IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
JACKSON DIVISION

UNITED STATES OF AMERICA *EX REL.* JOANNE HARTWIG, *Relator*, v. MEDTRONIC, INC., *et al*., *Defendants.*	)	CIVIL ACTION NO. 3:11-CV-413-CWR-LRA

DEFENDANTS MEDTRONIC, INC.'S AND
MEDTRONIC SOFAMOR DANEK USA, INC.'S
MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO DISMISS
RELATOR'S COMPLAINT UNDER RULES 12(b)(1), 12(b)(6), AND 9(b)

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

CASES **PAGE(S)**

STATUTES

OTHER AUTHORITIES

Defendants Medtronic, Inc. and Medtronic Sofamor Danek USA, Inc. (collectively, "Medtronic") respectfully submit this memorandum in support of their motion to dismiss with prejudice Relator Joanne Hartwig ("Relator")'s complaint pursuant to Fed. R. Civ. P. 12(b)(1), 12(b)(6), and 9(b).

PRELIMINARY STATEMENT

Contrary to blackletter law barring the filing of a False Claims Act ("FCA") complaint predicated on previous public disclosures, Relator's complaint cobbles together a jumble of irrelevant facts that are *entirely* based on publicly-available information. Indeed, Relator's complaint even cites to newspaper articles, previous lawsuits, and other public documents as part of an improper attempt to obtain a windfall FCA recovery, without contributing any new information. In addition, impelled by a deep misunderstanding of the medical device industry and its regulation by the FDA, Relator's complaint fails to assert a viable cause of action as a matter of law. The Court should dismiss the complaint in its entirety for several reasons:

- *First*, Relator merely repeats publicly-available information concerning highly-publicized—and now closed—government investigations and prior civil litigation focusing on Medtronic's promotion of its INFUSE® Bone Graft ("INFUSE") product and its collaboration with physician-consultants. Congress has *jurisdictionally barred* FCA suits based upon previous public disclosures, recognizing the danger and expense associated with frivolous lawsuits brought by bystanders simply seeking an undeserved share of a potential FCA recovery.

- *Second*, Relator's FCA allegations fail to allege key elements of an FCA claim, including—and most critically—that Medtronic knowingly caused the submission of any false claim for payment by the United States.

- *Third*, Relator's Anti-Kickback Statute ("AKS") allegations are premised upon a mistaken assumption that payments made by industry to physicians are *per se* illegal. These allegations fail to allege key elements of a violation of the AKS and the FCA.

- *Fourth*, Relator's FCA allegations fail to meet the specificity required by Fed. R. Civ. P. 9(b).

- *Finally*, Relator's remaining allegations assert violations of a grab bag of other statutes and regulations for which no private right of action exists.

FACTUAL AND PROCEDURAL BACKGROUND

Medtronic, Inc. is one of the world's leading medical technology companies, and develops and sells devices to treat a wide range of life-altering medical conditions, including cardiovascular conditions, diabetes, spinal disorders, and neurodegenerative disorders. Compl. App. J at 5. Medtronic Sofamor Danek USA, Inc. is a subsidiary of Medtronic Sofamor Danek, Inc., which is, in turn a subsidiary of Medtronic, Inc. Dkt. # 41. Since 2002, Medtronic has sold INFUSE Bone Graft. INFUSE is a revolutionary medical device that contains a genetically-engineered human protein that induces human bone growth. In July 2002, FDA approved INFUSE marketing and labeling for use in certain spinal fusion procedures in which a damaged disk is removed and the vertebrae are fused to together to alleviate pain. Compl. App. B. FDA has subsequently approved INFUSE marketing and labeling for other applications that require stimulated bone growth, including healing severe fractures of the tibia (shin bone) and in oral maxillofacial surgery. Medtronic's Pyramid Plate device has been cleared by FDA for marketing and labeling as supplemental fixation when a surgeon uses bone graft in a spinal fusion procedure. Compl. App. G at 9; Compl. App. S at 3–4, 8–9.

The Complaint. Relator Joanne Hartwig initiated this action on July 8, 2011 by filing under seal a *qui tam* complaint against Medtronic. Having had nearly a year to investigate Relator's claims, the United States declined to intervene in this case on May 8, 2012. *See* Government's Notice of Election to Decline Intervention, Dkt. # 8. Relator's Complaint was subsequently unsealed and served on Medtronic's registered agent on September 5, 2012, only a few days before the expiration of the 120-day service requirement of Rule 4. Dkt. # 15, 16.

Relator alleges that Medtronic violated the FCA (31 U.S.C. §§ 3729(a)(1), (a)(2), and (a)(3) (2006)) by allegedly conspiring with the physician defendants to disseminate favorable peer-reviewed journal articles regarding INFUSE and to perform experimental procedures with the Pyramid Plate. Compl. ¶¶ 28–59, 68. Relator next generally asserts that Medtronic paid kickbacks to the physician defendants which resulted in false claims for payment through false certifications of compliance with the AKS. Compl. ¶¶ 58–59, 67, 69, 71–72, 78, 80–89, 92–93. The complaint's remaining counts assert claims based on a miscellany of additional statutes, regulations, Medtronic's Corporate Integrity Agreement ("CIA") with the Department of Health and Human Services ("HHS"), and "unjust enrichment." Compl. ¶¶ 105–14. Each of Relator's claims focuses on two factual themes that, as discussed below, are exclusively taken from widely available press reports and other public documents.

The INFUSE Publication Allegations. Relator's first set of factual allegations (the "INFUSE Publication Allegations") involve allegedly improper collaboration between defendants Medtronic, Dr. Thomas Zdeblick, and Dr. Curtis Dickman to increase use (including off-label use) of INFUSE through the drafting of certain peer-reviewed publications. Compl. ¶¶ 28–59. Relator attempts to characterize each publication as misleading or otherwise improper based on information gleaned from the face of the article or subsequent media reports characterizing the publications, not her own knowledge or research. *See* Compl. ¶¶ 24–26, 31–33, 35–38, 41–48, 50–53, 56–58, 73, App. L. In an attempt to link these publications to her FCA claims, Relator states that Medtronic cited one of the articles in a 2003 annual report to shareholders coupled with the statement that INFUSE "may become the 'new gold standard' in spinal fusion surgery." Compl. ¶¶ 50; Compl. App. J at 13.

The Pyramid Plate Experimentation Allegations. Relator's second set of factual allegations (the "Pyramid Plate Experimentation Allegations") describe a purported relationship between defendant Medtronic and defendant Dr. Adam Lewis, who had previously performed two spinal operations on Relator, in 2001 and 2005. Compl. ¶¶ 60–72, 84–90. Relator alleges that her 2005 surgery involved an off-label use of the Pyramid Plate.[1] Compl. ¶ 71. Apparently based on an allegation that Dr. Lewis provided unspecified Pyramid Plate data to a Dr. Jeffrey Kozak (not Medtronic) one year *before* Relator's surgery, Relator characterizes Dr. Lewis's surgery on Relator as "experimentation" without informed consent. Compl. ¶¶ 66–68, 70, 71; Compl. App. R at 2. The complaint also does not allege any connection between Dr. Kozak and Medtronic. Compl. ¶¶ 67–68.

Despite having had the benefit of discovery during her prior malpractice suit, Relator alleges no facts regarding the amount or timing of any of Medtronic's purported payments to Dr. Lewis. Compl. ¶ 83. Instead, the complaint concocts a fanciful "scheme to launder payments" from Medtronic to Dr. Lewis, via Dr. Dickman and Dr. Zdeblick. Compl. ¶¶ 71, 81, 85, 88. The supposed connection appears to be the existence of a Mississippi corporation with the same business address as Dr. Lewis that also happens to have the same initials as Dr. Zdeblick. Compl. ¶ 88. Elsewhere in her complaint, however, Relator identifies two different occasions during discovery and at her medical malpractice trial where Dr. Lewis testified that he had never received funds from Medtronic. Compl. ¶¶ 62–64. In addition, Medtronic's on-line disclosure of payments to physicians does not report any payments to Dr. Lewis either. Compl. ¶¶ 83–84.

[1] Relator won a jury verdict on a medical malpractice claim stemming from the surgery. Compl. ¶¶ 61, 71; Compl. App. O. This verdict is presently on appeal to the Mississippi Supreme Court. Declaration of Andrew A. Caffrey, III ("Caffrey Decl.") Ex. 1 at 6 (Hartwig Docket). Relator now appears to seek a second bite at the apple by suing Dr. Lewis *again* and dragging in additional defendants.

In sum, Relator's supposed "proof" that Medtronic paid money to Dr. Lewis consists solely of (1) Dr. Lewis's sworn testimony to the contrary, and (2) the absence of any evidence from Medtronic indicating payments.

ARGUMENT

I. THE COURT LACKS SUBJECT MATTER JURISDICTION OVER RELATOR'S FCA *QUI TAM* ACTION (COUNTS I-III) BECAUSE THE GOVERNMENT WAS ALREADY AWARE OF THE ALLEGED "FRAUD."

Relator's FCA *qui tam* claims are jurisdictionally barred because, well before Relator's complaint, the government was already aware of allegations concerning Medtronic's promotion of its INFUSE® Bone Graft ("INFUSE") product and its collaboration with physician-consultants. The FCA's *qui tam* provisions encourage true "whistle-blowing insiders with genuinely valuable information" to come forward, but the jurisdictional bar ensures that the government will not share any recovery with "opportunistic plaintiffs who have no significant information to contribute of their own." *Graham County Soil & Water Conservation Dist. v. U.S. ex rel. Wilson*, 130 S. Ct. 1396, 1406 (2010) (quotation marks omitted); 31 U.S.C. § 3730(e)(4) (U.S.C.A. 2009). Indeed, to allow relator's claims to survive this motion to dismiss could potentially flood the courts with dozens of lawsuits filed by opportunistic plaintiffs seeking to profit off long-public allegations regarding INFUSE.

Relator's instant FCA *qui tam* action is precisely the type of suit that Congress has expressly prohibited: it merely parrots allegations regarding Medtronic's relationships with physician consultants that have been explored at length by the media and investigated on several occasions by both the U.S. Department of Justice and the Senate Finance Committee for at least five years before Relator filed her complaint.[2]

[2] Where, as here, a Rule 12(b)(1) motion challenges the existence of subject matter jurisdiction, and not simply the adequacy of the jurisdictional allegations, "[t]he burden of proof . . . is on the

- *DOJ Investigation*. On December 3, 2008, Medtronic disclosed publicly that it had received a subpoena from the U.S. Attorney's Office for the District of Massachusetts in connection with an investigation related to INFUSE. Caffrey Decl. Ex. 2 at 47. The press widely described this investigation as centered on Medtronic's relationships with physicians, as well as alleged off-label promotional activities involving INFUSE. *See, e.g.*, Caffrey Decl. Ex. 3 (April 12, 2011 New York Times article). The press specifically stated that the U.S. Attorney's Office investigated allegations that a doctor "overstated INFUSE's benefit" in a medical journal publication. *Id*. at 1–2.[3] Following the public disclosure of the DOJ investigation, shareholders filed a securities class action, captioned *Minneapolis Firefighters Relief Assoc. v. Medtronic*, No. 08-6324, alleging insufficient disclosure of the conduct under investigation. *See* Caffrey Decl. Ex. 5 (December 10, 2008 Marketwire press release), Ex. 6 (*Minneapolis Firefighters Relief Assoc. v. Medtronic* Amended Complaint). The complaint alleged that Medtronic paid physician consultants to "write favorably" about off label uses of INFUSE. Caffrey Decl. Ex. 6 at ¶¶ 128–44.

- *Congressional Inquiry*. Medtronic has publicly reported that, as early as September 2007, Senator Charles Grassley requested information regarding, among other things, financial ties between Medtronic and physicians who use INFUSE, as well as communications with physicians regarding INFUSE clinical research. Caffrey Decl. Ex. 2 at 47. Senator Grassley's well-publicized inquiry explored the impact of Medtronic's financial relationships with physicians in a variety of contexts, including alleged payment of "royalties to disguise kickbacks," and alleged conflicts of interest in Medtronic clinical research. *See, e.g.*, Caffrey Decl. Ex. 7 (October 2, 2008 Sen. Grassley Press Release); Caffrey Decl. Ex. 8 (January 12, 2009 Sen. Grassley Letter); Caffrey Decl. Ex. 9 (October 22, 2010 Sen. Grassley Letter).

- *The Spine Journal*. On June 28, 2011 (one month before Relator's complaint), a medical journal entitled *The Spine Journal* published an issue that characterized many of the publications identified in Relator's complaint as "misleading and biased." Caffrey Decl. Ex. 10 (June 29, 2011 New York Times article). At around the same time, the press reported that Senator Grassley, joined by Senator Baucus, had asked the Company for information concerning relationships between clinical trial investigators and Medtronic. Compl. ¶ 79; Caffrey Decl. Ex. 11 (June 21, 2011 Sen. Grassley/Sen. Baucus Letter). Other press reports from this time, and earlier, focused specifically on the relationship between Defendant Dr. Zdeblick and Medtronic. Caffrey Decl. Ex. 12 (September 14,

---

party asserting jurisdiction," *Ramming v. United States*, 281 F.3d 158, 161 (5th Cir. 2001), and "no presumptive truthfulness attaches to plaintiff's allegations" regarding its jurisdiction. *Williamson v. Tucker*, 645 F.2d 404, 413 (5th Cir. 1981) (quotation marks omitted). When evaluating a Rule 12(b)(1) motion to dismiss for lack of subject matter jurisdiction based on the FCA's public disclosure bar, a court may evaluate evidence submitted by defendants to determine whether the facts alleged by Relator are part of the public record. *U.S. ex rel. Jamison v. McKesson Corp.*, No. 2:08CV214, 2010 WL 1276712, at *1 (N.D. Miss. Mar. 25, 2010).

[3] Medtronic announced on May 16, 2012 that this investigation closed without any action taken by the United States against the Company. Caffrey Decl. Ex. 4.

2010 Milwaukee Journal Sentinel article); Caffrey Decl. Ex. 13 (September 4, 2010 Saint Paul Pioneer Press article); Caffrey Decl. Ex. 14 (June 30, 2011 Wisconsin State Journal article).

- *Prior Qui Tam Litigation.* Nearly ten years before Relator filed her complaint, the United States intervened in an earlier *qui tam* action that alleged, in part, "that Medtronic paid physicians to encourage the use of INFUSE for off-label purposes." Caffrey Decl. Ex. 15 (January 6, 2009 Finance & Commerce article); *United States ex rel. Doe v. Medtronic*, Civil Action No. 02–2709 (W.D. Tenn. 2002). In July 2006, Medtronic settled any claims arising from the *Doe* complaint including claims arising from "payments made pursuant to consulting, royalty, fellowship and research agreements with" a number of physicians (including Dr. Zdeblick) from January 1, 1998 to April 1, 2003, a period that covers his authorship of the three articles described in the instant complaint. Caffrey Decl. Ex. 16 at 2 (2006 Settlement Agreement). In addition, a second *qui tam* action raised the same allegations as the *Doe* complaint and was dismissed in connection with the government's settlement of *Doe*. *See U.S. ex rel. Poteet v. Medtronic*, 552 F.3d 503 (6th Cir. 2009). Finally, a third *qui tam* action ("*Poteet II*") alleged that 120 spine surgeons and 18 medical device distributors committed violations of the FCA by accepting kickbacks from Medtronic. Caffrey Decl. Ex. 17 (*U.S. ex rel. Poteet v. Lenke* Complaint). The court dismissed this third complaint in March 2009, reasoning that its allegations were jurisdictionally barred because of prior public disclosure of the allegations. Caffrey Decl. Ex. 18 at 4, 7 (Poteet II Opinion).

A. The Court Lacks Subject Matter Jurisdiction Because the Allegations in the Complaint Are Based upon Previously Disclosed Information.

"An FCA qui tam action even partly based upon public allegations or transactions is nonetheless based upon such allegations or transactions" and should be dismissed. *U.S. ex rel. Reagan v. E. Tex. Med. Ctr. Reg'l Healthcare Sys.*, 384 F.3d 168, 176 (5th Cir. 2004) (quotation marks omitted); 31 U.S.C. § 3730(e)(4)(B).[4] A public disclosure occurs when the "essential

[4] The FCA's public disclosure bar provides that "[n]o court shall have jurisdiction over an [FCA *qui tam*] action . . . based upon the public disclosure of allegations or transactions in a . . . civil, criminal or administrative hearing, in a congressional, administrative . . . report, hearing, audit, or investigation, or from the news media, unless . . . the person bringing the action is an original source of the information." 31 U.S.C. § 3730(e)(4)(B) (U.S.C.A. 2009). The public disclosure bar was amended by the Patient Protection and Affordable Care Act ("PPACA"), Pub. L. 111-148, 124 Stat. 119 (2010), signed into law on March 23, 2010. The amendments are irrelevant here because they do not apply retroactively to alleged false claims made before March 23, 2010, and Relator has not identified any claims occurring after that date. *U.S. ex rel. Osheroff v. Humana, Inc.*, No. 10-24486-cv, 2012 WL 4479072, at *4 n.8 (S.D. Fla. Sept. 28, 2012) (citing *Graham County*, 130 S. Ct. at 1400 n.1).

elements" of the allegedly fraudulent transaction are released into the public domain. *U.S. ex rel. Branch Consultants v. Allstate Ins. Co.*, 560 F.3d 371, 377 (5th Cir. 2009). Every fact supporting a relator's allegations need not be publicly disclosed, as long as there is enough information "alert[] the government to . . . the fraud." *U.S. ex rel. Jamison v. McKesson Corp.*, 649 F.3d 322, 329 (5th Cir. 2011) (quotation marks omitted). Disclosures that create an "inference of fraud," which can be drawn from facts revealed in different sources, are sufficient. *U.S. ex rel. Colquitt v. Abbott Labs.*, 864 F. Supp. 2d 499, 519 (N.D. Tex. 2012) (quotation marks omitted). A *qui tam* action is "based upon" public disclosures if "the same as or substantially similar to those that have been disclosed" publicly. *U.S. ex rel. Lam v. Tenet Healthcare Corp.*, 481 F. Supp. 2d 673, 683 (W.D. Tex. 2006).

Careful parsing of each individual factual allegation in Relator's complaint makes clear that the key allegations are *entirely* based on publicly-available information. *First*, Relator's INFUSE Publication Allegations are premised wholly upon facts from newspaper articles, Senate Finance Committee investigation letters, FDA submissions,[5] prior *qui tam* litigation, and peer-reviewed medical journals.[6] Compl. ¶¶ 22–38, 40–53, 55–59, 79, 82. These public disclosures and government inquiries have addressed: (1) Medtronic's promotion of INFUSE; (2) Medtronic's relationships with physician consultants generally and Dr. Zdeblick specifically; and (3) the veracity of the publications regarding INFUSE clinical trials, including the publications addressed in the complaint. *See* pp. 8–9, above. As such, the "essential elements" of Relator's claims here were in the public domain years before she filed her complaint. *See Branch Consultants*, 560 F.3d at 377.

[5] *See, e.g., U.S. ex rel. Gilligan v. Medtronic, Inc.*, 403 F.3d 386, 390 (6th Cir. 2005) (statements made to the FDA sufficient to put the government on notice of potential fraud).
[6] *See Colquitt*, 864 F. Supp. 2d at 518 (applying the term news media as used in the False Claims Act statute to "scholarly, scientific, and technical periodicals") (citations omitted).

Additionally, Relator's Pyramid Plate Experimentation Allegations rely exclusively on the information from two prior public lawsuits,[7] supplemented by additional publicly-disclosed information. Compl. ¶¶ 61–64, 66–67, 70–77, 81, 83–86. Indeed, when comparing relator's prior lawsuits and the instant matter, each complaint addresses (1) Dr. Lewis' off-label use of Medtronic's Pyramid Plate, (2) the alleged services provided by Dr. Lewis to Medtronic, (3) purported representations made by Dr. Lewis about the efficacy of the Pyramid Plate, (4) the alleged connection between Dr. Zdeblick and Dr. Lewis, and (5) payments from Medtronic to Dr. Zdeblick and Dr. Dickman. *See* pp. 6–7, above. Moreover the additional information alleged in the instant matter arises from, by Relator's own admission, administrative filings with the Mississippi Secretary of State and content on Medtronic's physician relationships website.

These disclosures fit squarely within the FCA's specified public sources. 31 U.S.C. § 3730(e)(4)(A) (enumerating administrative hearings, reports, or investigations and news media); *U.S. ex rel. Jones v. Collegiate Funding Servs., Inc.*, 469 Fed. App'x 244, 256 (4th Cir. 2012) ("[B]ecause documents created by private parties constitut[e] materials of 'administrative hearings' for the FCA . . . privately-created SEC filings can . . . constitute an administrative report."); *U.S. ex rel. Repko v. Guthrie Clinic, P.C.*, No. 11-3682, 2012 WL 3104883, at *1 (3d Cir. Aug. 1, 2012) (characterizing website content as a public disclosure). Relator's complaint amounts to nothing more than a synthesis of general allegations of fraud "based" on facts from public reports of these investigations. *See Reagan*, 384 F.3d at 176 ("An FCA *qui tam* action even partly based upon public allegations or transactions is nonetheless based upon such allegations or transactions." (quotation marks omitted)).

[7] *See Fed. Recovery Servs., Inc. v. United States*, 72 F.3d 447, 450 (5th Cir. 1995) ("Any information disclosed through civil litigation and on file with the clerk's office should be considered a public disclosure of allegations in a civil hearing for purposes of section 3730(e)(4)(A) (2009)." (quotation marks omitted)).

B. Relator is Not an Original Source.

Where, as here, a complaint is based entirely upon public disclosures, the action is jurisdictionally barred unless Relator establishes that she is an original source. 31 U.S.C. § 3730(e)(4)(A). To qualify as an original source, Relator must "possess direct and independent knowledge of the information on which the publicly disclosed allegations are based." *Reagan*, 384 F.3d at 177 (quotation marks omitted). Relator's allegations demonstrate neither "direct" nor "independent" knowledge of any publicly disclosed information. To the contrary, Relator's INFUSE Publication Allegations are derived entirely from public disclosures. *See* pp. 6–7, above; *Reagan*, 384 F.3d at 179 (second-hand information is not direct and independent knowledge "simply because the plaintiff discovered through investigation or experience what the public already knew"). Even if Relator contributed new non-public details regarding Dr. Lewis (which she did not, because that information was obtained from publicly-disclosed financial documents or from her public lawsuit with Dr. Lewis) her claims would still be subsumed within the same underlying theory of unapproved promotion and sales alleged in prior complaints and should be dismissed. *See, e.g.*, *Branch Consultants*, 560 F.3d at 378 (relator cannot avoid the first-to-file bar "by simply adding factual details or geographic locations to the essential or material elements of a fraud claim against the same defendant described in a prior compl[ai]nt").

Despite the multiple public disclosures outlined above (which allege the same facts in Relator's Complaint), Relator has made nothing more than a conclusory allegation that she is an original source, stating that "after she read various media reports, she conducted an investigation"—which amounted to reviewing publicly-available material on the Mississippi Secretary of State's Office website. Compl. ¶ 86. Thus, Relator *admits* that she has relied entirely on publicly-released information as the foundation of her *qui tam* complaint. The FCA

requires that duplicative lawsuits such as hers must be dismissed. 31 U.S.C. § 3730(e)(4)(A); *Stennett v. Premier Rehab., LLC*, 479 Fed. App'x 631, 634 (5th Cir. 2012).

C. The FCA's First-to-File Rule Bars a Relator from Bringing an Action Based upon the Same Facts as a Previously-Filed FCA Action.

This Court also lacks subject matter jurisdiction over Relator's allegations under the FCA's first-to-file rule. Under the FCA, once a *qui tam* action has been filed, "no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5) (2006). Like the public disclosure bar, the first-to-file bar is intended to stem abuse of the FCA by "'parasitic' relators who bring FCA damages claims based on information within the public domain or that the relator did not otherwise uncover." *U.S. ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 16 (1st Cir. 2009). The first-to-file rule furthers Congress's objective of encouraging early disclosure of fraud to the government and preventing the filing of duplicative lawsuits. *U.S. ex rel. Denenea v. Allstate Ins. Co.*, No. 07-2795, 2011 WL 231780, at *3 (E.D. La. Jan. 24, 2011).

The first-to-file bar prevents subsequent claims that state all the "essential facts" or the same "elements of fraud" of a previously-filed claim. *Branch Consultants*, 560 F.3d at 378. The later claim need not allege "identical" facts, but rather is barred "even if that claim incorporates somewhat different details." *Id.* at 377. The analysis applies on a claim-by-claim basis. *See Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 476 (2007) (explaining that, in the context of the public disclosure bar, the FCA "does not permit jurisdiction in gross" merely because there is jurisdiction over some claims).

Here, a claim-by-claim comparison shows that Relator's allegations related to physician payments are based on the same essential facts as those alleged in the prior FCA cases. Indeed, payments to Dr. Zdeblick during the time period in which he drafted the peer-reviewed

publications at issue here were released pursuant to the terms of Medtronic's 2006 *qui tam* settlement. Caffrey Decl. Ex. 16 at 2, 4. In addition, the later *Poteet II* complaint alleged that Medtronic consultants and royalty earners, including Dr. Zdeblick, initiated "a coordinated campaign" in part through publication in peer-reviewed medical journals "to expand the market for INFUSE." Caffrey Decl. Ex. 17 at ¶ 290–92.

In short, Relator has the burden of establishing that the Court has jurisdiction over her Complaint despite the numerous public disclosures described above. In light of the significant prior disclosures, including the extensive prior FCA litigation precisely on point, Relator has failed to carry her burden. *Reagan*, 384 F.3d at 176.

II. THE COMPLAINT FAILS TO STATE A COGNIZABLE CLAIM UNDER THE FCA (COUNTS I–III) BECAUSE RELATOR HAS NOT ALLEGED THAT MEDTRONIC KNOWINGLY CAUSED THE SUBMISSION OF ANY FALSE CLAIM.

Relator appears to advance three general theories of FCA liability: *first*, that Medtronic collaborated with the physician defendants to disseminate favorable peer-reviewed journal articles to "broaden the use" of INFUSE; *second* that Medtronic conspired with Dr. Lewis to perform experimental procedures with the Pyramid Plate to expand the use of that product; and *third* that Medtronic caused false and fraudulent claims for payment to federal healthcare providers by making or causing false representations of compliance with the AKS. Compl. ¶¶ 28–59, 68, 92–93. Relator, however, has failed to allege the most basic elements of an FCA claim.

To avoid dismissal under Federal Rule of Civil Procedure 12(b)(6), a complaint "must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quotation marks omitted). Although "[t]he plausibility standard is not akin to a 'probability requirement,'" plaintiff must show more than "a

sheer possibility that a defendant has acted unlawfully." *Id.*; *see also Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Relator must allege facts from which one may "draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. Courts have held that to properly plead a FCA complaint relator must at a minimum allege "(1) a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that is presented to the government." *U.S. ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 267 (5th Cir. 2010).[8] As discussed further below, she has not done so.

A. Relator Has Failed to Identify Any Material False Claim or False Record for Payment.

The *sine qua non* of an FCA violation is a false claim. *U.S. ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002); *U.S. ex rel. Jamison v. McKesson Corp.*, 784 F. Supp. 2d 664, 676 (N.D. Miss. 2011). Count I must be dismissed because the complaint fails to allege that any false claims were "presented" to the government. 31 U.S.C. § 3729(a)(1); *see U.S. ex rel. Nunnally v. W. Coast Calcasieu Cameron Hosp.*, No. 2:08 CV 0371, 2012 WL 1866586, at *2 (W.D. La. May 21, 2012). Similarly, Count II must be dismissed because Relator never alleges that a "false record or statement" was used to get a "false or fraudulent claim." 31 U.S.C. § 3729(a)(2); *see Nunnally*, 2012 WL 1866586, at *2. Indeed, nowhere in the complaint does Relator describe any information provided to the Government in connection with a claim for reimbursement, let alone information that proved to be false.[9] *See, e.g., Colquitt.*, 864 F.

[8] On May 20, 2009, Congress passed the Fraud Enforcement and Recovery Act of 2009 ("FERA"), amending the Federal False Claims Act, altering the language of these subsections and re-designating them as § 3729(a)(1)(A), § 3729(a)(1)(B), and § 3729(a)(1)(C), respectively. *See* Pub. L. No. 111-21m, 123 Stat. 1617, 1621 (2009). Relator's claims fail under either version of the statute.

[9] Relator's pleading deficiency is magnified in the context of her own surgery, where she failed to allege whether Relator's procedure would have been paid for by a federal healthcare program as opposed to a private insurer, information that would have been in the purview of Relator's personal knowledge. *Nunnally*, 2012 WL 1866586, at *3.

Supp. 2d at 530 ("[L]iability 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."). At best, the complaint sets out a series of allegations that, she says, indicate a general marketing scheme "designed to broaden the application of [INFUSE and Pyramid] by end users." Compl. ¶ 15. In addition, the complaint avers in a conclusory manner that Defendants falsely certified compliance with the AKS in connection with claims for reimbursement. Compl. ¶ 93. Neither allegation is sufficient, as a matter of law, to raise a plausible claim for relief. *U.S. ex rel. Rafizadeh v. Cont'l Common, Inc.*, 553 F.3d 869, 873 (5th Cir. 2008) (Relator "must state the factual basis for the fraudulent claim with particularity and cannot rely on speculation or conclusional allegations.").

Broadened Application of INFUSE and Pyramid. As the Supreme Court has noted, "off-label use [of medical devices] is generally accepted" in medical practice, *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 351 (2001), and is expressly permitted under the FDCA, *see* 21 U.S.C. § 396 (2006). Off-label use is also not a bar to federal reimbursement. *U.S. ex rel. George v. Bos. Sci. Corp.*, 864 F. Supp. 2d 597, 600 (S.D. Tex. 2012) ("The FDA does not restrict hospitals from purchasing, or physicians from prescribing or using, products for off-label uses. To the contrary, off-label use of many medical devices and drugs is an accepted medical practice."). Accordingly, allegations of off-label promotion are insufficient to bring rise to FCA liability. *U.S. ex rel. King v. Solvay S.A.*, 823 F. Supp. 2d 472, 510 (S.D. Tex. 2011), *partially vacated on other grounds* 2012 WL 1067228 (S.D. Tex. Mar. 28, 2012) ("FCA liability does not attach to violations of federal law or regulations, such as marketing of drugs in violation of the Food, Drug, & Cosmetic Act, that are independent of any false claim." (citations omitted)); *U.S. ex rel. Bennett v. Bos. Sci. Corp.*, No. H-07-2467, 2011 WL 1231577, at *29 (S.D. Tex. Mar. 31, 2011) ("[E]ven if a drug or device manufacturer's marketing or promotion activities violate FDA

regulations, that is insufficient to plead that the manufacturer caused physicians or hospitals to submit false claims for reimbursement.").[10]

The mere fact that a claim involves off-label use of a product does not make such a claim false, because it does not have a "natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Steury*, 625 F.3d at 269 (quotation marks omitted). As noted above, Relator must establish materiality for her claim to survive. *Id.* at 267. Federal Health Care Programs allow reimbursement for off-label use of approved products and typically reimburse at a flat rate based on the procedure at issue rather than the products used. *See* 42 U.S.C. § 1395ww(d) (2006); 42 C.F.R. § 412.20 (2012); *see, e.g., U.S. ex rel. Stephens v. Tissue Sci. Labs., Inc.*, 664 F. Supp. 2d 1310, 1318 (N.D. Ga. 2009) ("[E]ven if Relators' allegations regarding the fraudulently induced off-label uses of [a device] are true, the [device's] use would not have impacted the amount of reimbursement . . . . Under the [prospective payment systems ("PPS")], Medicare would have paid the same [diagnosis-related group ("DRG")] amount if [the device] was used on-label, off-label, or if an entirely different product were used."). Relator's off-label promotion allegations therefore amount to no more than an impermissible attempt to use the FCA—which focuses entirely on the falsity of claims submitted to the government, not off-label promotion—to bring her own private cause of action. *See Buckman*, 531 U.S. at 349 n.4, 351. Reimbursement for off-label uses of a product is based on whether the use of the item is "reasonable and necessary for the diagnosis or treatment" of an illness. 42 U.S.C. § 1395y(a)(1)(A) (2006). Relator has made not a single allegation that the alleged scheme

[10] *See also Hughes v. Bos. Sci. Corp.*, 631 F.3d 762, 775 (5th Cir. 2011) (noting that a private plaintiff cannot "assert a freestanding federal cause of action based on violation of the FDA's regulations"); *Cross v. Amtec Med. Inc.*, No. 3:09-cv-00168, 2012 WL 4603396, at *9 (S.D. Miss. Sept. 30, 2012) ("[E]ven if Amtec marketed . . . for an off-label use, only the FDA or the Department of Justice possesses the power to enforce the FDCA.").

caused any physician to make a claim for use of INFUSE for medically unnecessary reasons, or that that any of the alleged activities were in any way material to the government's decision to reimburse any such claim. *Colquitt*, 864 F. Supp. 2d at 534 ("[T]he 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."). As such, Relator has failed to establish the reasonable inference that any claims were submitted to the government for unlawful reimbursement and thus its FCA claims must be dismissed.

Purported AKS Claims. Relator's complaint suggests that the publication of certain articles by authors who happened to be Medtronic consultants somehow caused the submission of false claims. She alleges no such submitted claims and seems to rely on a general theory that there must have been claims submitted that falsely certified compliance with the AKS. In addition to the lack of causation pled here, the complaint cannot allege false certifications of the AKS without an underlying AKS violation. *U.S. ex rel. Jamison v. McKesson Corp.*, No. 2:08cv214, 2012 WL 4499136, at *11 (N.D. Miss. Sept. 28, 2012) (rejecting FCA claim premised upon AKS violation "because there was no violation of the Anti-Kickback Statute"). The AKS prohibits the solicitation or receipt of remuneration in return for referrals of patients covered by federal government programs and the payment of remuneration to induce such referrals. 42 U.S.C. § 1320a-7b (2006). FCA liability arises only where a defendant "makes a knowingly false certification of compliance with a statute or regulation; and [] the certification is a prerequisite to payment." *Nunnally*, 2012 WL 1866586, at *3 (citing *United States v. Southland Mgmt. Corp.*, 288 F.3d 665, 679 (5th Cir. 2002)).

Without sufficient allegations of a predicate AKS violation, Relator's complaint fails as a matter of law to assert any false claim. Relator's complaint does nothing more than to allege that

Medtronic had pecuniary relationships with the physician defendants and that such payments were "shams." Compl. ¶¶ 58, 69, 80, 82–83; Compl. App. W, X. Relator's allegations here are premised upon a mistaken assumption that payments made by industry to physicians are *per se* illegal. Only payments that were intended to induce referrals or otherwise improperly influence physician decisions, however, are barred by the AKS, 42 U.S.C. § 1320a-7b, not those that were intended for other, lawful purposes. *Jamison*, 2012 WL 4499136, at *15 (N.D. Miss. Sept. 28, 2012). Relator must allege that Medtronic (1) knowingly and willfully (2) solicited or received, or offered or paid remuneration (3) in return for, or to induce, referral or program-related business. *See* 42 U.S.C. § 1320a-7b. The AKS is an intent-based statute that requires a defendant to intend to violate the law or, at the very least, act with the "intent to do something the law forbids." *United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998) (quotation marks omitted). Moreover, the statute and governing regulations provide for explicit safe harbors from AKS liability for certain payments made to physicians, including those for "personal services" contracts. 42 C.F.R. § 1001.952(d) (2012). In light of this detailed regulatory regime, under well-established precedent, merely hurling conclusory allegations that the alleged payments were "shams" is not enough to sustain an action under the FCA. *Nunnally*, 2012 WL 1866586, at *3 (dismissing an FCA claim premised upon false certification of compliance with the AKS where the complaint failed to allege that payments "induced any improper referrals"). Without facts to support such allegations, Relator has failed to plead that the payments to physicians were intended to induce referrals and therefore her claims predicated upon an alleged AKS violation must be dismissed. *Id*.

In addition, Relator has failed to assert the existence of a false certification of compliance. *Gonzalez v. Fresenius Med. Care N. Am.*, 689 F.3d 470, 475 (5th Cir. 2012). Instead, Relator

summarily concludes that "in making claims for services and product reimbursements, the Defendants, and each of them, represented compliance with a material condition of payment that was not met."[11] Compl. ¶ 93; *see U.S. ex rel. Willard v. Humana Health Plan of Tex., Inc.*, 336 F.3d 375, 379 (5th Cir. 2003) ("[C]onclusory allegations will not suffice to prevent a motion to dismiss and neither will unwarranted deductions of fact." (quotation marks and citations omitted)). It is well-established that a violation of the AKS alone does not create a cause of action under the FCA because evidence of an actual false claim is essential to an FCA violation. *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 785 (4th Cir. 1999) ("The statute attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the 'claim for payment.'" (citation omitted)); *U.S. ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266 (9th Cir. 1996). Thus, even if there was an underlying violation of the AKS, there must still be a false claim for payment. *Harrison*, 176 F.3d at 785. Relator's general allegations merely assume that such claims for payment were made without identifying any single such actual claim. Generalized allegations like the ones advanced by Relator have been ruled insufficient to allege a false certification theory in this Circuit. *See Bennett*, 2011 WL 1231577, at *32 (dismissing for failure to state a claim where "the relator has not alleged that the defendants caused any hospital or physician to certify compliance with the antikickback statute").

B. Relator Has Failed to Allege that Medtronic Knowingly Caused the Submission of Any False Claim.

Counts I and II must also be dismissed because the complaint fails to assert that the Company "caused . . . physicians or hospitals to make false certifications of compliance."

[11] Relator also avers that Defendants submitted false certifications "to avoid further payments, penalties, or obligations under the reverse false claims provisions of 31 U.S.C. § 3729(a)(7)." Compl. ¶ 99. The Fifth Circuit has not adopted implied certification of liability as actionable under the FCA. *Willard*, 336 F.3d at 381–82; *Jamison*, 2012 WL 4499136, at *10–*11. As a result, relator cannot assert a claim based on any certification that is not alleged to be a prerequisite to payment. *Id*.

Bennett, 2011 WL 1231577 at *32. The FCA requires that Relator make a showing of "some degree of participation in the claims process," or at the very least "an ongoing business relationship with a repeated false claimant" coupled with knowledge "that claims are being submitted to the United States." *United States v. President & Fellows of Harvard Coll.*, 323 F. Supp. 2d 151, 186-87 (D. Mass. 2004). Alternatively, to violate (a)(1)(B), "a person must have the purpose of getting a false or fraudulent claim 'paid or approved by the Government' in order to be liable under § 3729(a)(2)." *Allison Engine Co. v. U.S. ex rel. Sanders*, 553 U.S. 662, 669–70 (2008). There is no allegation that Medtronic submitted any claims for reimbursement—false or otherwise—to the government. Moreover, the complaint fails to allege facts showing that any actions or statements by Medtronic caused the submission of any false claim by anyone else, much less does it allege that Medtronic knowingly caused the submission of any such false claim. *See Steury*, 625 F.3d at 267. The complaint contains no allegations, besides conclusory statements, from which it can be inferred that Medtronic was even aware of any physician defendant claims for reimbursement, let alone that the Company took any action to advise the defendants on the substance of those claims. *See, e.g.*, Compl. ¶ 92; *Colquitt*, 864 F. Supp. 2d at 535 (requiring Relator to "identify the supposedly false statements" made by defendant medical device manufacturers in reimbursement guides to survive a motion to dismiss). As such, Relator has failed to properly allege a critical element and the complaint should be dismissed.

C. Relator Has Failed to Allege that Medtronic Knowingly Conspired to Defraud the Government.

Count III of the Relator's complaint, which alleges that the Defendants conspired to submit false claims, must be dismissed because the complaint fails to allege facts revealing any such conspiracy. Indeed, the complaint includes no allegations regarding any agreement between Medtronic and the other defendants, the substance of any discussions between

Medtronic and Dr. Zdeblick, Dr. Dickman, or Dr. Lewis *at all*, and certainly none regarding claims for reimbursement. *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 193 (5th Cir. 2009) (requiring "(1) the existence of an unlawful agreement between defendants to get a false or fraudulent claim allowed or paid by [the Government] and (2) at least one act performed in furtherance of that agreement" (quotation marks omitted)).

The complaint's allegations concerning Medtronic's payments to Dr. Zdeblick and Dr. Dickman pursuant to royalty and consulting agreements in no way show that the agreements were unlawful or in any way connected to a conspiracy to submit false claims for reimbursement. To state a claim, Plaintiff must plead "conduct which was designed to present false information" to establish the requisite intent under the statute. *U.S. ex rel. Hess v. Sanofi-Synthelabo, Inc.*, No. 4:05CV2195MLM, 2006 WL 1064127, at *10 (E.D. Mo. April 26, 2006). The complaint does not allege that Medtronic instructed either physician to draft an article with supposedly false information, that Medtronic disseminated the articles with the knowledge that they conveyed allegedly false information, or that the articles caused a false claim. This pleading is not enough to state a claim.[12]

[12] Relator's § 3729(a)(2) and (a)(3) claims also fail because it is insufficient for a plaintiff to merely allege that "a false statement resulted in the use of Government funds to pay a false or fraudulent claim." *Allison Engine*, 553 U.S. at 671–72 ("If a subcontractor or another defendant makes a false statement to a private entity and does not intend the Government to rely on that false statement as a condition of payment, the statement is not made with the purpose of inducing payment of a false claim 'by the Government."). Under *Allison Engine*, a plaintiff must prove that the defendant intended that the false record or statement be material to the government's decision to pay or approve the false claim. *See id.* at 665. Applying this standard, the Eleventh Circuit held that relators' section (a)(2) and (a)(3) claims based on defendant's alleged off-label marketing failed because the relators failed to allege "that the defendants intended for the government to rely on the substance of their off-label marketing campaign to decide to pay a claim." *Hopper v. Solvay Pharms., Inc.*, 588 F.3d 1318, 1330 (11th Cir, 2009). Similarly here, Relator has not alleged any "facts" that would indicate that Defendants intended to deceive the government.

D. Relator's FCA Claims In Connection with Allegations Regarding Medtronic's Payments to Dr. Zdeblick Are Barred by Release.

The FCA operates to "effect[] a partial assignment of the government's damages claim" to the relator. *Vt. Agency of Natural Res. v. U.S. ex rel. Stevens*, 529 U.S. 765 (2000). Accordingly, a *qui tam* relator cannot pursue a claim that has been released by the government through settlement. *See U.S. ex rel. Barajas v. Northrop Corp.*, 147 F.3d 905, 911 (9th Cir. 1998). As relevant here, in connection with the 2006 settlement agreement with Medtronic of the *Doe* and *Poteet qui tam* actions, the federal government released any "claim or cause of action the United States has or may have against Medtronic or MSD under the False Claims Act" related to "payments made pursuant to consulting, royalty, fellowship and research agreements with the physicians and entities listed as defendants in the [*U.S. ex rel. Doe v. Medtronic* and *U.S. ex rel. Poteet v. Medtronic*] *qui tam* suits…between January 1, 1998 and April 30, 2003." Caffrey Decl. Ex. 16 at 2, 4. Dr. Zdeblick was listed as a defendant in *U.S. ex rel. Poteet v. Medtronic*. Caffrey Decl. Ex. 19 at 3.

Furthermore, because any alleged payments made to Dr. Zdeblick are not actionable, Relator cannot bring a cause of action based on inferences that Dr. Zdeblick somehow funneled funds to Dr. Lewis on Medtronic's behalf. *See* Compl. ¶ 88. Relator makes no allegation that Medtronic's payments to Dr. Zdeblick were not made pursuant to "consulting, royalty, fellowship and research agreements." Caffrey Decl. Ex. 16 at 2. To the contrary, the complaint repeatedly references Dr. Zdeblick's royalties on the LT-CAGE® Lumbar Tapered Fusion Device. Compl. ¶ 38, 41. Relator has not alleged any other facts sufficient to even imply that Dr. Lewis may have been paid by Medtronic *for any services*. As a result, the 2006 settlement agreement eviscerates Relator's purported theories of FCA liability with respect to any of the alleged payments to Dr. Zdeblick.

III. THE COMPLAINT'S VAGUE ASSERTIONS REGARDING MEDTRONIC'S PHYSICIAN RELATIONSHIPS AND PROMOTIONAL ACTIVITY DO NOT SATISFY THE PARTICULARITY REQUIRED BY RULE 9(B).

Claims brought under the FCA must be pled with the particularity required by Fed. R. Civ. P. Rule 9(b). *U.S. ex rel. Thompson v. Columbia/HCA Healthcare*, 125 F.3d 899, 903 (5th Cir. 1997). Rule 9(b) not only ensures that defendants receive adequate notice of specific conduct alleged to have been fraudulent, but also stands "as a gatekeeper to discovery, a tool to weed out meritless fraud claims sooner than later." *Grubbs*, 565 F.3d at 185. To guard against such meritless suits, this Circuit has required, at an absolute minimum, that Relator allege "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Id.* at 190. An FCA complaint cannot survive a motion to dismiss without providing particular details to describe the "who, what, when, where, and how" of the fraud. *Thompson*, 125 F.3d at 903 (quotation marks omitted). Here, Relator has failed to allege *any* particular details, provide *any* reliable indicia that a false claim was actually submitted, or explain how *any* purported fraudulent scheme worked. *See U.S. ex rel. Hebert v. Dizney*, 295 Fed. App'x 717, 722 (5th Cir. 2008).

Nowhere in her 114 paragraph complaint does Relator identify a single reimbursement claim submitted to any government payor by Medtronic or any other provider. Although Relator has cobbled together an elaborate set of disparate facts, she has utterly failed to identify any claim of payment as a result of this conduct (including basic facts such as who made the claim; why they made the claim; and when the claim was made). *Grubbs*, 565 F.3d at 186; *Thompson*, 125 F.3d at 903 (complaint failed to meet particularity requirements of Rule 9(b) where it "did not identify any specific physicians . . . or any specific claims . . . submitted by defendants").

Moreover, the complaint's INFUSE Publication Allegations are utterly devoid of particular facts tending to show any indicia of a purported scheme to cause false claims to be

submitted. *Bennett*, 2011 WL 1231577, at *17 (dismissing complaint where relator "relie[d] only on the allegation that defendants extensively promoted" a medical device without pleading "representative examples of specific fraudulent acts conducted pursuant to [a] scheme" or "an instance of submission" (quotation marks omitted)). To the contrary, the allegations pile inference upon inference generally alleging that certain physician authors published articles about INFUSE in various peer-reviewed journals, and that Medtronic allegedly paid these authors using "sham consulting fees, royalty fees, and other educational fees and benefits," as part of effort to "broaden the application of both products by end users." Compl. ¶ 15, 90. The complaint contains no specific allegations of any communications between the Defendants to form such a scheme. Nor does the complaint allege that Medtronic knowingly joined in or conspired to effect any such purported scheme. *See Hess*, 2006 WL 1064127, at *9–*10. Relator makes no claim as to Medtronic's knowledge that any purported false statements were part of a scheme to submit false claims. *Id*. Finally, Relator does not plead that any publications or recommendations made by Defendants caused the submission of specific claims for non-reimbursable uses. *See Colquitt*, 864 F. Supp. 2d at 534–55.

Relator's Pyramid Plate allegations similarly fail to allege with the particularity required by Rule 9(b) that a conspiracy existed between Dr. Lewis and Medtronic to cause false claims. *See Hess*, 2006 WL 1064127 at *11. Again, Relator strings together disparate facts stemming from her medical malpractice lawsuit and her research on public databases to assert that Dr. Lewis conspired with Medtronic by "experimenting on patients by using the Pyramid Plate and Infuse to provide cover for sham agreements, whereby information gathered from use on [] unknowing patients could be passed off as justifications for the Defendant physicians real contributions" and to expand the approved use of these devices by showing successful off-label

uses on "unknowing human subjects." Compl. ¶ 68-70. This conspiracy theory fails to allege any relationship (financial or otherwise) between Dr. Lewis and Medtronic, let alone a conspiracy to submit false claims. *Grubbs*, 565 F.3d at 193 ("[A] plaintiff alleging a conspiracy to commit fraud must plead with particularity the conspiracy as well as the overt acts taken in furtherance of the conspiracy." (quotation marks and ellipsis omitted)). The complaint identifies no specific communication between Dr. Lewis and Medtronic about Relator's surgery, nor any discussions about submitting a claim for reimbursement. Relator does not allege that the procedure was reimbursed by the federal government (*i.e.*, any specific claim for payment). Nor does Relator assert that the procedure was one which would not have been reimbursed by government payers. *Colquitt*, 864 F. Supp. 2d at 531. Moreover, Relator does not identify *any payments* made by Medtronic, Dr. Zdeblick, or Dr. Dickman to Dr. Lewis. Indeed, the only facts pled in the complaint establish that there *were no such payments*. Compl. ¶¶ 62–64, 83–84.

Finally, Relator's AKS false certification allegations summarily fail to show specific facts indicating that any claim was submitted, a certification was made in connection with that claim, that certification was false, or that Medtronic knowingly caused such a claim. Relator has pled no facts, let alone "reliable indicia," that would support a "strong inference" that any false claim was submitted. *Grubbs*, 565 F.3d at 185. Moreover, Relator assumes that payments to Defendants implicate the AKS simply because they were made. *See U.S. ex rel. Osheroff v. Tenet Healthcare Corp.*, No. 09-22253-CIV, 2012 WL 2871264, at *8 (S.D. Fl. July 12, 2012) (requiring "factual allegations suggesting any *quid pro quo* of [remuneration] in exchange for referrals."). But she alleges no specific illegal payment that violates the AKS and therefore may serve as a predicate to a false certification claim. *See Jamison*, 2012 WL 4499136 at *17 (requiring the underlying elements of AKS to be pled to establish an FCA violation); *U.S. ex rel.*

Obert-Hong v. Advocate Health Care, 211 F. Supp. 2d 1045, 1049 (N.D. Ill. 2002) (finding that complaint must allege specific facts that payments to doctors were unreasonable). In reality, Relator's false certification pleadings amount to generic assertions that Defendants must have committed fraud. S*ee* Compl. ¶ 93. Such generic statements require dismissal because they fail to provide *any* indicia—let alone a strong one—to even suggest that a false claim was submitted or that the Defendants conspired to submit a false claim. *Nunnally*, 2012 WL 1866586, at *4 (dismissing Relator's complaint as deficient because it "does not identify any specific physicians, patients, services, or claims involved in the alleged scheme"). In short, the Complaint is utterly devoid of the required specificity in identifying and describing the transactions that are alleged to have violated the FCA, and accordingly must be dismissed. *Thompson*, 125 F.3d at 903.

IV. COUNTS IV, V, VI, AND VII MUST BE DISMISSED BECAUSE NO PRIVATE RIGHT OF ACTION EXISTS FOR THE STATUTES, REGULATIONS, AND AGREEMENTS RELIED UPON BY RELATOR.

Relator's remaining counts assert a hodgepodge of allegations (including stand alone violations of the AKS, violations of various criminal states and regulations, and a claim for relief based on a settlement agreement between Medtronic and the United States). These allegations are frivolous and should be dismissed. None of the statutes and regulations at issue affords an express or implied private right of action even under the FCA. The AKS "is framed as a general prohibition or command to a federal agency" and, therefore, the statute cannot be enforced by the public. *W. Allis Mem. Hosp., Inc. v. Bowen*, 852 F.2d 251, 255 (7th Cir. 1988); *see also U.S. ex rel. Reagan v. E. Tex. Med. Ctr. Reg. Healthcare Sys.*, 274 F. Supp. 2d 824, 839 (S.D. Tex. 2003). Moreover, the federal criminal statutes alleged in Count V are "purely penal" in nature and, therefore, "evidence[] no intent of Congress to grant additional federal question jurisdiction in a civil case." *Napper v. Anderson, Henley, Shields, Bradford & Pritchard*, 500 F.2d 634, 636 (5th Cir. 1974) (addressing mail fraud (18 U.S.C. § 1341) and wire fraud (18 U.S.C. § 1343); *see*

also Bell v. Health-Mor, Inc., 549 F.2d 342, 346 (5th Cir. 1977).[13] Nor can Relator premise an FCA claim based on alleged violations of these criminal provisions, because compliance with these provisions is "not a 'condition' or 'prerequisite'" for any of the Defendants to receive reimbursement from the government health programs. *Steury*, 625 F.3d at 268.

Similarly, Relator's claims centering on the "common rule" regulations, 45 C.F.R. § 46.101 *et. seq.* (2012), are also improper. The "common rule" regulations govern the protection of human subjects in research supported by the federal government. No private right of enforcement exists anywhere in their text or history.[14] *See id.* Relator also cannot premise a claim for relief under the FCA on an alleged violation of the common rule since compliance with the common rule is not a condition or prerequisite for payment by government programs. *Steury*, 625 F.3d at 268. In any event, no violation of the regulations occurred because Relator has not even alleged that any federally-funded research took place.

Finally, Count VII, based on alleged breaches of Medtronic's Corporate Integrity Agreement ("CIA"), must be dismissed because Relator is not a party to the contract. *See* Caffrey Decl. Ex. 20 at § I (Medtronic CIA) (specifying that the CIA is "enter[ed] into . . . with the Office of the Inspector General (OIG) of the United States Department of Health and Human Services (HHS)"). The terms of the CIA plainly state that remedies for a breach of the agreement are available only to the Office of the Inspector General of HHS. *Id.* § X (specifying

[13] The complaint cites non-existent §§ 1352, 1356, and 1357, but appears to mean §§ 1952, 1956, and 1957. Though no court in this circuit has addressed the viability of private rights of action under §§ 1952, 1956, and 1957, other courts have dismissed such claims on similar logic as *Napper* and *Bell*. *See, e.g., Schwartz v. F.S. & O. Assoc.*, No Civ. A. 90-1606, 1991 WL 208056, at *2–*3 (S.D.N.Y. Sept. 27, 1991).

[14] In fact, Congress recently considered available enforcement mechanisms for the "common rule," but failed to act. *See* Research Revitalization Act of 2002, S. 3060, 107th Cong. § 501 (2002) (proposed bill was never enacted and did not provide for a private right of enforcement).

"remedies available to the OIG if MSD fails to satisfy its obligations under [the] CIA"). This claim is accordingly frivolous and should be dismissed with prejudice.

The Complaint contains a final count asserting, in conclusory fashion, that the "Defendants' conduct," generally, would constitute an unjust enrichment "if allowed." Compl. ¶ 113. Relator's last ditch effort to articulate a legal theory of recovery should be dismissed because, to the extent that these state law claims are predicated upon violations of the FDCA and FDA regulations, they are preempted by the FDCA. 21 U.S.C. § 337(a) (2006); *Buckman*, 531 U.S. at 349 n.4. Moreover, even if the complaint was not preempted, it would still fail to state a claim for unjust enrichment. Under Mississippi law, Relator must "allege and show that the defendant holds money which in equity and good conscience belongs to" Relator. *Owens Corning v. R.J. Reynolds Tobacco Co.*, 868 So. 2d 331, 342 (Miss. 2004) (quotation marks omitted). But, Relator has not identified what monies Medtronic holds that in "good conscience" belong to her.

CONCLUSION

For the reasons set forth, Medtronic respectfully requests that the Complaint be dismissed with prejudice.[15]

[15] Relator's conclusory allegations are utterly insufficient to meet the standard of pleading required by Rule 9(b). As a result, Relator's complaint should be dismissed with prejudice, as it cannot be cured by amendment.

Dated this 26th day of November, 2012.

MEDTRONIC, INC. and MEDTRONIC SOFAMOR DANEK USA, INC.

By: /s/ Michael K. Fee

Michael K. Fee *(admitted pro hac vice)*
James P. Dowden *(pro hac vice motion pending)*
Andrew A. Caffrey, III *(admitted pro hac vice)*
Michael J. Vito *(admitted pro hac vice)*
ROPES & GRAY LLP
Prudential Tower
800 Boylston Street
Boston, MA 02199-3600
(617) 951-7000
michael.fee@ropesgray.com

ADAMS & REESE, LLP
Sharon F. Bridges (Miss. Bar No. 99423)
Laura Ford Rose (Miss. Bar No. 102256)
1018 Highland Colony Parkway, Suite 800
Ridgeland, MS 39157
(601) 353-3234
sharon.bridges@arlaw.com

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing document was served upon all counsel of record via ECF electronic filing on November 26, 2012.

/s/ Michael K. Fee
Michael K. Fee