UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

UNITED STATES OF AMERICA and THE STATE OF CALIFORNIA, *ex rel.* STEVEN HIGGINS,

Plaintiffs,

v.

Case No. 11-cv-2453 (JNE/SER)
ORDER

BOSTON SCIENTIFIC CORP.,

Defendant.

Relator Steven Higgins brings this *qui tam* action pursuant to 31 U.S.C. §§ 3730(b)(1) and (c)(3), alleging that Defendant Boston Scientific Corp. ("BSC") violated the federal False Claims Act, 31 U.S.C. § 3729(a)(1), and the California False Claims Act, Cal. Gov't Code § 12651(a). After the Government and the State of California declined to intervene, Higgins filed an Amended Complaint [Dkt. No. 61], which BSC moves to dismiss. Dkt. No. 63.

I. Allegations

The heart of Higgins' allegations is BSC's sale of particular models of Cognis CRT-D and Teligen ICD defibrillators in the United States from August 2008 through July 2009. *See, e.g.*, Am. Compl. ¶¶ 6, 12. The Amended Complaint alleges that BSC, a company that develops, makes, and sells medical devices, caused physicians to make false claims for Medicare and other federal health care program reimbursements by certifying that these defibrillators were reasonable and necessary for the medical procedures in which the devices were implanted. *See, e.g.*, *id.* ¶¶ 175, 182-83.

Defibrillators are medical devices that attach to a patient's heart by connectors called "leads" and can deliver shocks from the device's pulse generator to attempt to restore the patient's heartbeats to a healthy rhythm. *See* Am. Compl. ¶¶ 52-56. The leads are connected to

the pulse generator through a "header," which is a cap on top of the pulse generator that has openings into which the leads are secured using "set screws," which are then covered with "seal plugs." *Id.* ¶¶ 54-55. The attachment of the leads to the pulse generator through the header must be secure for the device to deliver shocks as needed. *See id.*

Higgins alleges that as part of a so-called "CRM [*i.e.*, Cardiac Rhythm Management] Identity Campaign" in around 2008, BSC introduced redesigned defibrillators under the new branding of Cognis and Teligen. *See* Am. Compl. ¶¶ 71-77. The Cognis and Teligen defibrillators were designed to be smaller and thinner than competitors' devices, and BSC also marketed them as having an "[i]mproved header, set screws and seal plugs." *Id.* ¶¶ 80-81.

A medical device like a defibrillator, which is classified by the United States Food and Drug Administration ("FDA") as a Class III device, must receive FDA premarket approval ("PMA") "to provide reasonable assurance of its safety and effectiveness" before it can be sold in the United States. 21 U.S.C. §§ 360c(a)(1)(C), 360e(c)(1); Am. Compl. ¶ 36. After the device has been approved, if the manufacturer wants to make certain changes to the device, it must submit a PMA supplement for FDA review and approval. 21 C.F.R. § 814.39(a); Am. Compl. ¶ 37. BSC filed a PMA supplement for the Cognis and Teligen defibrillators on December 7, 2007. Am. Compl. ¶ 39.

In February 2008, BSC began selling its new Cognis and Teligen devices in Europe. Am. Compl. ¶ 83. Higgins alleges that European physicians who began implanting the defibrillators in patients quickly began to experience problems with the devices' set screw/header configuration, and the doctors reported the problems to BSC. *Id.* at ¶¶ 84-85. In layman's terms, the problems were that the leads were not securely connecting to the header and pulse generator even when doctors followed standard implant protocol, which undermined the devices' ability to

reliably provide shocks. *See id.* ¶¶ 86-92. BSC allegedly responded to the reports of problems by sending the lead engineer for Cognis and Teligen, Sumi Dahm, to Europe to "investigate and deal with the complaints," including by developing "coaching and implant technique changes to the process of attaching the leads to the set screw/header design," which were mere "workaround" solutions but not "a real fix" to the design defects in the header/set screw configuration. *Id.* at ¶ 93.

Higgins alleges that in light of the problems being reported by European physicians, BSC should have amended its PMA supplement, which was still pending, to "alert the FDA as to the screw/header malfunctions . . . ." Am. Compl. ¶ 94. By failing to amend its PMA supplement, BSC allegedly misled the FDA in its review of the defibrillators and rendered its supplement false and misleading in presenting the devices as safe and effective. *Id.* ¶¶ 96-97. "Without the additional information about Cognis and Teligen which BSC learned from the European launch, the FDA approved the devices on May 8, 2008 for sale in the United States." *Id.* ¶ 98.

BSC allegedly also concealed the problems being reported in Europe from its United States sales staff—and other insiders, including Higgins, who served on a BSC advisory board—as the company prepared to launch the devices for United States sales in summer 2008. Am. Compl. ¶¶ 100, 103-07. Domestic sales began August 4, 2008, and doctors immediately began implanting Cognis and Teligen defibrillators in patients. *Id.* ¶ 109. Allegedly within days of launch, BSC began receiving reports from all over the country about malfunctioning with the set screws and header connections. *Id.* ¶ 110. "Less than three weeks after launch, [] in an effort to avoid a recall of Cognis and Teligen in the wake of a huge volume of reported defects, BSC misleadingly introduced revised implant instructions which suggested that the problems had to do with the implant techniques used by physicians," rather than defects with the devices

themselves, and published these revised instructions in a "white paper" on August 21, 2008. *Id.* ¶¶ 111-12 (describing BSC's revised instructions to perform a "tug test"). These instructions "were highly unusual because typically connecting the leads to a cardiac defibrillator is a straightforward, uncomplicated part of implant surgery." *Id.* ¶ 116.

BSC received complaints from doctors across the country about malfunctions related to the header and set screws. *See* Am. Compl. ¶¶ 118, 121, 136. At a meeting with particular customers to address their complaints, BSC representative Dahm admitted that BSC had been "aware of the malfunctions involving the set screws/headers because the devices had been launched earlier in the year in Europe and similar problems had occurred there and had been reported to BSC." Am. Compl. ¶ 124 (emphasis omitted); *see also id.* ¶ 127 (similar allegations with regard to a second meeting).

Higgins alleges that BSC implemented an informal policy to deceptively minimize the FDA's awareness of issues with Cognis and Teligen devices. Federal law required BSC to report malfunction complaints to the FDA in adverse event reports also referred to as medical device reports (MDRs). *See* Am. Compl. ¶¶ 134-35; *see also* 21 C.F.R. §§ 803.1(a) (referring to medical device reporting requirements), 803.50(a) (requiring the submission of adverse event reports by manufacturers). Instead of reporting all of the complaints it received, at the direction of its Cardiac Rhythm Management President Fred Colen, BSC allegedly adopted an informal policy to submit adverse event reports only if "a patient needed a re-operation because of a faulty device," but not if a doctor "had a difficult time with implantation . . . and there were no significant patient complications." Am. Compl. ¶ 138.

BSC also began developing revised versions of the Cognis and Teligen defibrillators to fix what it allegedly knew were design defects with the devices' set screw/header configuration.

See Am. Compl. ¶ 142. BSC submitted a PMA supplement for FDA approval of the changes to Cognis—but not Teligen—and deceptively referred to the revisions as modifications without disclosing that they were fixing defects in the initial versions of the device. *Id.* ¶¶ 143-44, 147. "Lacking a full and accurate description of the new Version 2 of the set screw/header, the FDA approved the PMA Supplement on March 18, 2009 without any required action as to the defective Version 1 devices." *Id.* ¶ 148.

BSC began selling "Version 2" of the devices in March 2009 but did not recall or stop selling the allegedly defective original versions, which physicians continued to implant. Am. Compl. ¶¶ 149-52. The company prioritized sending the new, corrected versions to customers who had complained the most. *Id.* at ¶¶ 153-54.

Higgins or his peers at the same hospital implanted the devices in at least 14 patients between September 2008 through February 2009 for whom the hospital sought and received Medicare or Medicaid/Medi-Cal reimbursement. *See* Am. Compl. ¶ 201; *id.* Ex. A.

On July 20, 2009, the FDA issued a notice for the Class II recall of the Cognis and Teligen devices "containing the original set screw system." Am. Compl. ¶ 161 (quoting FDA notice). Allegedly based on BSC's misleading assurances to the FDA that any issues with the devices became apparent within 30 days of implanting, the FDA's recall was limited to devices that had been implanted less than 30 days before the recall. *Id.* ¶ 162.

II. Subject Matter Jurisdiction

The Court raised the question of whether it had subject matter jurisdiction under 31 U.S.C. § 3730(e)(4)(A) of the False Claims Act and requested briefing. *See* Dkt. No. 89. The parties, and the federal government in its Statement of Interest, agree that the pre-2010 version of § 3730(e)(4)(A) applies to this action, which challenges conduct occurring in 2008 through 2009. *See* Gov't SMJ Br. 1-2, Dkt. No. 90; Def.'s SMJ Br. 1-4, Dkt. No. 91; Rel.'s SMJ Br. 5-6, Dkt.

No. 92; *e.g.*, *Cause of Action v. Chicago Transit Auth.*, 815 F.3d 267, 273 n.6 (7th Cir. 2016); *U.S. ex rel. Antoon v. Cleveland Clinic Found.*, 788 F.3d 605, 614-15 (6th Cir. 2015); *U.S. ex rel. May v. Purdue Pharma L.P.*, 737 F.3d 908, 915 (4th Cir. 2013). The applicable version of the statute is jurisdictional. *E.g.*, *U.S. ex rel. Ketroser v. Mayo Found.*, 729 F.3d 825, 828 (8th Cir. 2013). The statute provides that "[n]o court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions" in enumerated sources unless "the person bringing the action is an original source of the information." 31 U.S.C. § 3730(e)(4)(A) (2009). The Court may consider matters outside the pleadings in determining whether it has jurisdiction. *Osborn v. United States*, 918 F.2d 724, 730 (8th Cir. 1990).

The "jurisdictional bar to an FCA claim exists only when the essential elements comprising [the] fraudulent transaction have been publicly disclosed so as to raise a reasonable inference of fraud; to bar the action, the disclosure must reveal the critical elements of the fraudulent transaction themselves." *United States ex rel. Hixson v. Health Mgm't Sys., Inc.*, 613 F.3d 1186, 1188 (8th Cir. 2010) (internal quotation marks omitted) (quoting *United States ex rel. Rabushka v. Crane Co.*, 40 F.3d 1509, 1512-14 (8th Cir. 1994)). Thus, the disclosure "must reveal both the true state of facts and that the defendant represented the facts to be something other than what they were." *Minn. Ass'n of Nurse Anesthetists v. Allina Health Sys. Corp.*, 276 F.3d 1032, 1044 (8th Cir. 2002). "[T]he bar is given effect when the essential elements comprising that fraudulent transaction have been publicly disclosed so as to raise a reasonable inference of fraud." *Rabushka*, 40 F.3d at 1514.

BSC argues that the allegations of Higgins' Amended Complaint are substantially similar to (and thus "based upon" within the meaning of the statute) publicly disclosed facts, that Higgins is not an original source, and that the Court therefore lacks jurisdiction. BSC describes

several disclosures of problems or potential problems with the Cognis and Teligen devices. *See* Def.'s SMJ Br. 8-9. It cites publicly filed adverse event reports about the defibrillators that refer to "connection error," "loose or intermittent connection," and related terms, and also cites some statements or documents that refer to issues or potential issues with the set screws and header. *See id.* BSC also argues that the FDA's Class II recall notice was a public disclosure of the potential problems with the devices, stating that they "could be subject to a potential for acute non-secure lead connections when implanted." *Id.* at 9 (quoting July 20, 2009 recall notice).[1]

Without deciding whether all of these disclosures fit within the enumerated sources in § 3730(e)(4)(A), the Court finds that the statements identified by BSC, while alerting the public to potential issues with the devices, did not disclose essential elements of the fraud alleged by Higgins. The statements did not disclose that BSC allegedly knew the problems were caused by design defects and deceptively hid this fact from the FDA and physicians—and by extension, from the arm of the federal government responsible for fulfilling Medicare and other reimbursement requests, the Centers for Medicare and Medicaid Services ("CMS"). The mere fact that the devices had malfunctioned or had the potential to malfunction would not, by itself, "raise a reasonable inference of fraud." *See Rabushka*, 40 F.3d at 1514. To take one example, BSC argues that hundreds of adverse event reports gave notice that the Cognis and Teligen defibrillators as initially released were potentially malfunctioning. But the filing of an adverse event report "is not necessarily an admission that the device . . . caused or contributed to the reportable event." 21 C.F.R. § 803.16. Moreover, those reports did not disclose the fraudulent

[1] Higgins quoted the same two sentences from the Class II recall notices. *See* Am. Compl. ¶ 161. The recall notices for Cognis and Teligen, respectively, are available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?id=84049 (last accessed August 29, 2017), and https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=84050 (last accessed August 29, 2017).

elements alleged by Higgins, such as that BSC improperly and deceptively chose not to file many other adverse event reports. Nor does it disclose that BSC allegedly hid from the FDA the numerous malfunction reports it was receiving from Europe as the FDA was considering the PMA Supplement filed in December 2007. Similarly, in its motion-to-dismiss papers, BSC itself cautions against inferring fraud from the mere fact of the recall. *See, e.g.*, Def.'s May 9, 2017 Ltr. 3, Dkt. No. 87. In summary, none of the statements brought to the Court's attention disclosed "the critical elements of the fraud[]." *Hixson*, 613 F.3d at 1188. Therefore, the public disclosure bar does not apply, and the Court is satisfied that it has jurisdiction over this action.

III. BSC's Motion to Dismiss

BSC moves to dismiss the Amended Complaint pursuant to Federal Rules of Civil Procedure 12(b) and 9(b) for failure to state a claim on which relief can be granted and failure to plead fraud with particularity.

To survive a motion to dismiss, a complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Neubauer v. FedEx Corp.*, 849 F.3d 400, 404 (8th Cir. 2017) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). "A pleading that offers labels and conclusions or a formulaic recitation of the elements of a cause of action will not do. Nor does a complaint suffice if it tenders naked assertions devoid of further factual enhancement." *Id.* (quoting *Iqbal*, 556 U.S. at 678).

Moreover, "complaints alleging violations of the FCA must comply with Rule 9(b)." *United States ex rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552, 556 (8th Cir. 2006). The rule requires that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake," although "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). To satisfy the rule, "the complaint must plead such facts as the time, place, and content of the defendant's false

representations, as well as the details of the defendant's fraudulent acts, including when the acts occurred, who engaged in them, and what was obtained as a result." *Joshi*, 441 F.3d at 556 (citations omitted). "In other words, 'the complaint must identify the who, what, where, when, and how of the alleged fraud.'" *Olson v. Fairview Health Servs. of Minn.*, 831 F.3d 1063, 1070 (8th Cir. 2016) (quoting *Joshi*, 441 F.3d at 556).

To state a claim under 31 U.S.C. § 3729(a)(1),[2] Higgins must show that BSC "knowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval," *id.* § 3729(a)(1)(A),[3] or "knowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim," *id.* § 3729(a)(1)(B). A "claim" under the statute "includes direct requests to the Government for payment as well as reimbursement requests made to the recipients of federal funds under federal benefits programs." *Universal Health Servs. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1996 (2016) (citing 31 U.S.C. § 3729(b)(2)(A)). "Knowingly" means "that a person, with respect to information—(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information . . . ." 31 U.S.C. § 3729(b)(1). The knowledge requirement does not require "proof of specific intent to defraud." *Id.* § 3729(b)(1)(B). The term "material" means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Id.* § 3729(b)(4). "If it alleges a systematic practice of submitting fraudulent claims, the FCA

[2] The parties agree that analysis of Higgins' second claim, which alleges violation of the California False Claims Act, should be consistent with an analysis of the federal claim. *See* BSC MTD Br. 31, Dkt. No. 66; Rel. MTD Opp. 38, Dkt. No. 70.

[3] The Eighth Circuit has summarized the elements of a § 3729(a)(1)(A) claim as requiring that "(1) the defendant made a claim against the United States; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent." *Olson*, 831 F.3d at 1070 (citation omitted).

complaint 'must provide *some* representative examples of [the] alleged fraudulent conduct,' specifying 'the time, place, and content of the defendant's fraudulent acts, including when the acts occurred, who engaged in them, and what was obtained as a result.'" *United States ex rel. Roop v. Hypoguard USA, Inc.*, 559 F.3d 818, 822 (8th Cir. 2009) (citations omitted). Moreover, the "falsehood in the claim must be material to the payment decision." *Olson*, 831 F.3d at 1070 (citation omitted); *see also Escobar*, 136 S. Ct. at 1996 ("A misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the False Claims Act.").

Relators must plead with particularity actual claims that were submitted to the federal government and are allegedly false. *See Roop*, 559 F.3d at 824-25 (affirming dismissal where relator did not plead with particularity "the details of any false Medicare reimbursement claim presented to, or paid by, the United States or its agent"). Violations of another statute or regulation will not create False Claims Act liability if they are "independent of any false claim;" thus, it does not suffice to "[m]erely alleg[e] that a scheme was wide-ranging—and, therefore, that a fraudulent claim was *presumably* submitted . . . ." *United States ex rel. Kelly v. Novartis Pharms. Corp.*, 827 F.3d 5, 13-14 (1st Cir. 2016) (emphasis added).

BSC argues that Higgins' False Claims Act claim advances a "fraud on the FDA" theory of liability that courts have rejected. BSC sums up Higgins' theory as follows: BSC misled the FDA; if the FDA had not been misled, it would have taken different action and might not have approved the Cognis or Teligen defibrillators for domestic sales or might have recalled them earlier; and as a result, BSC caused healthcare providers to submit false claims for these devices. BSC maintains that this theory of causation fails to state a False Claims Act claim as a matter of law. Higgins counters that he has adequately pleaded False Claims Act liability under theories of

fraudulent inducement, false certification, and "defective device." The Government, although it does not take a position on the merits of the case, urges generally that False Claims Act claims may be based on fraudulent inducement, fraudulent nondisclosure, or a theory that a defective device was represented to be something different than what was provided.

A. Whether the Amended Complaint Fails to State a Claim

Setting aside for the moment whether they are pleaded with adequate particularity, Higgins' False Claims Act theories could be viable. According to the allegations, which are accepted as true at this stage, BSC made multiple misleading statements and misstatements-by-omission to the FDA. First, the PMA supplement that BSC submitted to the FDA in December 2007 was rendered false and misleading when BSC failed to update its pending submission to inform the FDA of the many malfunction reports that BSC received from European physicians after BSC launched Cognis and Teligen defibrillators in Europe in February 2008. BSC could have but did not amend its pending PMA supplement to provide this additional information. *See* 21 C.F.R. §§ 814.37(a), (c)(1) (allowing an applicant to amend a pending PMA supplement "to revise existing information or provide additional information" and noting that the FDA's review may take longer if the applicant submits a "major PMA amendment" that contains "significant updated data" or "significant required information previously omitted").[4] Allegedly uninformed of this material information, the FDA approved the devices on May 8, 2008. Once the devices were approved and introduced to the United States market, BSC allegedly continued to keep the FDA in the dark by adopting an informal policy to suppress the number of adverse event reports

[4] A PMA supplement must comply with the procedures set out in 21 C.F.R. § 814.20, which requires, among many other fields of information, "[a]n identification, discussion, and analysis of any other data, information, or report relevant to an evaluation of the safety and effectiveness of the device known to or that should reasonably be known to the applicant from any source, foreign or domestic, including information derived from . . . commercial marketing experience." 21 C.F.R. §§ 814.39(c)(1), 814.20(b)(8)(ii).

it was required by law to submit to the FDA, *see* 21 C.F.R. § 803.50(a),[5] and by failing to seek FDA approval for the revised implantation instructions that BSC published on August 4, 2008, *see* 21 C.F.R. §§ 814.39(a)(2), (d)(2) (requiring submissions to the FDA before making labeling changes, including changes "that add or strengthen an instruction that is intended to enhance the safe use of the device"). Higgins also alleges that BSC misled the FDA when it submitted a PMA supplement for revised versions of the Cognis defibrillators but omitted that the revisions were intended to fix defects in the original version, which BSC was thus able to keep on the market for a while longer. Lastly, Higgins alleges that even once the FDA and BSC began the process of recalling the first version of the Cognis and Teligen devices in mid-2009, BSC misled the FDA by representing that the recall need only extend to devices implanted within 30 days of the recall, when in fact defects in implanted units could remain latent for longer than 30 days.

Higgins then pleads how these alleged violations of FDA regulations and laws and omissions of information to the FDA "cause[d]" false claims "to be presented . . . for payment or approval." *See* 31 U.S.C. § 3729(a)(1)(A). Without the FDA's approval, BSC would not have been able to market its revised Class III medical devices domestically. *See* 21 U.S.C. § 360e(a); 21 C.F.R. § 814.39(a)(6). Higgins alleges that had the FDA been informed of the European reports, it would not have approved the new versions of these defibrillators for marketing in the United States. This allegation might be considered mere speculation. *See Roop*, 559 F.3d at

[5] Defendants argue that this allegation is not plausibly alleged, asking the Court to take judicial notice of the fact that numerous adverse event reports for Cognis and Teligen defibrillators were filed in a publicly accessible database, MAUDE. Even if the Court were to take judicial notice of the fact that some reports were filed, however, it would not negate Higgins' allegation that many more reports were suppressed based on the informal policy identified in the Amended Complaint. *See* Am. Compl. ¶ 138. BSC acknowledges that sophisticated medical devices will almost inevitably have a predictable failure rate. *See* BSC MTD Br. 14. The submission of *some* adverse event reports therefore would not necessarily alert the FDA to the alleged fact that the true malfunction rates merited recalling the devices.

825. But Higgins also alleges that had BSC not misled the FDA after the devices were approved in May 2008—by, for example, suppressing the submission of adverse event reports relating to United States physicians' complaints—the FDA would have recalled Cognis and Teligen earlier. *See* Am. Compl. ¶ 187 ("[O]nce the truth about Cognis and Teligen became (partially) known, the devices were recalled."). This allegation is removed from the realm of pure speculation by the fact that the FDA, once allegedly more fully informed about issues with the devices, did issue a recall of the devices.[6]

Moreover, Higgins alleges that the recall is material to medical care providers' reimbursement claims because "medical devices that lack approval from the FDA are not reimbursable." Am. Compl. ¶ 187 n.3 (citing 42 C.F.R. §§ 411.15(o) and 405.211(c)). Claims are not reimbursable under Medicare, which is just one of the programs at issue here, if the medical items or services "are not reasonable and necessary for the diagnosis or treatment of illness or injury . . . ." 42 U.S.C. § 1395y(a)(1)(A). FDA approval is required for CMS to consider Class III medical devices to be reasonable and necessary, although it is not the only consideration. *See, e.g.*, 42 C.F.R. § 405.201(a)(1) (establishing that CMS "uses the FDA

[6] BSC asserts that it initiated the recall before the FDA acted, a point that Higgins appears to concede in post-hearing briefing. *See* May 4, 2017 Notice 4, Dkt. No. 86. Even if BSC did voluntarily request that customers return the original versions of Cognis and Teligen, it is still significant that the FDA then characterized that request as a recall. The FDA's recall notices explain that "[a] record in this database is created when a firm initiates a correction or removal action. *The record is updated if the FDA identifies a violation and classifies the action as a recall . . . .*" *E.g.*, FDA, Class 2 Device Recall Boston Scientific COGNIS CRTD, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?id=84049 (emphasis added). *See also* 21 C.F.R. § 7.46(a) ("A firm may decide of its own volition and under any circumstances to remove or correct a distributed product. . . . Such removal or correction will be considered a recall only if the *Food and Drug Administration regards the product as involving a violation that is subject to legal action, e.g.*, seizure.") (emphasis added). The Court may take judicial notice of the recall notices on a motion to dismiss, because they are embraced by the pleadings and are in the public record. *See In re K-tel Int'l, Inc. Secs. Litig.*, 300 F.3d 881, 889 (8th Cir. 2002).

categorization of a device as a factor in making Medicare coverage decisions"); CMS, *Medicare Program; Revised Process for Making Medicare National Coverage Determinations*, 68 FR 55634-01, 2003 WL 22213011 (Sept. 26, 2003) ("[A]n FDA-regulated product must receive FDA approval or clearance (unless exempt from the FDA premarket review process) for at least one indication to be eligible for Medicare coverage."); CMS, *Medicare Benefit Policy Manual*, CMS Pub. No. 100-02, Ch. 14 § 10 (Rev. 198) ("Devices that may be covered under Medicare include the following categories: *Devices approved by the FDA through the Pre-Market Approval (PMA) process*; Devices cleared by the FDA through the 510(k) process; FDA-approved Investigational Device Exemption (IDE) Category B devices; and Hospital IRB-approved non-significant risk devices.") (emphasis added), available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html (last accessed August 29, 2017);[7] *see also Int'l Rehab. Scis. Inc. v. Sebelius*, 688 F.3d 994, 1002 (9th Cir. 2012) ("FDA clearance . . . is *necessary*, but not *sufficient*, for Medicare coverage. . . . To be 'reasonable and necessary' for treatment, a device must be 'safe and effective,' but other considerations are also relevant—like whether there are less costly but equally effective devices available.") (citations omitted).

Finally, Higgins alleges some specific examples of claims for federal reimbursement for implanting Cognis or Teligen devices. *See* Am. Compl. ¶ 201 & Ex. A. He alleges that these

[7] BSC argues that defibrillators are subject to Medicare coverage pursuant to National Coverage Determinations that authorize coverage of this type of device for certain "[c]overed [i]ndications." *See* CMS, *Medicare National Coverage Determinations Manual*, CMS Pub. No. 100-03, Part 1 Ch. 1 §§ 20.4, 20.8 (Rev. 192), available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html. These coverage determinations specify medical conditions that the agency has deemed appropriate to treat using the devices, but they do not supplant the requirement that the devices be approved by the FDA as indicated in the *Medicare Benefit Policy Manual*. *See id.*, Part 1, Foreword (stating in reference to the "Benefit Policy" and other CMS manuals that "[t]here should be no inconsistencies among the instructions in any of these manuals and the NCD Manual pertaining to coverage.").

claims for reimbursement were false because they falsely certified, on certain forms, that "the services provided were 'medically necessary and appropriate for the health of the patient,'" or "necessary to the health of the patient," Am. Compl. ¶¶ 174-75, when in fact the Cognis and Teligen devices were not medically necessary because of their defects and the availability of more reliable alternative devices on the market, *see, e.g.*, Am. Compl. ¶¶ 179, 183.

Such allegations, broadly speaking, might state a claim for relief under the False Claims Act under the theories of implied false certification and fraudulent inducement. The theory of implied false certification, which the Supreme Court endorsed in *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016), provides a basis for False Claims Act liability where "a defendant makes representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements . . . ." *Id.* at 1999. "[T]hose omissions can be a basis for liability if they render the defendants' representations misleading with respect to the goods or services provided." *Id*. As the Supreme Court noted, the act "imposes civil liability on 'any person who . . . knowingly presents, or *causes to be presented*, a false or fraudulent claim for payment or approval . . . ." *Id.* (quoting 31 U.S.C. § 3729(a)(1)(A)) (emphasis added); *see also United States ex rel. Marcus v. Hess*, 317 U.S. 537, 542-43 (1943), *superseded by statute on other grounds as recognized by Schindler Elevator Corp. v. United States ex rel. Kirk*, 563 U.S. 401, 412 (2011). The gist of Higgins' allegations fits this mold: He alleges that BSC defrauded the FDA into approving and maintaining its approval of the Cognis and Teligen defibrillators as safe and effective; that the devices would not have been approved had the FDA been fully informed; that the devices were therefore not medically necessary as required for Medicare reimbursement; and that BSC thus caused doctors to select their products and then to unwittingly falsely certify to the government that the devices were medically necessary in

submitting their reimbursement claims. Higgins' allegations suggest that the claims filed did "not merely request payment, but also ma[de] specific representations about the goods or services provided," and that BSC's "failure to disclose" to the FDA BSC's "noncompliance with material statutory, regulatory, or contractual requirements makes those representations" by its customers, who thought they implanted devices that met FDA standards, "misleading half-truths." *See Escobar*, 136 S. Ct. at 2001. Materiality is a demanding standard, *id.* at 2003, but Higgins' allegations appear calculated to meet it. *Cf. United States v. Adler*, 623 F.2d 1287, 1291 (8th Cir. 1980) ("What makes a statement material is that it is required to put the claimant in a position to receive government benefits, whether rightfully or wrongfully."). In essence, Higgins' theory appears to be that BSC misleadingly convinced doctors that Cognis and Teligen were in "compliance with a condition of eligibility to even participate in a federal program" when the devices actually would not have been approved and thus would have been categorically ineligible for Medicare reimbursement had the FDA known the truth. *See Escobar*, 136 S. Ct. at 2002. This theory appears to have merit.

In addition, courts have recognized fraudulent inducement as a basis for False Claims Act liability. *E.g.*, *United States ex rel. Miller v. Weston Educ., Inc.*, 840 F.3d 494, 499 (8th Cir. 2016); *In re Baycol Prods. Litig.*, 732 F.3d 869, 876 (8th Cir. 2013) (discussing *Hess*, 317 U.S. at 543-44). The False Claims Act "incorporates the common-law meaning of fraud." *Escobar*, 136 S. Ct. at 1999. And the common law recognized fraud by misrepresentation or misleading omission. *See id.* at 2000 (referring to "the rule that half-truths—representations that state the truth only so far as it goes, while omitting critical qualifying information—can be actionable misrepresentations"); *Olson*, 831 F.3d at 1074 ("[A]t common law, fraud encompassed material nondisclosures by those with a duty to disclose."). Courts have applied these common-law

principles to statements made to induce the extension of government benefits or funding contingent on government certification. *E.g.*, *United States v. Perry*, 757 F.3d 166, 176 (4th Cir. 2014) (affirming conviction under different statutory provision for fraudulently obtaining Social Security benefits based on the common-law principle that "suppression of the truth with the intent to deceive," *i.e.*, concealment, may "give rise to an action for fraud") (citing *United States v. Phythian*, 529 F.3d 807, 812 (8th Cir. 2008)); *United States ex rel. Main v. Oakland City Univ.*, 426 F.3d 914, 916-17 (7th Cir. 2005) (False Claims Act claim could lie if university applied for certification making it eligible to receive federal funds knowing that it would not comply with regulations) (quoted in *Miller*, 840 F.3d at 500). Indeed, the Eighth Circuit Court of Appeals has applied the fraudulent inducement theory to False Claims Act claims, *see, e.g.*, *Miller*, 840 F.3d at 499; *Baycol*, 732 F.3d at 876, and has given no indication that the theory would not apply to such claims where the allegedly false representations were made to the FDA as a link in the causal chain to the extension of Medicare or other government benefits. In *Baycol*, the relator alleged that the defendant was liable for False Claims Act violations under a fraudulent inducement theory where defendant had allegedly fraudulently obtained FDA approval for a drug and thereby fraudulently caused the government to reimburse claims under Medicare and other programs. Although the appellate court affirmed the district court's dismissal of claims based on this theory, the dismissal was for failure to meet the pleading standards, not for failure to state a claim as a matter of law, a question that went unmentioned. *See Baycol*, 732 F.3d at 877-80; *see also United States ex rel. Roop v. Hypoguard USA, Inc.*, 559 F.3d 818, 825 (8th Cir. 2009) (dismissing for failure to meet Rule 9(b) pleading standards where plaintiff only alleged conclusorily the connection between FDA approval and Medicare reimbursement and did not plead any particular reimbursement claims). The *Baycol* and *Roop*

decisions did not cast doubt as a matter of law on the fraudulent inducement theory in the context of federal healthcare reimbursements for products subject to FDA approval.[8] Indeed, the *Baycol* Court's summary of the relator's theory included several citations suggesting that the theory had merit as a general principle, even if it was not adequately fleshed out to meet the pleading standards. *See* 732 F.3d at 878.

Courts in other circuits have allowed False Claims Act claims based on a fraudulent inducement theory in this context or, like the Eighth Circuit, avoided rejecting the theory as a matter of law. *See, e.g.*, *Campie*, 862 F.3d at 902, 904; *D'Agostino v. ev3, Inc.*, 845 F.3d 1 (1st Cir. 2016). In *D'Agostino*, the First Circuit Court of Appeals found that the relator did not adequately plead causation or materiality because although the FDA had been aware of the alleged device deficiencies for years, it had not recalled the devices in question. 845 F.3d at 8. The court carefully noted that it was not rejecting the fraudulent inducement theory and offered that "[c]ertainly some official action by the FDA confirming that its approval was actually procured by the alleged fraudulent representations would fill that particular gap in the proposed complaint." *Id.* at 9. The First Circuit recently reaffirmed this key point in *United States ex rel. Nargol v. Depuy Orthopaedics, Inc.*, No. 16-1442, 2017 WL 3167622, at *4-5 (1st Cir. July 26, 2017), holding that there could be no showing of materiality or causation where the FDA, once

[8] BSC also argues that the "worthless services" theory discussed in the *Roop* decision, *see* 559 F.3d at 824, should bar Higgins' claims. The Government contends that this theory has been misapplied. The Court does not reach the question of whether Higgins has pleaded a valid "worthless services" claim. This theory does not act as a shield to bar claims based on separate theories such as implied false certification or fraudulent inducement. *See, e.g., United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 900 (9th Cir. 2017) (noting distinction between a "worthless services" claim and a "nonconforming goods" claim). The *Roop* decision implies that even if a relator does not succeed on a "defective product" claim where the product was not worthless, there might be False Claims Act liability if a relator could "allege with particularity how any product defect or failure to submit MDR reports to the FDA was material to . . . the government's decisions to pay" reimbursement claims. *See* 559 F.3d at 825.

informed of alleged defects, still took no adverse action. In this case, by contrast, Higgins alleges that the FDA took action by recalling the first versions of the Cognis and Teligen devices.[9] This alleged fact also distinguishes this case from *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481 (3d Cir. 2017), in which the court noted that the FDA had taken no adverse action and that the relator "essentially concede[d] that CMS would *consistently reimburse* these claims with full knowledge of the purported noncompliance." *Id.* at 490.

In summary, the outline of Higgins' fraudulent inducement claim appears viable. The Court does not, however, decide whether the Amended Complaint states a claim as a matter of law, because even assuming that the allegations could state a claim, the Amended Complaint does not satisfy Federal Rule of Civil Procedure 9(b).[10]

B. Whether the Amended Complaint Fails to Plead Fraud with Particularity

The Amended Complaint fails to plead fraud with particularity. Higgins does avoid one hazard that often ensnares relators. Unlike the relators in *Roop* and *Baycol*, Higgins alleges particular claims that were submitted *to CMS* and received federal reimbursements. Nonetheless, he still does not "state with particularity the circumstances constituting fraud or mistake," *see*

[9] BSC construes *Nargol* as on all fours with this case because the *Nargol* defendant voluntarily discontinued its product, *see* 2017 WL 3167622, at *4, which is what BSC asserts happened here. Even accepting as true that BSC initiated the return of its devices, the fact that the FDA affirmatively characterized BSC's actions as a "recall" is meaningful. *See supra* note 6. In *Nargol*, there is no mention that FDA issued a recall notice.

[10] Like *Baycol* and *Roop*, some of the other authorities cited by BSC likewise did not reach the question of whether the relator's claims failed as a matter of law, and these cases therefore do not support BSC's argument that courts have rejected the theories entirely. *E.g.*, *U.S. ex rel. Ge v. Takeda Pharm. Co.*, 737 F.3d 116, 119 (1st Cir. 2013). Further, some cases apply the condition-of-payment materiality analysis rejected in *Escobar*, 136 S. Ct. at 1996, 2003-04. *E.g.*, *United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 701 (6th Cir. 2014) (finding in part that relator's claim based on a manufacturer's regulatory violations in manufacturing an FDA-approved drug failed because the Medicare and Medicaid statutes "do not require compliance with" the regulations "as *a precondition* to reimbursement") (emphasis added). The Court will not specifically address each non-binding case cited by BSC.

Fed. R. Civ. P. 9(b), because he does not plead with particularity the acts taken or statements made to allegedly defraud *the FDA*. The essence of the Amended Complaint is that BSC defrauded the FDA, and that this fraud permeated the consequent submissions of reimbursement claims. The Amended Complaint describes generally what actions or omissions by BSC were misleading—for instance, failing to submit a PMA amendment to update the FDA about reports coming in from Europe, suppressing the submission of adverse event reports, and downplaying the alleged device defects in the first versions of the devices when submitting a PMA amendment for the second versions. But the generalized allegations as to these acts do not identify "the time, place, and content of the defendant's false representations, as well as the details of the defendant's fraudulent acts, including when the acts occurred, [and] who engaged in them . . . ." *Joshi*, 441 F.3d at 556 (citations omitted). The Amended Complaint does not, for example, identify any specific statements in any of BSC's submissions to the FDA that were allegedly misrepresentations or misleading by omission. Nor does it provide any representative examples of adverse events that BSC should have reported but did not, or provide some other details about the allegedly unreported events that would "give[] sufficient notice . . . to permit the preparation of an effective defense." *Streambend Props. II, LLC v. Ivy Tower Minneapolis, LLC*, 781 F.3d 1003, 1010 (8th Cir. 2015) (citation omitted). Moreover, although the Amended Complaint alleges that the FDA recalled the Cognis and Teligen devices, it does not allege whether CMS subsequently denied any requests for reimbursement for implanting those versions of the devices. *See Escobar*, 136 S. Ct. at 2003-04; *D'Agostino*, 845 F.3d at 7.

Arguing that the Amended Complaint satisfies the "who, what, where, when, and how" requirement, *see Olson*, 831 F.3d at 1070 (citation omitted), Higgins points to disparate alleged facts that do not add up to complete examples of fraudulent representations. For example,

Higgins contends that the "who" requirement is satisfied by, for one, the Amended Complaint's citing Sumi Dahm as admitting to customers that "BSC was aware of the malfunctions involving the set screws/headers because the devices had been launched earlier in the year in Europe and similar problems had occurred there and had been reported to BSC." Am. Compl. ¶ 124 (emphases omitted). This allegation does not, however, indicate who in BSC *made misrepresentations to the FDA*, or the "when," "how," or "what" of alleged misrepresentations.

The Amended Complaint thus fails to meet the Rule 9(b) standards and will be dismissed.

C. Leave to Amend the Complaint

Higgins requests leave to file a second amended complaint if the Court finds the Amended Complaint deficient. In light of the Court's determination that the allegations do not appear to fail to state a claim as a matter of law, amendment would not necessarily be futile. Because leave to amend should be freely given in the interest of justice, Fed. R. Civ. P. 15(a), the Court in its discretion will allow Higgins 21 days to file an amended complaint to attempt to cure the Rule 9(b) pleading deficiencies. The Court therefore dismisses without prejudice and defers entry of judgment pending the anticipated filing of a second amended complaint.

Based on the files, records, and proceedings herein, and for the reasons stated above, IT IS ORDERED THAT:

1. Defendant Boston Scientific Corporation's Motion to Dismiss Relator's Amended Complaint [Dkt. No. 63] is GRANTED consistent with the above opinion.

2. The Amended Complaint is DISMISSED WITHOUT PREJUDICE.

3. Relator Steven Higgins is GRANTED LEAVE TO AMEND. Relator's Second Amended Complaint may be filed no later than 21 days from the date of this Order.

Dated: August 29, 2017

s/ Joan N. Ericksen
JOAN N. ERICKSEN
United States District Judge