UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES – GENERAL

Case No.	LA CV15-01212 JAK (ASx)	Date	September 11, 2017
Title	United States of America ex rel. v. Medtronic, Inc., et al.		

Present: The Honorable	JOHN A. KRONSTADT, UNITED STATES DISTRICT JUDGE

Andrea Keifer	Not Reported
Deputy Clerk	Court Reporter / Recorder
Attorneys Present for Plaintiffs:	Attorneys Present for Defendants:
Not Present	Not Present

Proceedings: **(IN CHAMBERS) ORDER RE DEFENDANTS' MOTION TO DISMISS FIRST AMENDED COMPLAINT (DKT. 57)**

I. Introduction

On February 19, 2015, The Dan Abrams Company LLC ("Relator") filed its initial *qui tam* complaint in this action ("Complaint" (Dkt. 1)), alleging violations of the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733, and parallel state statutes. The First Amended Complaint ("FAC" (Dkt. 32)), which is the operative one at this time, was filed on July 29, 2016. It was filed on behalf of the federal government, 31 states and the District of Columbia. *Id.* All of them have declined to intervene. Dkt. 18. The defendants in the FAC include: Medtronic Inc.; Medtronic PLC; Sofamor Danek USA, Inc.; Warsaw Orthopedic, Inc.; Medtronic Sofamor Danek Deggendorf GMBH; and Medtronic Puerto Rico Operations co., Humacao (collectively "Defendants"). The allegations relate to the development, sale and marketing by Defendants of certain spinal implant devices ("Subject Devices").

On October 14, 2016, Defendants moved to dismiss the FAC ("Motion" (Dkt. 57)). Relator opposed the Motion (Dkt. 64) and Defendants replied. Dkt. 67. A hearing on the Motion was held on February 13, 2017, and it was taken under submission. Dkt. 70.

For the reasons stated in this Order, the Motion is **GRANTED**.

II. Factual Background

A. The Subject Devices

Medtronic, Inc. manufactures, markets and sells products for the treatment of various medical disorders. Dkt. 32 ¶ 31; Dkt. 57-1 at 11. Medtronic, PLC is a corporation headquartered in Ireland. Dkt. 32 ¶ 25. The other defendants named in this case are subsidiaries of Medtronic, Inc. *Id*. ¶¶ 26-31. The FAC alleges that "Defendants are the world's largest manufacturer of spinal implants." *Id*. ¶ 36.

Relator is an LLC whose sole member, Bryan Shapiro, is a former employee of Medtronic, Inc. *Id.* ¶24; Dkt. 53. Relator alleges that Shapiro has inside information about Defendants' business practices.

The spinal implant products manufactured and sold by Defendants include the Verte-Stack brand, which includes devices used in spinal fusion surgeries. Dkt. 57-1 at 11. In such a surgery, the vertebrae are "essentially welded, or fused, together so they heal into a single, solid bone." *Id*. Verte-Stack products include various "vertebral body replacement devices, which are used to replace the space left by the removal of both a vertebra (or part of it) and an adjacent disc." *Id.* at 12. Bone grafting material adheres to the devices. This results in the fused vertebrae and implant healing into a single solid bone. *Id.* at 12. The procedure of interbody fusion is referred to as a corpectomy. Dkt. 32 ¶ 156. In other procedures, devices are used to replace a disk that has been removed. Devices used in such procedures are defined as those for "interbody fusion" or "intervertebral body fusion." Defendant states that the design and functionality of vertebral body replacement devices and interbody fusion devices are similar.[1] Both are commonly referred to as "cages" or "spacers."

The Verte-Stack brand includes several "families" of products, with different designs. Each family includes a variety of stackable components. This permits a range of sizes that can be matched to a particular patient's anatomy and the space created by the corpectomy. Dkt. 57-1 at 12. These devices, and certain other related devices, are the basis of the FAC.

B. Request for Judicial Notice

Defendants have filed a request for judicial notice (Dkt. 58) as to the following:

- *FDA Medical Devices Advisory Committee, Orthopedic and Rehabilitation Devices Panel, Transcript of Open Session (Dec. 11, 2003)*, available at FDA's website: www.fda.gov/ohrms/dockets/ac/03/transcripts/4011T1.doc.
- Verte-Stack Spinal System, 510(k) Summary (Mar. 14, 2007), available at FDA's website: https://www.accessdata.fda.gov/cdrh_docs/pdf7/K070173.pdf (last visited on October 11, 2016).
- Medicaid and CHIP Payment and Access Commission, Medicaid Inpatient Hospital Services Payment Policy (Mar. 2016), available at Medicaid and CHIP Payment and Access Commission's website: https://www.macpac.gov/wpcontent/uploads/2016/03/Medicaid-Inpatient-Hospital-Services-Payment-Policy.pdf.
- CMS, Medicare-Diagnosis Related Group Codes (2008), available at Centers for Medicare and Medicaid Services' website: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareFeeforSvcPartsAB/downloads/DRGdesc08.pdf.

All of these are official documents that have been made available by the U.S. Food and Drug Administration ("FDA") and the Centers for Medicare & Medicaid Services ("CMS"). They provide facts that are capable of accurate and ready determination by referring to sources whose accuracy cannot reasonably be questioned. Fed. R. Evid. 201(b). Therefore, judicial notice is appropriate as to these materials, and the request that the Court do so is **GRANTED**.

[1] In support of this position, Defendant cites "FDA Medical Devices Advisory Committee, Orthopedic and Rehabilitation Devices Panel, Transcript of Open Session, at 44, 106, 162 (Dec. 11, 2003) ("FDA Transcript"), available at www.fda.gov/ohrms/dockets/ac/03/transcripts/4011T1.doc. On the grounds stated below, a court may take judicial notice of such public records in connection with analyzing a motion to dismiss. Fed. R. Evid. 201; *United States v. Ritchie*, 342 F.3d 903, 907-08 (9th Cir. 2003).

C. FDA Approval of Medical Devices

Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq*., the FDA regulates whether devices may be sold and promoted for particular purposes. *See* 21 U.S.C. §§ 301 *et seq*. The FDCA classifies such medical devices into three categories, with corresponding levels of regulatory review. *Id*. § 360c(a)(1). Class III devices include those that present an unreasonable risk of illness or injury. *Id*. § 360c(a)(1)(C). They are subject to a rigorous premarket approval ("PMA") process. It requires the manufacturer to submit valid scientific evidence demonstrating that there is reasonable assurance that the device is safe and effective for its intended use. *Id*. §§ 360c(a)(1)(C), 360e(a), (c), (d); 21 C.F.R. pt. 814. After the PMA process is complete, Class III devices may be granted premarketing clearance, thereby allowing their sale. 42 C.F.R. § 405.201(b). If a Class III device is without PMA approval, it may be deemed "adulterated," and cannot be offered for sale. *See* 21 U.S.C. § 351(f)(1)(B)(ii) ("A . . . device shall be deemed to be adulterated . . . if it is a class III device . . . which . . . is required to have in effect an approved application for premarket approval . . . and . . . which has an application which has been suspended or is otherwise not in effect.").

In general, Class II devices may be marketed and sold once they receive "§ 510(k)" clearance. That clearance may be granted when a device is shown to be "substantially equivalent" to another legally marketed device that has FDA clearance, or meets other criteria. *See* 21 U.S.C. § 360c(i). Section 510(k) clearance is not equivalent to FDA "approval" of a device. 21 C.F.R. § 807.97. Instead, the FDA only clears such devices for the limited uses identified by the manufacturer in the § 510(k) application. *See* 21 C.F.R. § 801.5.

When a medical device has been cleared, or granted PMA approval, for a certain use, that use must be disclosed on its label. "Any use by a physician which differs from the use described in the label or from the patient conditions described in the label is called 'off-label.'" *Carson v. Depuy Spine, Inc*., 365 Fed. Appx. 812, 815 (9th Cir. 2010). Under the FDCA, physicians are permitted to prescribe medical devices for off-label use. 21 U.S.C. § 396; *see also Buckman Co. v. Plaintiffs' Legal Committee,* 531 U.S. 341, 351 & n.5 (2001) (citing James M. Beck & Elizabeth D. Azari, *FDA, Off–Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 FOOD & DRUG L.J. 71, 72 (1998) ("Off-label use is widespread in the medical community and often is essential to giving patients optimal medical care, both of which medical ethics, FDA, and most courts recognize.")). However, the FDCA restricts manufacturers from marketing or promoting off label uses. Thus, 21 U.S.C. § 331 prohibits, "[t]he introduction or delivery for introduction into interstate commerce of any . . . device . . . that is adulterated or misbranded." *See also* 21 C.F.R. § 814.80 ("A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device."). The sale of a device for off-label use does not constitute a *per se* violation of the FDCA. Instead, the manufacturer must have marketed or promoted the device for that purpose. *See Carson*, 365 Fed. Appx. at 815.

The vertebral body replacement devices at issue here are treated by the FDA as Class II devices. Therefore, to be marketed they must have § 510(k) clearance on the basis of similar products that have been approved through the PMA process. *See* 21 C.F.R. § 888.3060. The devices at issue were reclassified as Class II in July 2007. That is when the FDA adopted final regulations that reclassified from Class III to Class II intervertebral body fusion devices used in all regions of the spine. *See* 21 C.F.R. §

888.3080. One reason cited as a basis for this regulation was that such devices were similar to other vertebral body replacement devices that had been treated as Class II devices. *See* FDA Transcript at 44, 106, 162.

D. Medicare and Medicaid Coverage of Medical Devices

Medicare and Medicaid are federally funded health insurance programs for the aged, impoverished and disabled. 42 U.S.C. §§1395 *et seq.* (the "Medicare Act"). Both programs are overseen by CMS. 42 U.S.C. §§ 1395 *et seq*. Medicare is administered through local contractors; Medicaid is administered by the states. Medicaid provides reimbursement for medical treatments for the "medically needy." 42 C.F.R. § 440.230. Each state Medicaid program has discretion to determine those medical procedures that will be covered and how to define "medically necessary." *See PhRMA v. Walsh*, 538 U.S. 644, 665 (2003); *Detgen ex rel. Detgen v. Janek*, 752 F.3d 627, 631 (5th Cir. 2014) ("States have broad discretion to implement the Medicaid Act.").

Under the Medicare Act, health care coverage is available only when the covered product or service is "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). In order of preference, determinations of whether coverage is appropriate are based on "[i] Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and [ii] General acceptance by the medical community (standard of practice), as supported by sound medical evidence." Medicare Program Integrity Manual § 13.7.1. Whether there is FDA clearance for a device is one factor that is considered in making decisions as to coverage under Medicare. 42 C.F.R. § 405.201(a)(1) ("CMS uses the FDA categorization of a device as a factor in making Medicare coverage decisions."). In general, devices that do not have FDA clearance are not eligible for Medicare reimbursement. *See* Medicare Benefit Policy Manual §§ 14.10, 14.20. CMS does not categorically prohibit reimbursement for off-label use of FDA-approved medical devices. *See id*.

E. Allegations Regarding Defendants

1. Alleged False Certification Scheme

The FAC alleges that Defendants made willful misrepresentations about the Subject Devices to obtain § 510(k) clearance. These include allegations that Defendants represented that the Subject Devices were substantially equivalent to other devices used to replace vertebrae in the back ("thoracolumbar") regions of the spine. Dkt. 32 ¶¶ 39-40. The FAC alleges that the Subject Devices were in fact designed and intended to be used for the replacement of vertebrae in the neck ("cervical") region of the spine. *Id*. The FAC also alleges that Defendants "submitted false statements omitting any reference to cervical corpectomy, cervical interbody fusion or worst-case design scenario in the cervical spine, in order to obtain 510(k) marketing clearance." *Id*. ¶ 266. Such misrepresentations were allegedly made about five specified devices. *Id*.

The FAC alleges that the Subject Devices were specifically designed for use in cervical corpectomies, rather than the uses for which they were cleared. *Id*. ¶189. These devices were not interchangeable: the FAC alleged that the end cap components of one of the Subject Devices are "of a size fitted for the cervical spine," and "the threaded insertion ports only permit cages and components to be implanted via

an anterior approach into the neck." *Id*. These design features allegedly reflect that the Subject Devices were intended for cervical use, and that failure to disclose this to the FDA was a willful omission.

The FAC further alleges that certain components of the Subject Devices were sold without any FDA certification. Many of the Subject Devices had several component parts. Dkt. 32 ¶ 126. The Subject Devices were allegedly approved by the FDA for use only when these components were used together as a single device. *Id*. ¶¶ 40, 126. The FAC alleges that Defendants separately marketed the struts and end caps of the devices as a combined "cage" device for use in cervical corpectomy, independent of the other components. *Id*. ¶¶ 222, 267-68. Defendants allegedly did not obtain § 510(k) clearance for these devices until 2007. *Id*. ¶ 239. The FAC also alleges that this clearance was granted on the basis of dissimilar predicate devices. *Id*.

By obtaining FDA clearance on the basis of false representations, Defendants were allegedly able to avoid additional testing for safety and efficacy. In support of this position, it is alleged that devices for use in cervical corpectomy were required to meet the heightened PMA approval standards. *Id*. ¶ 222. It is also alleged that "[i]f the true intended use . . . of the device designs had been disclosed to the FDA, the Subject Devices would not have been 510(k) cleared by the FDA." *Id*. ¶ 266. The FAC alleges that the "FDA has never cleared or approved a cervical corpectomy device manufactured by Defendants." *Id*.

2. Alleged Off-Label Promotion Scheme

The FAC alleges that, after obtaining § 510(k) certification for the Subject Devices, Defendants marketed them for off-label use in the cervical spine. Therefore, it alleges that they engaged in "misbranding, mislabeling, or adulterating," contrary to the FDCA. Dkt. 64 at 7. The FAC alleges that "[a] device designed, tested, and intended for use as an implantable device to replace a lumbar (or thoracic) vertebral body . . . cannot fit in the cervical spine without modifications of the device design," and that therefore, "[a] legally marketed device cannot be used in an off-label manner in the cervical spine." Dkt. 32 ¶ 140.

The FAC also alleges that Defendants engaged in an expensive marketing process to facilitate the sale of these products for off-label use. *See id*. ¶ 138. This included training surgeons and other medical professionals about the use of the Subject Devices in ways not approved by the FDA. *Id*. ¶¶ 138, 241. In this regard, the FAC identifies "a 2008 email from a Medtronic sales manager in which 3 different Medtronic spine products are promoted to a local hospital value analysis committee for uses for which the FDA had not approved them." *Id*. ¶ 42. It also alleges that Defendants coached their sales representatives to pressure doctors to purchase and use the devices, including by having the representatives in operating rooms when procedures were performed. *Id*. ¶ 137. Defendants also allegedly contributed to articles published in medical journal articles to promote the Suspect Devices. *Id*. ¶ 139. They also allegedly conducted clinical studies on the use of the Subject Devices in the cervical spine without first obtaining the required investigational device exemption. *Id*. ¶222.

It is alleged that these actions presented dangers to patients, some of whom were injured as a result. *Id*. ¶ 286. Defendants were allegedly on notice that their conduct was improper, because the FDA issued warnings during the relevant time period that its approval of cervical disk replacement devices was required before their marketing. *Id*. ¶¶ 131, 133.

3. Alleged Kickbacks

The FAC also alleges that Defendants paid "illegal kickbacks" to surgeons to increase sales of the products at issue. *Id*. ¶¶ 296-330. These include allegations that, "[b]ased on Defendants' internal documents, Defendants' sales agreements with Hospitals contain inducements in the form of rebates or kickbacks for purchasing mislabeled device components, where the components were designed for non-FDA approved uses in the cervical and lumbar spine . . . ." *Id.* ¶134. Defendants also allegedly recruited individual surgeons: it is alleged that one physician was paid more than $120 million from Defendants. *Id*. ¶ 136.

The FAC alleges that Defendants use "quid pro quo" methods to funnel business to physicians. *Id*. ¶¶ 298-300. This allegedly involved recruiting physicians to participate in "referral" or "co-marketing" programs designed to increase sales of the Subject Devices. *Id*. Specifically, Defendants allegedly host dinners and conferences for surgeons who use the Subject Products, in order to generate referrals to them. *Id*. ¶ 299-302. Defendants also allegedly provided illegal compensation to these physicians who used the Subject Devices, through dinners, events, paid travel, speaking fees, publicity and referrals. *Id*.

III. Analysis

A. Legal Standards on a Motion to Dismiss

To survive a motion brought pursuant to Fed. R. Civ. P. 12(b)(6), a complaint must include allegations that have sufficient specificity to "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (internal quotations omitted). Although a complaint need not contain detailed factual allegations, it "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) (quoting *Twombly*, 550 U.S. at 570). However, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. . . . While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations." *Id*. at 678-79.

Claims "brought under the FCA must fulfill the requirements of Rule 9(b)" of the Federal Rules of Civil Procedure. *United States ex rel. Lee v. SmithKline Beecham, Inc*., 245 F.3d 1048, 1051 (9th Cir. 2001). Under Rule 9(b), "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." Fed. R. Civ. P. 9(b). Stating with particularity requires "an account of the time, place, and specific content of the false representations as well as the identities of the parties to the misrepresentations." *Swartz v. KPMG LLP*, 476 F.3d 756, 764 (9th Cir. 2007); *see also Vess v. Ciba–Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003) (claims sounding in fraud must be accompanied by "the who, what, when, where, and how of the misconduct charged"); *Edwards v. Marin Park, Inc*., 356 F.3d 1058, 1066 (9th Cir. 2004). "Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." *Id*.

B. First and Second Causes of Action: FCA

1. Legal Standards

"The essential elements of an FCA claim are (1) a false statement or fraudulent course of conduct, (2) made with requisite scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due." *United States v. Corinthian Colleges*, 655 F.3d 984, 992 (9th Cir. 2011). "One violates the [FCA] if one has 'actual knowledge' that one is submitting a false or fraudulent claim for payment or approval, acts in deliberate ignorance of the truth or falsity of one's false claim, or acts in reckless disregard of the truth or falsity of one's false claim." *Wang v. FMC Corp*., 975 F.2d 1412, 1420 (9th Cir. 1992); *Hagood v. Sonoma Cnty. Water Agency*, 929 F.2d 1416, 1421 (9th Cir. 1991).

"Evidence of an actual false claim is the sine qua non of a False Claims Act violation." *United States ex rel. Aflatooni v. Kitsap Physicians Serv*., 314 F.3d 995, 1002 (9th Cir. 2002); *see also Cafasso, United States ex rel. v. General Dynamics C4 Systems, Inc*., 637 F.3d 1047, 1055 (9th Cir. 2011) ("It seems to be a fairly obvious notion that False Claims Act suit ought to require a false claim. [T]he [FCA] attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the 'claim for payment.'" (*quoting Aflatooni*, 314 F.3d at 997; *then quoting United States v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995) (internal alterations in original))).

"The archetypal *qui tam* FCA action is filed by an insider at a private company who discovers his employer has overcharged under a government contract." *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266 (9th Cir. 1996). "However, FCA actions have also been sustained under theories of . . . false certification." *Id*. Therefore,

> [t]o survive a Rule 9(b) motion to dismiss, a complaint alleging implied false certification must plead with particularity allegations that provide a reasonable basis to infer that (1) the defendant explicitly undertook to comply with a law, rule or regulation that is implicated in submitting a claim for payment and that (2) claims were submitted (3) even though the defendant was not in compliance with that law, rule or regulation.

Ebeid ex rel. United States v. Lungwitz, 616 F.3d 993, 998 (9th Cir. 2010).

"Major questions relating to liability in [false certification] cases are: (1) whether the false statement is the cause of the Government's providing the benefit; and (2) whether any relation exists between the subject matter of the false statement and the event triggering Government's loss." *Hopper*, 91 F.3d at 1266 (quoting John T. Boese, *Civil False Claims and Qui Tam Actions* 1–29 to 1–30 (1995)). Such a claim must also show that the false certification was material to the government's decision to make a payment. *See, e.g.*, 31 U.S.C. § 3729(b)(4); *United States ex rel. Hendow* v *Univ. of Phoenix*, 461 F.3d 1166, 1172 (9th Cir. 2006). "'Material' means having a natural tendency to influence. . . ." 31 U.S.C. § 3729(b)(4).

2. Application

a) Claim Submissions

The FAC does not allege that Defendants ever submitted any false claims on their own. Instead, it avers that Defendants caused such false claims to be submitted by others through claims for reimbursement for off-label uses of the Subject Devices. These include claims made to Medicare and Medicaid. Additionally, the FAC alleges that "the Department of Veterans Affairs, the Department of Defense's TRICARE program, and the Federal Employees Health Benefit Plan each purchase and reimburse prescription devices with funds provided by the United States." Dkt. 32 ¶ 195. Specifically, it is alleged that reimbursement was not proper as to the cost of either the Subject Devices or the surgeries used to implant them, when the device was used in a manner that had not been approved by the FDA. *Id.* ¶¶ 69, 75-77. It is further alleged that reimbursement was improper because the Devices were "experimental" and lacked clearance or approval by the FDA.

b) False Certification

One theory alleged in the FAC, is that the Subject Devices were "not eligible to be purchased by Medicare, Medicaid or any other health insurance program funded by the United States" because they had not been properly authorized by the FDA. *Id.* ¶ 334. In connection with this claim, it is also alleged that the certifications of the Subject Devices actually granted by the FDA were fraudulently obtained. As noted, the FDA provided the Subject Devices with § 510(k) clearance for certain thoracocolumbar (back) uses. However, the FAC alleges that, because the devices were designed for cervical (neck) use, this clearance was improper. As noted, Medical devices without FDA certification through a § 510(k) clearance or PMA, cannot form the basis for a request for reimbursement under Medicaid. Causing the government to make a reimbursement for the cost of the use of an uncleared device would constitute a false claim under the FCA.

Defendants argue that, even if the Subject Devices were intended for off-label use, FDCA clearance would not be void as to uses that actually received § 510(k) clearance. Indeed, they contend that the FDCA specifically contemplates that some devices may be cleared through the § 510(k) process even if off-label uses are obvious or expected. For this reason, 21 U.S.C. § 360c(i)(1)(E) authorizes the FDA to require a limitation or other statement in the labeling of a device if "there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling . . . [and] such use could cause harm." Therefore, the allegation that the Subject Devices were intended for an off-label purpose is not itself sufficient to support a claim of improper clearance through the § 510(k) process.

Further, claims of fraud are disfavored if made by third parties who seek to second guess a decision by the FDA to certify a device. Relator's claims are in effect such a challenge as to the decision of the FDA to grant § 510(k) clearance for the Subject Devices. Alleged fraudulent conduct directed to the FDA, without more, is inadequate to support an FCA claim. *Buckman Co.*, 531 U.S. at 355. There, the Court upheld dismissal of a state tort claim alleging fraud on the FDA by a medical device manufacturer that had obtained approval for a device through the § 510(k) process. *Id*. The Court found that the state law fraud scheme was preempted by federal law, and that

> the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Administration can be skewed by allowing fraud-on-the-FDA claims under state tort law.

Id. at 348.

The Court added that the FDA has sufficient enforcement jurisdiction and processes to police FDCA violations, including fraudulent submissions made in connection with an approval or clearance. The remedies available to the FDA include enjoining violations (*see* 21 U.S.C. § 332), seizing unauthorized or misbranded devices (*id*. §334(a)(2)(D)), or pursuing a criminal prosecution. *Id*. § 333(a).

Given the resources available to the FDA to investigate and approve medical devices, and to pursue remedies for alleged violations that arise in connection with the process, the policy concerns expressed in *Buckley* are material here. The premise of the alleged fraud in the FAC is that Defendants misled the FDA during the § 510(k) certification process. However, an FCA action is not the proper way to bring such a claim. *See United States ex rel. D'Agostino v. EV3, Inc*., 153 F. Supp. 3d 519, 539 (D. Mass. 2015) ("[A]n FCA action is not the appropriate vehicle for this court to exercise its judgment in second-guessing decisions taken by the FDA in approving the use of medical devices simply because the government happens to pay for some of them."); s*ee also United States ex rel. Thompson v. Columbia/HCA Healthcare Corp*., 125 F.3d 899, 902 (5th Cir. 1997) ("[C]laims for services rendered in violation of a statute do not necessarily constitute false or fraudulent claims under the FCA."); *Hopper*, 91 F.3d at 1266-67 ("Violations of laws, rules, or regulations alone do not create a cause of action under the FCA.").

For these reasons, and in the absence of allegations as to a complete FDA enforcement process premised on the misconduct alleged in the FAC, allegations of fraud on the FDA alone cannot support an FCA claim. At the hearing on February 13, 2017, counsel for Relator stated that Relator does not intend to pursue a cause of action based on fraud on the FDA. However, the allegations of the FAC assert that the Subject Devices did not have proper clearance from the FDA due to the manner in which Defendants allegedly pursued the FDA process. Therefore, the disavowal is not material to the determination that the present allegations are not sufficient to state an FCA claim.[2]

c) Off-Label Promotion and Use

The FAC alleges that the Subject Devices were developed and marketed for unapproved, off-label uses. This claim is based on the allegation that "Medicare and Medicaid do not pay for devices or drugs that are used for non-FDA approved indications." Dkt. 32 ¶ 338. Relator argues that claims for reimbursement of

[2] Relator also claims that Defendants marketed component parts of the Subject Devices without FDA certification. These allegations refer only to sales that occurred prior to 2007. However, as of July 2007, all intervertebral body fusion devices were treated as Class II devices, that required only § 510(k) clearance. 21 C.F.R. § 888.3080. The FAC alleges that § 510(k) applications were submitted to the FDA for interbody fusion devices (formerly Class III devices) that were identical to the component pieces (the end caps) of devices that the FDA previously cleared under the Verte-Stack brand name as Class II devices. Dkt. 32 ¶¶ 233, 239, 246-55. Relator does not contest that the six year statute of limitations under the FCA (31 U.S.C. § 3731(b)(1)) bars claims of any fraud that took place prior to February 19, 2009. Therefore, these allegations are insufficient.

the Subject Devices submitted to Medicare and Medicaid were false, because

> [u]napproved use of devices is not covered by the government health insurance programs where the use is not medically reasonable or necessary, or where the device is "adulterated" within the meaning of the Food, Drug, and Cosmetic Act. 42 U.S.C. § 1395y(a). When a device is not covered by the government health insurance programs, a claim for payment for that use is not reimbursable by the government. A non-reimbursable claim for payment is a false claim under the FCA. *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 996-98 (9th Cir. 2010).

Dkt. 64 at 10. Relator continues that "[a] company's violation of the misbranding provision of the Federal Food, Drug, and Cosmetic Act, on its own and as a matter of law, makes subsequent claims for reimbursement for the misbranded device false under the FCA." Dkt. 64 at 9.

Other courts that have addressed this issue have found that off-label sale and use of products does not necessarily preclude reimbursement under Medicare and Medicaid. Instead, they have noted that under the Medicare Act, health care coverage is available when the covered product or service is "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). *See*, *e.g., United States ex rel. Modglin v. DJO Glob. Inc*., 48 F. Supp. 3d 1362, 1392 (C.D. Cal. 2014) ("Courts have recognized, however, that Medicare does not impose an absolute ban on coverage for off-label use of drugs and devices."); *United States ex rel. Nowak v. Medtronic, Inc*., 806 F. Supp. 2d 310, 345, 347 (D. Mass. 2011) ("'Medicare and Medicaid reimbursement for off-label uses of medical devices is more permissive than reimbursement for off-label uses of pharmaceuticals.' . . . Off-label promotion cases involving medical devices are uniquely complicated by the relatively more permissive and undefined nature of Medicare and Medicaid cover of 'off-label' medical devices."); *Strom ex rel. United States v. Scios, Inc*., 676 F. Supp. 2d 884, 886 (N.D. Cal. 2009) ("Medicare does indeed cover off-label uses of drugs in some contexts."). Thus, Medicare or Medicaid may allow coverage of a cleared device used off label, when the use is "medically necessary," or "reasonable and necessary" to treat a given patient. The determination whether a cleared medical device was medically necessary — and thus, whether a given claim for payment was false — is ordinarily a patient-specific inquiry.

Under these standards, to allege a violation of the Medicare Act, requires an averment that the Subject Devices were neither "reasonable" nor "necessary" for treating patients. As *Strom* concluded with respect to an alleged scheme to market and sell a pharmaceutical product for off-label use:

> [T]he FCA can be used to create liability where failure to abide by a rule or regulation amounts to a material misrepresentation[ ] made to obtain a government benefit. Thus, the failure of Congress to provide a cause of action for money damages against a pharmaceutical manufacturer for marketing off-label drugs does not preclude an FCA claim where the manufacturer has knowingly caused a false statement to be made to get a false claim paid or approved by the government. . . .

676 F. Supp. 2d at 890. The operative complaint in *Strom* included detailed allegations "that the drug was not, in fact, effective when used for the off-label purpose." *Id*. at 891. Therefore, "[b]ecause the Medicare statute permits reimbursement only for 'reasonable and necessary' treatments, . . . a prescription of [the

subject pharmaceutical] in a context where it is not 'reasonable' or 'necessary' would be statutorily ineligible for reimbursement." *Id*.; *see also United States ex rel. Brown v. Celgene Corp.,* No. CV 10-3165-GHK SSX, 2014 WL 3605896, at *4 (C.D. Cal. July 10, 2014) ("While it may be true that an FCA claim cannot be predicated on off-label promotion alone, here Brown alleges not only that Celgene engaged in off-label promotion, but also that Celgene's promotion caused false claims to be submitted for reimbursement.").

The FAC presents only the conclusory allegation that the Subject Devices were not medically "reasonable," and were therefore ineligible for reimbursement under Medicare or Medicaid. Allegations that address this issue include the assertion that "[t]he cervical use of the Verte-Stack Subject Devices has resulted innumerous injuries that the FDA never contemplated since the Defendants did not disclose the objective intent was actually for cervical indications." Dkt. 32 ¶ 284. It is also alleged that "[t]he FDA's MAUDE database reports nearly 100 adverse events where Defendants' vertebral body replacement devices resulted in device-related malfunctions and/or serious, life-altering injuries in the cervical spine." *Id*. ¶ 285.

These allegations are insufficient under Rule 9(b) to state a claim that the Subject Devices were not medically "reasonable and necessary," and could not qualify for reimbursement under Medicare or Medicaid. That a medical device was used in a manner that caused injury to one or more patients does not necessarily mean that it was not suitable for use in a different manner or with other patients. Therefore, such general allegations are not sufficient to establish that there would be no circumstances under which the product would provide a basis for a reimbursement claim. Instead, the allegations must be sufficient to support the claim that the Subject Devices were unsafe, untested or otherwise unfit for the purposes for which they were used, and that Defendants nevertheless knowingly promoted them.

3. Sufficiency of Allegations that the Alleged Fraud Caused the Payment of Claims

To provide the basis for a claim under the FCA, the alleged fraud must have been material to causing the government to make a corresponding payment. Defendants argue that the FAC does not adequately plead this element of the cause of action. *See Universal Health Servs., Inc. v. United States*, 136 S. Ct. 1989, 2003 (2016). Defendants contend that government health care programs do not pay for the Subject Devices based on each usage or procedure. Instead, "Medicare and most state Medicaid programs pay a flat fee based on a patient's diagnosis and the procedures performed during an inpatient hospital stay, regardless of the particular treatment or the actual cost of providing it to a particular patient." Dkt. 57-1 at 23. Defendants contend that under this reimbursement model, the amount paid by the government for a spinal surgery is not affected by whether one or more of the Subject Devices, or components of them, are used. Similarly, they contend that the amount is not affected by whether a spinal fusion procedure involved a corpectomy. Defendants also contend that those responsible for making reimbursement decisions as to Medicare and Medicaid coverage, would not know whether one or more of the Subject Devices had been used in a particular surgical procedure.

Even assuming, *arguendo*, that these positions are correct, they are not sufficient to bar the claim here as a matter of law. Thus, this claimed decision-making process does not mean that the government has not, in establishing general payment policies, has assigned no value to products that have been approved through an FDA process. It is for this reason that "courts are in broad agreement that a claim for reimbursement from Medicare or Medicaid is 'false' when it is statutorily ineligible for such reimbursement." *Brown.,* No. CV 10-3165-GHK SSX, 2014 WL 3605896, at *4 *(citing, inter alia*, *Ebeid,*

616 F.3d at 1001 (because certification of compliance with Medicare regulations may be inferred from the submission of a Medicare claim, regulations that set forth conditions of payment may serve as the basis for an implied false certification); *Peterson v. Weinberger,* 508 F.2d 45, 52 (5th Cir. 1975) (claims for services that were not covered by Medicare were false under the FCA); *United States ex rel. Colquitt v. Abbott Labs*., 864 F. Supp. 2d 499, 530 (N.D. Tex. 2012) ("Medicare claims for expenses that are not covered and are ineligible for payment are false claims."); *Strom,* 676 F. Supp. 2d at 891 ("Because [Medicare] permits reimbursement only for 'reasonable and necessary' treatments, a prescription of [a drug] in a context where it is not 'reasonable' or 'necessary' would be statutorily ineligible for reimbursement. This satisfies the FCA's requirement of a 'false' statement."). If a defendant unlawfully promotes a product for uses that are not reimbursable, and makes such promotions to individuals and entities that will foreseeably make claims for reimbursement to the government, it is foreseeable that these actions will result in the submission of false claims. *See Brown*, No. CV 10-3165-GHK SSX, 2014 WL 3605896, at *3 ("[E]ven though Celgene did not itself falsely certify compliance with any legal condition of payment, it is still susceptible to liability because it allegedly caused claimants to implicitly make such false certifications and thereby caused the submission of false claims.").

Based on the foregoing, the claimed insufficiency of the allegations of causation is not a sufficient, independent basis to support the Motion.

* * *

As shown in the preceding discussion, the FAC does not adequately allege all necessary elements of a viable claim under the FCA. Therefore, the Motion is **GRANTED**, without prejudice, as to the First and Second Causes of Action.

C. Third Cause of Action (Conspiracy) and Fourth Cause of Action (Reverse FCA Claim)

The Third Cause of Action in the FAC is based on the allegation that "Defendants engaged in a conspiracy with physicians and facilities that made or presented false or fraudulent claims and performed one or more acts to effect payment of false or fraudulent claims." Dkt. 32 ¶ 368. The Fourth Cause of Action, for "Making or Using False Record or Statement to Avoid an Obligation to Refund" ("Reverse FCA" claim) is based on the following allegation:

> by virtue of the acts alleged herein Defendants knowingly made, used or caused to be made or used false records or false statements, i.e., the false certifications made or caused to be made by Defendants material to an obligation to pay or transmit money to the Government or knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the Government.

Id. ¶ 379.[3]

[3] The "reverse false claims" section of the FCA, 31 U.S.C. § 3729(a), creates liability for "any person who . . . makes, uses or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the government. . . ." *See generally United States v. Universal*

Relator concedes that the factual allegations in the FAC advanced to support these two causes of action are not sufficient. Dkt. 64 at 15-16. Therefore, the Motion is **GRANTED**, without prejudice as to the Third and Fourth Causes of Action; provided, however, insofar as Relator did not expressly seek leave to amend or explain the potential basis to do so, any amendment shall be made in good faith and in compliance with the requirements of Fed. R. Civ. P. 11.

D. Fifth Cause of Action: AKS Violations

1. Legal Standard

The Anti-Kickback statute ("AKS") prohibits "knowingly and willfully offer[ing] or pay[ing] any remuneration . . . to any person to induce such person . . . to purchase . . . [any] item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2)(B). It would be a violation of the statute to provide a financial benefit to a person with the specific intent to induce purchases or reimbursements by a government health care program. *Id*. Compliance with the AKS is a prerequisite to receiving payment from federally funded healthcare programs, including Medicaid and Medicare. *United States ex rel. Hutcheson v. Blackstone Med*., *Inc.*, 647 F.3d 377, 381 (1st Cir. 2011). A claim for payment to a Federal Health Care Program that includes "items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g).

2. Application

a) Whether the Alleged Violations of the AKS Have Been Pleaded With Sufficient Particularity

The FAC alleges that Defendants remunerated surgeons by paying the costs, including food and promotional expenses, in connection with certain business development events. At such events, the surgeons would speak about their practices and use of Medtronic products to other physicians. Defendants refer to these events as "co-marketing," "referral" or "Therapy Awareness Programs." Similarly, Defendants allegedly reimbursed the travel costs of physicians who attended events at which they were instructed in the use of the Subject Devices, and arranged conferences and speaking events that featured physicians that had made use of the devices. Defendants also allegedly provided rebates to hospitals that purchased the Subject Devices.

These general allegations do not identify any physicians, or categories of them, who actually received payment in connection with decisions — in which they participated — to purchase or use of any of the Subject Devices. Instead, the allegations provide details about circumstances when Defendants provided funding for marketing events or medical conferences in collaboration with physicians in certain relevant

Fruits & Vegetables Corp., 362 F.3d 551, 554 (9th Cir. 2004), *amended and superseded on reh'g*, 370 F.3d 829 (9th Cir. 2004).

markets.[4] Instead, it is alleged that, by paying the expenses for physicians who attended certain business development events, "Defendants knowingly caused to be submitted claims to the United States Government and to Government Health Care Programs as a result of the payment of kickbacks." Dkt. 32 ¶ 391. It is also alleged that "[a]s a result of the conduct set forth in this cause of action, the Government suffered harm as a result of paying or reimbursing for medical procedures, associated hospital and outpatient facility charges which, had the Government known were utilized as a result of the kickbacks, the Government would not otherwise have paid for and/or reimbursed." *Id*. ¶ 393.

These allegations are conclusory, and do not meet the pleading requirements of Fed. R. Civ. P. 9(b). As Defendants have pointed out, the FAC

> makes no attempt to allege any link between the supposed inducements and false claims for payment. It does not allege that any of these programs, or related services, in fact induced a surgeon to implant a Medtronic device in a federally insured patient or induced a physician to refer a federally insured patient to a surgeon who used a Medtronic device. Nor does it even identify the products that the Therapy Awareness Programs allegedly induced physicians to purchase. Nor does the Complaint allege who among the supposedly induced surgeons actually used a Medtronic device, what Medtronic device was used, when and where the kickback induced device was used, and whether a claim was submitted to a government health care program for payment.

Dkt. 57-1 at 29 (internal citations omitted).

Therefore, the FAC does not adequately allege this element of the AKS cause of action as required by Fed. R. Civ. P. 9(b).

b) Whether the Allegations Are Barred by the Public Disclosure Rule

Defendants also argue that the kickback allegations are jurisdictionally barred under the FCA. That statute precludes *qui tam* actions based on previously disclosed fraud, rather than on previously undisclosed information, unless the relator qualifies as an "original source." 31 U.S.C. § 3730(e)(4); *United States ex rel. Mateski v. Raytheon Co*., 816 F.3d 565, 570 (9th Cir. 2016). Defendants argue that "Medtronic's training and consulting payments, and their kickback implications, have been the subject of numerous previous FCA complaints." Dkt. 57-1 at 30 (citing *United States ex rel. Poteet v. Lenke*, No. 1:07-cv-10237 (D. Mass. Feb. 7, 2007); *United States ex rel. Poteet v. Medtronic, Inc.*, No. 2:03-cv-02979 (W.D. Tenn. Dec. 29, 2003); *United States ex rel. Doe v. Medtronic, Inc*., No. 2:02-cv-02709 (W.D. Tenn. Sept. 11, 2002). Defendants contend that the FAC does not include any allegations not encompassed by those made in these prior proceedings. Relator did not respond specifically to this issue.

It is unnecessary to reach the merits of this issue because, as stated above, the FAC lacks specificity required under Rule 9(b). However, if an amended complaint is filed, its allegations must be sufficient to satisfy this separate requirement, to the extent that it is not sufficiently addressed by the allegations in the

[4] *See*, *e.g.*, Dkt. 32 ¶ 312: "For example, for Dr. Dean of Mercy Medical Center in Baltimore, MD, a Medtronic sales rep noted in 2012 that referral marketing was a sales resource to help 'Develop' a FY13 contribution of $73,333, and that 'he wants to Co-Marketing Events with Medtronic.'"

FAC.

* * *

For the foregoing reasons, the Motion is **GRANTED** without prejudice as to the Fifth Cause of Action.

E. State Law Claims

The state law claims advanced in the FAC parallel those made under the FCA, but arise under state statutes. The legal theories that underlie these causes of action are the same as those that apply to the federal claims. Relator has not specifically alleged that Defendant caused any particular claim to be submitted to any state government personnel or agency. Therefore, these claims are not adequately pleaded for the reasons discussed earlier as to the FCA causes of action. *See, e.g., United States v. Shasta Servs. Inc*., 440 F. Supp. 2d 1108, 1114 (E.D. Cal. 2006).

Further, under the Maryland statute, an action like this one must be dismissed if the state of Maryland declines to intervene. Md. Code, Health – General, § 2-604(a)(7). No such intervention has been shown or alleged.

For the foregoing reasons, the Motion is **GRANTED** as to the Sixth through Thirty-Seventh Causes of Action. Relator's Nineteenth Cause of Action, under Maryland law, is **DISMISSED** with prejudice, and the remaining causes of action are **DISMISSED** without prejudice, *i.e.,* with leave to amend.

IV. Conclusion

For the reasons stated in this Order, the Motion is **GRANTED** with prejudice as to the Thirty-Seventh Cause of Action, and without prejudice as to the remaining causes of action. Any amended complaint shall be filed no later than October 2, 2017.

IT IS SO ORDERED.

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