to the government, without any exception for those who actually provided it. *Id.* at 25–26. Thus, courts that have rejected the rule proposed by the Defendants have found no conflict between the statutory text and Congress's intent.

The Fifth Circuit acknowledged the issue in *Reagan* but declined to decide it. 384 F.3d at 178 n.13 ("Unlike a number of circuits, this court has yet to decide whether a party who independently and directly learns of information already publicly disclosed may qualify as an independent source. . . . [W]e need not decide this question here."). Nevertheless, the Fifth Circuit's prior decision in *Federal Recovery Services* suggests that the approach adopted by the First and Eighth Circuits is the correct one. *See Fed. Recovery Servs., Inc. v. Cresent City E.M.S.*, 72 F.3d 447, 452 (5th Cir. 1995). There, after deciding that the relator's suit was barred by the public disclosure bar, the court turned to the relator's alternative argument that the

intervention of the United States in the action cured any jurisdictional defect. *Id.* The relator based her argument on a section of the FCA that limits the amount of the relator's recovery in cases where the government has intervened and where "the court [finds] the action to be based primarily on [public disclosures]." 31 U.S.C. § 3730(d)(1); *see Fed. Recovery Servs.*, 72 F.3d at 452. According to the relator, that provision would be rendered meaningless unless the government's intervention provided an exception to the public disclosure bar. *Fed. Recovery Servs.*, 72 F.3d at 452.

The Fifth Circuit disagreed, and in so doing, analyzed the legislative history and purpose of that provision:

> The legislative history discloses that Congress included that provision to provide for "the case *where the information has already been disclosed and the person qualifies as an 'original source'* but where the essential elements of the case were provided to the government or news media by someone other than the qui tam plaintiff." 132 Cong. Rec. H9389 (statement of Rep. Berman); *see also* 132 Cong. Rec. S11244 (statement of Sen. Grassley).

Id. (emphasis added). Thus, before the Fifth Circuit decided *Reagan*, it strongly suggested in *Federal Recovery Services* that a relator may qualify as an original source even if he provides information to the government after the allegations have been publicly disclosed.

The Court is convinced that the approach adopted by the Eighth and First Circuits is the correct one and is mindful of the suggestion in *Federal Recovery Services*. Therefore, the fact that Colquitt did not provide the information underlying his claims to the government until after the public disclosure does not prevent him from being an original source of that information.

d. Conclusion—Public Disclosure Bar

Colquitt's fraudulent inducement and off-label promotion theories are both based upon publicly disclosed allegations or transactions. The fraudulent inducement claims are publicly disclosed because, assuming the critical elements of that theory are what Colquitt contends they

are, those elements are disclosed in the 510(k) summaries. As for the off-label promotion theory, those elements were disclosed in the FDA warning letter and biliary stent advertisements placed in vascular specialty journals, and the action here is based upon those public disclosures. Colquitt is not an original source of the fraudulent inducement claims, and the Court thus lacks jurisdiction to entertain those claims. However, Colquitt is an original source of the off-label promotion claims. Further, the Defendants do not contend that the anti-kickback claims were ever publicly disclosed, so the Court has jurisdiction over those claims.

B. Failure to State a Claim or Plead Fraud with Particularity

The Defendants move to dismiss for failure to state a claim under Rule 12(b)(6), arguing that Colquitt has failed to state a plausible claim for relief as required by Rule 8, and that Colquitt's claims do not plead fraud with particularity as required by Rule 9(b). *See* Fed. R. Civ. P. 8(a)(2), 9(b). Because the Court does not have jurisdiction over Colquitt's fraudulent inducement claims, it need not examine the Defendants' arguments for dismissing those claims. Thus, the Court examines only the off-label promotion and anti-kickback claims to determine if they are sufficiently pleaded.

1. Off-Label-Promotion Claims

The Defendants argue that Colquitt's off-label promotion theory fails to state a plausible claim for relief because reimbursement claims for off-label use of biliary stents are not false or fraudulent. Additionally, the Defendants contend that Colquitt has not pleaded the off-label promotion theory with particularity because he has not alleged the details of any actually submitted false claims or of a particular scheme to submit false claims.

a. Claim Falsity

The Defendants first argue that Colquitt has failed to state a claim showing that he is plausibly entitled to relief. Under Federal Rule of Civil Procedure 8(a)(2), a pleading must

contain "a short and plain statement of the claim showing that the pleader is entitled to relief." The pleading standard Rule 8 announces does not require "detailed factual allegations," but it does demand more than an unadorned accusation devoid of factual support. *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (citations omitted). While a court must accept all of the plaintiff's allegations as true, it is not bound to accept as true "a legal conclusion couched as a factual allegation." *Id.* at 1949–50 (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). To survive a Rule 12(b)(6) motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face. *Twombly*, 550 U.S. at 570. Where the facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has stopped short of showing that the pleader is plausibly entitled to relief. *Iqbal*, 129 S. Ct. at 1950.

The Defendants argue that Colquitt's allegations do not allow a reasonable inference of FCA liability because claims submitted by healthcare providers for off-label use of biliary stents are not "false or fraudulent claims." The FCA is "aimed at false claims." *United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 674 (5th Cir. 2003) (en banc). The FCA defines a "claim" as "any request or demand, whether under a contract or otherwise, for money or property." 31 U.S.C. § 3729(c) (2006) (amended by 31 U.S.C. § 3729(b)(2) (Supp. III 2009)). As the Fifth Circuit has explained:

> [A claim] is a "request or demand" made in connection with a "contract or otherwise," the "contract or otherwise" allegedly warranting the making of the claim. Thus, whether a claim is valid depends on the contract, regulation, or statute that supposedly warrants it. It is only those claims for money or property to which a defendant is not entitled that are "false" for purposes of the False Claims Act.

Southland Mgmt., 326 F.3d at 674–75. Thus, liability under the FCA will attach only if the person making the claim to the government was not entitled to the money or property it

requested. Accordingly, Medicare claims for expenses that are not covered and are ineligible for payment are false claims. *See Peterson v. Weinberger*, 508 F.2d 45, 52 (5th Cir. 1975). In this case, then, Colquitt has stated a plausible claim for relief under the FCA only if he has sufficiently alleged that healthcare providers were not entitled to reimbursement from the government for off-label use of the Defendants' biliary stents.

Medicare is administered by the Center for Medicare and Medicaid Services ("CMS"), which contracts with private contractors to act as agents in reviewing and paying claims submitted by healthcare providers. 42 U.S.C. § 1395h; 42 C.F.R. §§ 421.3, 421.100. These contractors review claims to determine whether they are appropriate for reimbursement under Medicare. By statute, Medicare is not permitted to pay for any expense that is not "reasonable and necessary for the diagnosis of illness or injury." 42 U.S.C. § 1395y(a)(1)(A). CMS interprets the terms "reasonable and necessary" to mean that a service must be safe and effective, and not experimental or investigational. Mem. from Thomas A. Ault to All Regional Administrators, re: *Medicare Coverage of Investigational Devices* 1 (De. 28, 1994) (hereinafter, "*Ault Memo*") (J. Def. Ex. PP).[9] Absent exceptions not relevant to this case, federal regulations prohibit Medicare coverage for experimental or investigational devices. 42 C.F.R. § 411.15(o).

[9] The *Ault Memo* was prepared by the director of the Health Care Financing Administration, the predecessor to CMS, and was presented as a compilation of existing policies pertaining to the application of the "reasonable and necessary" requirement to the coverage of medical devices under Medicare. The *Ault Memo* was included in the Joint Defense Appendix, and was cited extensively by both parties in their briefs and at the hearing. In considering a motion to dismiss under Rule 12(b)(6), the Court generally "must limit itself to the contents of the pleadings, including attachments thereto." *Collins v. Morgan Stanley Dean Witter*, 224 F.3d 496, 498 (5th Cir. 2000). However, in situations where, as here, the plaintiff relies on extra-pleading documents to respond to the defendant's motion to dismiss, the documents may be considered in a Rule 12(b)(6) analysis as if they had been attached to the plaintiff's complaint. *See Walch v. Adjunct General's Dep't of Tex.*, 533 F.3d 289, 294 (5th Cir. 2008). Thus, the Court considers the *Ault Memo* as a part of the TAC.

A device is investigational if it has not been approved by the FDA through the premarket approval process or the 510(k) clearance process.[10]

Colquitt argues that off-label use of the Defendants' biliary stents is ineligible for reimbursement because such use is investigational and, alternatively, because such use has not been determined to be safe and effective. The TAC's allegations, taken as true, plausibly show that neither CMS nor its contractors have determined that off-label use of biliary stents in the vascular system is safe and effective, and therefore, the Court need not determine if such use of the Defendants' stents is investigational.

According to the *Ault Memo*, on which both parties rely, "[a]n approved or cleared device may be covered by Medicare for a labeled indication and, based on contractor discretion, for an unlabeled use as long as this does not conflict with FDA requirements." *Id.* The *Ault Memo* provides the following example of an off-label use that is reimbursable: "For example, an approved cardiac catheter, whose label only includes a diagnostic indication, may be covered by a contractor for an unlabeled therapeutic indication, based on the contractor's determination that the unlabeled use is safe and effective." *Id.*

Colquitt argues that contractors themselves have made a determination regarding the safety and effectiveness of off-label use of biliary stents that renders such use not reimbursable. The TAC alleges that "a service . . . cannot be reimbursed unless the [contractor] determines that it is safe and effective," and that "Medicare's [contractors] have issued non-coronary vascular stent local coverage determinations (LCDs) restricting coverage to FDA-approved vascular stents used for approved vascular system indications." (TAC ¶ 93.) In support of this allegation, the TAC quotes the following statement that the LCDs "typically" contain:

[10] Medicare may cover certain investigational devices that have received an Investigational Device Exemption, but that exception is not applicable here. *See* 42 C.F.R. § 411.15(o)(1).

> "Coverage for above indications [for example, renal artery, superficial femoral artery, iliac artery] for non-coronary vascular stents depends on the use of **an FDA approved stent**. Several different stents are currently used in the medical community. Each device has specific indications described by the FDA for approved market uses. **Stent placement is covered by Medicare only when an FDA approved stent is a) used for approved indications, or b) used for the above indications supported by the peer medical literature.**"

(*Id.* (alteration and emphasis added by TAC).) Colquitt argues that the LCD's reference only to FDA-*approved* stents limits Medicare coverage to reimbursement for Class III vascular stents that have received premarket *approval*—rather than Class II biliary stents subject to the 510(k) *clearance* process. Further, Colquitt notes that the LCD's reference to the "several" different stents currently used in the medical community must refer to the dozen or so FDA-approved Class III vascular stents, and not to the more than 700 Class II biliary stents currently on the market.

The quoted language of the LCD creates a plausible basis to infer that the LCD only provides coverage for off-label use of Class III vascular stents that have received approval through the premarket approval process. Not only does the LCD's reference to FDA-approved stents suggest coverage only for vascular stents approved via the premarket approval process, but the Defendants' reading would render that qualifier—which typical LCD uses twice—meaningless. In other words, if "FDA-approved stent" merely describes a stent that has completed some form of regulatory review—either 510(k) clearance or premarket approval—then limiting coverage to FDA-approved stents is no limitation at all, as reimbursement for a device that has not completed some form of regulatory review is prohibited by federal regulations. *See* 42 C.F.R. 411.15(o); *Medicare Benefit Policy Manual* § 14.10.[11] The

[11] This provision states, "Devices that may be covered under Medicare include the following categories: [1] Devices approved by the FDA through the Pre-Market Approval (PMA) process; [2] Devices cleared by the FDA through the 510(k) process; [3] FDA-approved IDE Category B

likelihood that the LCD would twice specify that coverage is limited to FDA-approved devices, when that term does not in fact limit coverage, is remote enough to render Colquitt's reading of the LCD plausible.

The Defendants contend that the TAC's reference to "typical" LCDs is insufficient to show a plausible entitlement to relief, because it cannot support an inference that the Defendants *knowingly* caused false claims to be submitted, or *knowingly* made false statements material to false claims. In other words, the Defendants argue that one cannot reasonably infer that the Defendants knew off-label use was not covered, when the coverage determination depends on a contractor-by-contractor analysis of LCDs. However, this argument is premised on the Defendants' assumption that "once a device is cleared or approved for marketing, services involving the use of that device—including any *off-label* use—are covered by Medicare unless CMS or one of its contractors determines that a particular use of a 510(k)-cleared device is *not* reasonable and necessary." (BSC Mot. Dismiss Br. 21.) But the TAC alleges that "a service is not reasonable and necessary and cannot be reimbursed unless the [contractor] determines that it is safe and effective, not experimental nor investigational, and appropriate." (TAC ¶ 91.) Contrary to the Defendants' argument, then, Colquitt alleges that coverage of an off-label use requires an affirmative decision by a contractor that the use is safe and effective, and that absent such a decision, off-label use is ineligible for reimbursement.

Although the Defendants cite the *Ault Memo* in support of their argument, that document actually lends support to Colquitt's theory. The memo states that an approved or cleared device may be covered for an unlabeled use based on contractor discretion, and provides an example where "an approved cardiac catheter, whose label only includes a diagnostic indication, may be

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devices; and [4] Hospital Institutional Review Board (IRB) approved IDE devices." *Medicare Benefit Policy Manual* § 14.10.

covered by a contractor for an unlabeled therapeutic indication, based on the contractor's *determination* that the unlabeled use is safe and effective." *Ault Memo* 6 (emphasis added). This language suggests that, absent an affirmative determination of safety and effectiveness by a contractor, off-label use of a cleared or approved device is not covered by Medicare.

Certainly, the Defendants will have the opportunity to pursue the theory that an affirmative contractor determination is not necessary for coverage, or that, even if it is, that contractors have made such affirmative determinations. But accepting the TAC's allegations as true, as the Court must at this stage, Colquitt has sufficiently alleged that Medicare's contractors have not, in their discretion, determined that the use of biliary stents in the vascular system is safe and effective and therefore eligible for reimbursement. Therefore, Colquitt's allegations create a plausible basis to infer that healthcare providers were not entitled to reimbursement for off-label use of the Defendants' biliary stents and, therefore, that claims for such reimbursement were "false or fraudulent" within the meaning of the FCA.

b. Failure to Plead with Particularity

The Defendants also challenge Colquitt's off-label promotion claims on the ground that they are not alleged with particularity as required by Rule 9(b). Specifically, the Defendants argue that Colquitt has not alleged the details of any actually submitted false claims or of any particular scheme to submit false claims.

A complaint alleging violations of the FCA must meet the heightened pleading standard of Rule 9(b), which provides that, "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b); *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 185 (5th Cir. 2009); *United States ex. rel. King v. Solvay S.A.*, No. 06-2662-H, 2011 WL 4834030, at *6–7 (S.D. Tex. Oct. 12, 2011). Although Rule 9(b) is often said to require a plaintiff to plead the "the time, place and contents of a false

representation, as well as the identity of the person making the misrepresentation and what that person obtained thereby," the Fifth Circuit has held that this standard is not a straitjacket for Rule 9(b). *Grubbs*, 565 F.3d at 186, 190. Thus, in alleging a presentment claim under the FCA, "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 [or cause others to submit] false claims paired with reliable indicia that lead to a strong inference that false claims were actually submitted." *Id.* at 190; *King*, 2011 WL 4834030, at *27.

The TAC does not allege the payment of specific claims—it does not identify any claim made by any specific healthcare provider or identify any physician or hospital that used one of the Defendants' stents for an off-label vascular indication, on a Medicare beneficiary. Nevertheless, Colquitt alleges specific instances of the Defendants promoting their biliary stents for off-label use in the vascular system. Not only did Colquitt allegedly engage in and witness such promotion in the hospitals and clinics he visited, but the Defendants advertised the release of new biliary stents in vascular journals, sometimes with language suggesting use in the vasculature. These allegations describe schemes by each Defendant to market and promote its biliary stents for off-label use. But the FCA is not a remedial statute for mere regulatory violations; it requires a scheme to submit—or in this case, cause others to submit—false claims for payment. Nothing about the Defendants' off-label promotion efforts alone implicates claims made to the government, as any off-label use could be paid for by private health insurance or individual patients.

Filling this gap, however, are allegations about reimbursement guides distributed by the Defendants to healthcare providers. The TAC alleges that the Defendants prepared and distributed these guides to instruct healthcare providers how to seek reimbursement for the use of

their stents in vascular procedures. Specifically, the TAC alleges that the "[t]he reimbursement guides were distributed to healthcare providers with instructions to use [reimbursement codes for vascular stenting procedures] when seeking reimbursement from Medicare, its [contractors], and Medicaid for placement of the unapproved biliary stents in the vascular system." (TAC ¶ 192.) Furthermore, the TAC contains specific allegations regarding the contents of the guides prepared by Abbott and Cordis, identifying the particular vascular stenting procedures for which healthcare providers were to seek reimbursement. As for Boston Scientific, the only allegation in the TAC connecting its off-label marketing to the submission of false claims is the general allegation that "Defendants prepared reimbursement guides to provide false coding and reimbursement information to physicians for the unapproved devices."

The TAC's allegations satisfy the particularity requirement of Rule 9(b) as to the off-label promotion claims against Abbott, but not as to those against Cordis and Boston Scientific. Regarding Boston Scientific, there are no "particular details" provided of a scheme to cause the submission of false claims. While the TAC specifically describes the reimbursement manuals distributed by Cordis and Abbott, its only allegations applicable to Boston Scientific pertain to "Defendants" generally. Thus, rather than containing particular details of a scheme by Boston Scientific to cause the submission of false claims, the TAC contains only general allegations.

The allegations against Cordis are also insufficient. The TAC alleges that Cordis's "Endovascular Payment and Reimbursement Guidelines" instructed healthcare providers "how to falsely bill the government for the placement of an FDA-approved renal stent when using [its] biliary stents." (TAC ¶ 195.) The TAC further states that "[n]one of [Cordis's] currently marketed stents have been approved by FDA for treatment of vascular disease in renal arteries." (*Id.*) Despite the allegation that Cordis does not currently market any stents approved for

treatment of vascular disease in the renal arteries, the TAC elsewhere alleges that Cordis has two FDA-approved vascular stents, one of which is approved for use in the renal arteries. (TAC 35 tbl.1.) Whether "currently marketed" or not, Colquitt cannot and does not dispute that Cordis could have properly instructed healthcare providers how to *properly* seek reimbursement for the use of these stents. Although the TAC alleges that Cordis's guide instructed healthcare providers to seek reimbursement for use of a biliary stent in the renal artery, those general allegations do not particularly describe a scheme to submit false claims, especially where Cordis had stents approved for use in the renal artery.

The allegations against Abbott, however, do amount to such a scheme. Colquitt alleges that Abbott has *no* FDA-approved vascular stents. Yet, according to the TAC, Abbott prepared and distributed to healthcare providers a "Guide to Outpatient and Physician Coding for Coronary and Peripheral Vascular Interventional Procedures," which instructed healthcare providers to seek reimbursement for the use of its stents in the iliac artery, the superficial femoral artery, and the renal arteries. (TAC ¶¶ 197–99.) These allegations, combined with the detailed allegations of Abbott's off-label promotional activities, provide particular details of a scheme to cause the submission of false claims. Furthermore, the allegations provide reliable indicia that claims were actually submitted. As the TAC alleges, and Abbott acknowledges, physicians have used biliary stents almost exclusively in vascular procedures. The ubiquitous off-label use of biliary stents, and Abbott's direct efforts to aid healthcare providers in seeking reimbursement from the government for that use, combine to create a strong inference that claims were submitted to the government seeking reimbursement for the off-label use of Abbott's stents.

In addition to the presentment claim discussed above, Colquitt alleges that the Defendants' off-label promotion and, in particular, their distribution of reimbursement guides,

provides the basis for a false-statement claim as well. Colquitt contends that the reimbursement guides contained knowingly false statements that were material to the submission of false claims. Like Colquitt's presentment theory, his false-statement theory is sufficient as to Abbott, but insufficient to plead fraud with particularity as to Cordis and Boston Scientific. The allegations against Boston Scientific lack the specificity to meet Rule 9(b)'s heightened pleading standard because they do not identify the supposedly false statements. Likewise, although the allegations against Cordis are more specific, they do not allow the Court to infer that the statements in its Endovascular Payment and Reimbursement Guidelines were false, because Cordis had FDA-approved vascular stents, including one approved for use in the renal artery. Abbott, however, had no such approval for any of its devices, and thus, the Court may infer that Abbott made materially false statements when it represented to healthcare providers that off-label, vascular use of Abbott stents was reimbursable.

c. Conclusion—Off-Label Promotion Claims

In summary, Colquitt has sufficiently alleged that reimbursement claims for off-label use of the Defendant's biliary stents were false claims, because the TAC's allegations allow the Court to reasonably infer that such use is not reimbursable by Medicare, either nationally or on a contractor-by-contractor basis. Furthermore, Colquitt has sufficiently pleaded his off-label promotion claims against Abbott because the TAC's allegations regarding Abbott's distribution of reimbursement guides, when Abbott had no FDA-approved vascular stents, provide particular details about a fraudulent scheme to cause the submission of false claims and reliable indicia that claims were actually submitted. However, Colquitt's off-label promotion claims against Cordis and Boston Scientific are not sufficiently pleaded because they do not contain such details, nor

do they allow the Court to infer that the reimbursement guidelines provided by Cordis and Boston Scientific contained material false statements.

2. Kickback Claims

Colquitt's third theory of FCA liability is based on violations of the federal Anti-Kickback statute (AKS). The factual allegations underlying Colquitt's AKS theory consist of the following: (a) Abbott granted rebates to specific hospitals based on specific market share criteria, such as the percentage of the hospital's stents purchased from Abbott in a given quarter, and these percentages were so high that the small number of biliary stenting procedures performed would not justify them; (b) Abbott bought dinners for physicians in order to encourage them to refer patients to vascular specialists who used Abbott's stents; and (c) upon information and belief, Cordis and Boston Scientific offered similar discounts on their stents, and paid substantial funds to at least one physician.

The AKS prohibits (1) the knowing and willful offer of remuneration to induce a person to recommend, order, or purchase any good or service for which payment may be made in whole or in part under a federal health program; and (2) the knowing and willful solicitation or receipt of remuneration in return for such recommendation, order, or purchase. *See* 42 U.S.C. § 1320a-7b(b)(1–2); *see also United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 901 (5th Cir. 1997). A violation of the AKS does not amount to an FCA violation unless claims for payment were conditioned on a certification of compliance with the AKS by the party requesting payment, and that party falsely certifies compliance with the AKS, thus making the claims "false." *See Thompson*, 125 F.3d at 901. Colquitt's theory, then, is that certain healthcare providers violated the AKS by receiving remuneration from the Defendants to use their stents off-label; that these providers then submitted claims for reimbursement that were false due to the certification of AKS compliance; and that the Defendants, as the source of the

remuneration given to the providers, caused the submission of those false claims (presentment liability) and/or caused the providers to make the false certifications that rendered the claims false (false-statement liability).

As with the off-label-promotion claims, the AKS allegations do not describe any details of the actual claims made by the physicians or hospitals that allegedly received kickbacks. But unlike the off-label-promotion theory, Colquitt's AKS allegations do not satisfy the requirements of Rule 9 as to any of the Defendants. First, the only allegations pertaining to Boston Scientific and Cordis recount statements by one physician that Boston Scientific and Cordis paid him $80,000 for his vascular fellowship program and provided him $15,000 for each training course he conducted. The TAC nowhere alleges that that doctor was a participant in any federal payer program nor that he ever certified compliance with the AKS as a condition of such participation. The AKS claims against Abbott are similarly deficient. Although Colquitt identifies specific hospitals and other healthcare providers that were offered rebates and discounts for the purchase of Abbott's biliary stents, there are no allegations in the TAC that these hospitals or healthcare providers participated in any federal payer program or certified compliance with the AKS as a condition of such participation. Such allegations do not satisfy the heightened pleading required by Rule 9(b).

To be clear, to the extent that Colquitt's kickback allegations simply describe conduct by the Defendants that caused the submission of claims for off-label use, those allegations describe additional instances of Colquitt's off-label promotion claims—that is, efforts by the Defendants to induce off-label use of their stents. It is only by providing another basis for claim falsity that the kickback allegations add a distinct theory to the TAC—false certification. However, because Colquitt has failed to adequately plead false certification or violations of the AKS by the

healthcare providers that allegedly received kickbacks, Colquitt has failed to state a claim for relief based on the AKS.

C. State Law Claims

In addition to his claims under the FCA, Colquitt alleges violations of the analogous state false claims statutes of California, Florida, Illinois, Louisiana, Massachusetts, Tennessee, Texas, Virginia, Delaware, Washington D.C., Michigan, Minnesota, New Jersey, and New York.[12] Colquitt's claims under these statutes fail because (a) the Court lacks subject matter jurisdiction over the fraudulent inducement and off-label promotion claims, and (b) the AKS allegations do not state a claim for relief.

All of the state false claims statutes invoked by Colquitt include public disclosure bars that are substantively identical to the FCA's. Cal. Gov't Code § 12652(d)(3); Fla. Stat. § 68.087(3); 740 Ill. Comp. Stat. § 175/4(e)(4)(A); La. Rev. Stat. Ann. § 46:439.1(D); Mass. Gen. Laws Ch. 12, §§ 5A(a), 5G(3); Tenn. Code Ann. § 71-5-183(e)(2)(A); Tex. Hum. Res. Code Ann. § 36.113(b); Va. Code Ann. § 8.01-216.8; Del. Code Ann. tit. 6, § 1206(c); D.C. Code § 2-308.15(c)(2); Mich. Comp. Laws Ann. § 400.610a(13); Minn. Stat.§ 15C.05(b)(3); N.J. Stat. Ann. § 2A:32C-9(c); N.Y. State Fin. Law § 190(9)(b). Thus, the Court lacks jurisdiction over Colquitt's state fraudulent inducement claims as to all Defendants for the same reasons it lacks jurisdiction over those claims brought under the FCA—they are based on publicly disclosed allegations and transactions, and are not based on information of which Colquitt is an original source.

Additionally, the Court lacks jurisdiction over Colquitt's state off-label promotion claims as to all Defendants because he does not qualify as an original source of those claims under the

[12] Thus far, six of the state governments named in the Third Amended Complaint have expressly declined to intervene, *see* Section I.D, *infra*, and no states or governments have intervened.

state statutes. Just as the FCA limits the definition of original source to relators who "voluntarily provided the information to the Government before filing an action under this section," each of the state false claims statutes conditions original source status on the relator's disclosure of information to the *state* government before filing suit. *Id.* However, the TAC contains no allegations of such disclosure to any of the states under whose false claims statutes Colquitt seeks relief, and Colquitt provided no evidence of such disclosure in response to the Defendants' Motions to Dismiss. Absent such allegations or evidence creating a fact issue as to Colquitt's disclosure to the relevant states, the Court must conclude that it lacks subject matter jurisdiction over Colquitt's off-label promotion claims because those claims were based on the public disclosure of allegations or transactions and Colquitt is not an original source under the state statutes.

Finally, although there is no contention that Colquitt's state AKS causes of action are subject to the public disclosure bar, as to all Defendants, those causes of action fail to state a claim for the same reasons the FCA-based AKS claims fail, as the provisions of the state and federal false claims acts are substantively identical.

III. CONCLUSION

The Court lacks jurisdiction over Colquitt's fraudulent inducement claims brought under the FCA and state false claims statutes, as well as his off-label promotion claims brought under the state false claims statutes, and these claims are therefore **DISMISSED** with prejudice. Colquitt's federal and state AKS claims against all the Defendants are **DISMISSED** without prejudice for failure to state a claim upon which relief can be granted, and his FCA off-label promotion claims against Cordis and Boston Scientific are **DISMISSED** without prejudice for failure to satisfy Rule 9(b)'s heightened pleading requirement. The Court will provide Colquitt leave to amend, but, because the Court has previously granted Plaintiff leave to amend to further

delineate the factual and legal bases for his claims, he may now amend only to attempt to cure the pleading deficiencies in his federal and state AKS claims and his FCA off-label promotion claims against Boston Scientific and Cordis.

Therefore, the Motions to Dismiss filed by Boston Scientific Corporation [Docket Entry #110] and Cordis Corporation and Johnson & Johnson [Docket Entry #112] are **GRANTED**, and the Motion to Dismiss filed by Abbott Laboratories and Abbott Vascular Solutions, Inc. [Docket Entry #115] is **GRANTED** in part and **DENIED** in part. If Colquitt chooses to amend his pleadings, he may do so on or before **April 27, 2012**, by filing a clean and red-lined Fourth Amended Complaint.

SO ORDERED.

March 30, 2012.

BARBARA M. G. LYNN
UNITED STATES DISTRICT JUDGE
NORTHERN DISTRICT OF TEXAS