UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

United States of America,
ex rel. James Allen,

Civil No. 11-22 (DWF/AJB)

Plaintiff,

v.

MEMORANDUM OPINION AND ORDER

Guidant Corporation,
Guidant Sales Corporation,
Cardiac Pacemakers, Inc.,
Guidant Ireland,
Boston Scientific Corporation,
Guidant LLC, formerly d/b/a
Guidant Corporation, and
Guidant Sales LLC,

Defendants.

Chad A. Blumenfield, and D. Gerald Wilhelm, Assistant United States Attorneys, and Jeffrey S. Gleason, Esq., and Jonathan H. Gold, Esq., U.S. Department of Justice, counsel for Plaintiff United States of America.

Dennis R. McCoy, Esq., and Thomas B. Cronmiller, Esq., Hiscock & Barclay LLP; Daniel C. Adams, Esq., Larson King LLP; and James Irving Myers, Esq., Myers, Quinn & Schwartz LLP, counsel for Relator James Allen.

Michael L. Koon, Esq., David T. Fischer, Esq., and Rachel A. Simek, Shook Hardy & Bacon LLP; James L. Volling, Esq., and Leif T. Simonson, Esq., Faegre Baker Daniels LLP, counsel for Defendants.

INTRODUCTION

This matter is before the Court on Defendants' Motion to Dismiss Relator's Claims (Doc. No. 77). For the reasons set forth below, the Court grants in part and denies in part the Motion to Dismiss.

BACKGROUND

I. Procedural History

James Allen ("Relator") brought this qui tam action on behalf of the United States under the False Claims Act ("FCA"), 31 U.S.C. § 3729, *et seq.*, against Guidant Corporation, Guidant Sales Corporation, Cardiac Pacemakers, Inc., Guidant Ireland, Boston Scientific Corporation, Guidant LLC, formerly doing business as Guidant Corporation, and Guidant Sales LLC (collectively, "Guidant" or "Defendants"). Relator filed his original complaint on July 10, 2008 *in camera* and under seal in the United States District Court for the Western District of New York. (Doc. No. 1, Rel. Compl.) In March 2010, the government declined to intervene. (Doc. No. 11.) Relator filed a First Amended Complaint on July 22, 2010. (Doc. No. 15, Rel. Am. Compl.) Defendants filed a Motion to Dismiss in September 2010. (Doc. No. 31.) The government then filed an unopposed motion to intervene in December 2010. (Doc. No. 34.) The government was granted leave to intervene, and the case was transferred to the District of Minnesota. (Doc. No. 36.) Defendants' Motion to Dismiss had not been ruled on at the time of transfer. (*See id.*) The government then filed its Intervenor Complaint in January 2011. (Doc. No. 45, Int. Compl.) Defendants renewed their Motion to Dismiss Relator's Claims in this district on September 27, 2011. (Doc. No. 77.)

II. Description of Products

Relator's Amended Complaint involves one line of implantable cardiac devices ("ICDs") manufactured by Guidant: the Ventak Prizm 2 DR Model 1861 (the "Prizm 1861"). (Rel. Am. Compl. ¶ 2.) The government's Complaint involves the Prizm 1861, as well as the Contak Renewal 1 and 2 (the "Renewal"), another line of ICDs manufactured by Guidant. (Int. Compl. ¶ 40.) ICDs prevent sudden cardiac death by treating such heart rhythm abnormalities as ventricular tachycardia, ventricular fibrillation, or significant thickening of the heart muscle resulting in arrhythmia. (*Id.* ¶¶ 40, 43.) These conditions can lead to loss of consciousness or death, "unless the device delivers the proper therapy to put the patient's heart back into a normal cardiac rhythm." (*Id.* ¶ 43.) An ICD works by detecting the heart rhythm abnormality and delivering an electric shock to the heart muscle, bringing the heart back to a normal rhythm. (Rel. Am. Compl. ¶ 25; Int. Compl. ¶ 44.)

Guidant received a supplemental pre-market FDA approval for the Prizm 1861 for a limited target population on August 4, 2000. (Rel. Am. Compl. ¶ 33; Int. Compl. ¶ 46.) Guidant received FDA approval for the Prizm 1861 on July 18, 2002 for "marketing, sale to and placement in patients who had spontaneous and/or inducible life threatening ventricular arrhythmias and those at high risk for developing such arrhythmias." (Rel. Am. Compl. ¶ 34.) Guidant received FDA approval for the Renewal sometime in 2002. (Int. Compl. ¶ 48.)

When a company makes changes to a device that affect the safety or efficacy of the device, the FDA requires the company to submit a pre-market approval application

("PMA") supplement to the FDA. (Rel. Am. Compl. ¶ 40; Int. Compl. ¶¶ 30-35.) When the changes do not affect safety and efficacy, the FDA requires the company to notify the FDA of the changes in annual post-approval reports. (Rel. Am. Compl. ¶ 42; Int. Compl. ¶ 61.)

In August 2003, Guidant reported in its Post-Approval Annual Report that it made changes to the Prizm 1861, effective November 13, 2002, that did not affect the safety or effectiveness of the device. (Rel. Am. Compl. ¶ 45; Int. Compl. ¶ 65.)

III. Summary of Allegations

A. Relator's Allegations

Relator's allegations pertain to the Prizm 1861. (Rel. Am. Compl. ¶ 2.) Relator claims that, after July 18, 2002, Guidant marketed and sold Prizm 1861 units that were manufactured from: (1) April 16, 2002 through November 13, 2002; and (2) November 13, 2002 through October 5, 2007, and that Guidant knew the units manufactured during these periods had the potential to arc, an electrical short circuit problem.[1] (*Id.* ¶¶ 36, 129.) Relator alleges that Guidant thus caused "hospitals,

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[1] Relator's Amended Complaint simply names arcing as the defect Guidant attempted to correct, but does not explain arcing. (Rel. Am. Compl. ¶¶ 59-61.) He refers to an electrical short circuiting problem in other parts of his complaint. (*Id.* ¶¶ 82-97, 108-15.) According to the Intervenor Complaint:

> Arcing occurs when the device detects the irregular heartbeat and delivers a shock, but instead of the current going to the lead and then the heart, the current "arcs" back to the device itself. This causes the device to divert energy away from the leads in a short circuit, rendering the device ineffective to deliver therapy. A failure to deliver the potentially life-saving shock to the patient can result in death.

(Int. Compl. ¶ 45.)

physicians and other providers to submit and receive payment for false and fraudulent Medicare and Veteran's Administration claims" for Prizm 1861 devices, manufactured between April 16, 2002 and November 13, 2002 and between November 13, 2002 and October 5, 2007, that were "known changed, defective, non-FDA submitted, experimental and investigational devices." (*Id.* ¶ 129.)

Relator asserts that Guidant's claim that it made changes to the Prizm 1861 effective April 16, 2002 may be false. (*Id.* ¶ 38.) If the changes were made, Relator claims that they were made to correct short circuiting problems and that Guidant did not seek the necessary FDA approval to sell these devices after the change. (*Id.* ¶¶ 40-41, 112.)

Relator also maintains that the statement in Guidant's August 2003 annual report regarding the November 13, 2002 changes to the Prizm 1861 was false. (*Id.* ¶¶ 45-48.) Relator claims that the purpose of the change was to address arcing and other electrical defects[2] that affected safety and efficacy and that the change failed to correct all of the known defects. (*Id.* ¶¶ 45-48, 60.) Relator claims that Prizm 1861 devices manufactured after the November 13, 2002 change through October 5, 2007 therefore had the potential for arcing or other electrical defects. (*Id.* ¶ 60.) Additionally, Relator alleges that the November 13, 2002 changes were not made for those units manufactured between April 16, 2002 and November 13, 2002, and that Guidant never disclosed known problems with the April 16, 2002 through November 13, 2002 units. (*Id.* ¶¶ 59-61.)

[2] Relator refers to "other electrical defects" without explanation of these defects. (Rel. Am. Compl. ¶¶ 59-61.)

Relator further claims that Guidant used non-FDA-approved adhesive/insulation in Prizm 1861 units manufactured between April 16, 2002 and November 13, 2002 and between November 13, 2002 and October 5, 2007, and that Guidant did not disclose this to the FDA, Medicare, physicians, or the public. (*Id.* ¶¶ 49-57.)

In support of his claim that Guidant knew about the electrical defects, Relator pleads facts concerning the defects of his own Prizm 1861 device, manufactured on June 13, 2002. (*Id.* ¶¶ 65-76.) Relator alleges that his device, implanted on August 27, 2002, failed twice,[3] and as a result, he attempted to have the device replaced in 2005. (*Id.* ¶¶ 65-71.) The surgery was cancelled, however, allegedly due to a Guidant salesperson, James Davis, advising the surgeon and Relator's insurance company that the Prizm 1861 was not recalled and was not defective. (*Id.* ¶¶ 72-74.) Relator proceeded to undergo surgery with a different doctor, who replaced his Prizm 1861 with a different company's defibrillator on December 5, 2005.[4] (*Id.* ¶¶ 75-76.)

From August 19, 2005 to March 15, 2006, Relator communicated with Daniel Tich, a manager in Product Performance Communications at Guidant, regarding Relator's experiences with the malfunctioning Prizm 1861. (*Id.* ¶¶ 82-97.) Mr. Tich allegedly

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[3] Relator claims the device first failed on December 2, 2002, "rendering Relator unconscious and causing additional myocardial damage." (Rel. Am. Compl. ¶¶ 66-67.) Relator claims the device failed again sometime in 2003, "causing him to fall down a flight of stairs." (*Id.* ¶ 69.)

[4] Relator states that his insurance company, Univera Healthcare, paid for the second procedure, but he does not state who paid for the implantation of his Prizm 1861 device. (Rel. Am. Compl. ¶¶ 65-76.)

informed Relator: that Relator's Prizm 1861 was not part of the June 17, 2005 recall action because that recall only concerned Prizm 1861 devices manufactured before April 2002; that the November 2002 change was "not really necessary for further protection"; and that no devices manufactured after April 2002 had experienced "an electrical short circuit in the lead connection area." (*Id.* ¶¶ 84-94.) Mr. Tich also allegedly informed Relator that Guidant received approval for its November 2002 changes to the Prizm 1861. (*Id.* ¶ 94.)

Relator additionally pleads that he discovered that other individuals' Prizm 1861 devices malfunctioned. (*Id.* ¶¶ 78-80, 98.) Relator claims he discovered an Adverse Event Report, dated February 2, 2004, that Guidant filed, which "falsely claimed FDA had approved certain manufacturing enhancements that it had purported to make." (*Id.* ¶ 78.) Relator claims he discovered this report "among the thousands that he reviewed." (*Id.* ¶ 79.) Relator asserts that his research revealed "that Guidant never submitted applications nor received FDA supplemental approval for the changes (or enhancements)." (*Id.* ¶ 80.) Relator states that his "research uncovered that the 11,000 devices manufactured between April and November 2002 had a significant rate of failure."[5] (*Id.* ¶ 98.) Relator also lists the serial numbers, implantation dates, and

[5] Relator does not specify the sources of his research. (*See* Rel. Am. Compl. ¶¶ 80, 98.)

implantation locations for five devices for which the Veteran's Administration allegedly paid.[6] (*Id.* ¶ 127.)

Relator maintains that "Guidant intentionally made misrepresentations of material fact to the FDA aimed at concealing from the FDA the defective and dangerous nature of the [Prizm] 1861 defibrillator, including, but not limited to, those units of the device manufactured from April 16, 2002 through November 13, 2002 and from November 13, 2002 through October 5, 2007." (*Id.* ¶ 134.) Relator also claims Guidant "knowingly presented or caused to be presented false or fraudulent claims to the United States, including Medicare and the Veterans Administration, for reimbursement relative to the [Prizm] 1861 defibrillator." (*Id.* ¶ 135.)

Based on these allegations, Relator asserts the following three claims: (1) violation of the FCA; (2) unjust enrichment; and (3) payment by mistake of fact. (*Id.* ¶¶ 130-45.)

B. Government's Allegations

1. Prizm 1861 Devices

The government claims that two physicians notified Guidant about two separate arcing defects in the Prizm 1861 device in February 2002 and March 2002 and that, in response, Guidant implemented an engineering modification for the Prizm 1861 device

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[6] These five devices were all implanted in the United States between September 13, 2002 and January 23, 2003. (Rel. Am. Compl. ¶ 127.) No manufacture dates are provided. (*Id.*)

on April 16, 2002.[7] (Int. Compl. ¶¶ 50-57.) The government alleges that Guidant believed the change corrected the arcing problem, but that it did not submit a PMA supplement to the FDA and did not disclose the action in the following two annual reports as required. (*Id.* ¶¶ 58-65.) The government also notes that, on or about November 13, 2002, Guidant made a second engineering change to the Prizm 1861 to address the arcing problem and that Guidant did not submit a supplemental PMA to the FDA before making this change. (*Id.* ¶¶ 62-64.)

The government further alleges that Guidant knew that the Prizm 1861 devices manufactured before April 16, 2002 would continue to have arcing problems "that would potentially put patients' lives at risk," and that Guidant received at least 26 reports of arcing events in pre-April 16, 2002 devices, but continued to sell its existing stock of these devices. (*Id.* at ¶¶ 67-81.) In May 2005, Guidant first notified physicians of the arcing problem with Prizm 1861 devices. (*Id.* at ¶¶ 123-26.) On June 17, 2005, Guidant issued letters to physicians fully disclosing the arcing problem with the Prizm 1861. (*Id.* ¶ 125.) According to the government, the FDA classified the June 17 letters as Class I recalls for the Prizm 1861 and determined the Prizm 1861 devices manufactured before April 16, 2002 were adulterated. (*Id.* ¶¶ 131-33.)

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[7] The government claims the arcing was caused by a breakdown in the polyimide insulation in a feedthrough wire in the Prizm 1861 device. (Int. Compl. ¶ 54.) "The change order called for additional medical adhesive coating to be added to the backfill tube to act as further insulation that would also prevent the feedthrough wire from coming too close to the backfill tube." (*Id.* ¶ 57.)

2. Renewal Devices

The government alleges that Guidant learned about four separate arcing events in Renewal devices between November 2003 and July 2004. (*Id.* ¶¶ 84-89.) On or about July 28, 2004, Guidant implemented a manufacturing change to address the arcing problem in the Renewal device. (*Id.* ¶ 87.) The government asserts that Guidant did not inform the FDA about this manufacturing corrective action. (*Id.* ¶ 88.) On August 26, 2004, Guidant ceased the manufacture and shipment of all Renewal devices from its factory. (*Id.* ¶¶ 90-93.) The government claims that Guidant concluded in September 2004 that the root cause of the arcing problem was the polyimide insulation in the Renewal devices. (*Id.* ¶¶ 94-95.) Despite this knowledge, however, Guidant allegedly continued to sell Renewal devices manufactured and shipped before August 26, 2004 and continued to receive reports of arcing events in those devices. (*Id.* ¶¶ 96-99.) Guidant did not inform physicians about the arcing problems in Renewal devices until June 2005. (*Id.* ¶ 126.) On June 17, 2005, Guidant issued letters to physicians fully disclosing the arcing problem with the Renewal devices. (*Id.* ¶ 125.) According to the government, the FDA classified the June 17 letters as Class I recalls for the Renewal devices and determined the Renewal devices manufactured before August 26, 2004 were adulterated. (*Id.* 131-33.)

3. Causes of Action

The government asserts two causes of action: (1) FCA; and (2) unjust enrichment. (*Id.* ¶¶ 138-42.) The government maintains that Guidant "knowingly caused to be presented false or fraudulent claims for payment or approval to the United States for the

implantation of defective Prizm [1861] and Renewal devices that were not reasonable and necessary and therefore were not reimbursable by the Medicare program." (*Id.* ¶ 139.)

IV. Criminal Case

On January 12, 2011, Guidant LLC was convicted of two misdemeanors regarding the arcing problems with the Prizm 1861 and Renewal devices.[8] *United States v. Guidant LLC*, 10-mj-67 (DWF) (Doc. No. 42). Guidant LLC pleaded guilty to one count of violating 21 U.S.C. §§ 331(q)(2), 360i, and 333(a)(1) for submitting a false or misleading report to the FDA and one count of violating 21 U.S.C. §§ 331(q)(1)(B), 360i(g), and 333(a)(1) for failing to give notification or other required material to the FDA. *Id.* The false submission related to Guidant's August 2003 annual report that stated that the November 2002 Prizm 1861 device change did not affect safety or effectiveness. *United States v. Guidant LLC*, 10-mj-67 (DWF) (Doc. No. 27); (Int. Compl. ¶ 134.) The failure to notify the FDA related to a March 2005 Product Update on the Renewal device. *Id.* The update was designed to reduce a risk to health, but did not reveal the arcing problems or possibility of death resulting from the defect in the Renewal devices. *United States v. Guidant LLC*, 10-mj-67 (DWF) (Doc. No. 27); (Int. Compl. ¶¶ 116-18).

V. Guidant MDL

The Prizm 1861 and Renewal devices were two of several devices that were the subject of a Multi-District Litigation ("MDL") based in this District that began in late 2005. *In re: Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, 05-md-1708

[8] The Court rejected the original plea agreement. *United States v. Guidant LLC*, 10-mj-67 (DWF) (Doc. No. 27).

(DWF/AJB) (Doc. No. 132, Master Compl.). The MDL plaintiffs claimed that Guidant knew about defects in the devices and failed to inform the FDA, the medical community, and the plaintiffs. (*Id.* ¶¶ 170-203.) Specifically, the MDL plaintiffs alleged that Guidant knew about malfunctions with Prizm 1861 devices manufactured before April 2002 and continued to sell these defective devices. (*Id.* ¶¶ 84-115.) The Master Complaint further noted that Guidant was aware of a failure "associated with a [Prizm 1861] that was manufactured after April 16, 2002." (*Id.* ¶ 114.) The MDL plaintiffs also alleged that Guidant knew about defects in the Renewal devices, which it failed to disclose, and continued to sell these defective devices. (*Id.* ¶¶ 116-33.)

Relator filed his Complaint by Adoption in the MDL in June 2007. *In re: Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, 05-md-1708 (DWF/AJB) (Doc. No. 2077); *Allen v. Guidant*, 06-cv-1826 (DWF/AJB) (Doc. No. 3). Relator adopted the allegations in the Master Complaint.[9] *Id.*

In December 2007, the parties entered into a Master Settlement Agreement ("MSA"). *See In re: Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*,

[9] Relator adopted Counts I-XII and Counts XVI-XVIII of the Master Complaint (strict liability-failure to warn; strict liability-design and/or manufacturing defect; negligence; negligence per se; breach of implied warranty; fraud; constructive fraud; unfair and deceptive trade practices under New York state law; violation of Senior Citizen and Handicapped Person Consumer Fraud Act, Minn. Stat. § 325F.71, and/or similar statutes in effect in other jurisdictions; negligent infliction of emotional distress; intentional infliction of emotional distress; gross negligence/malice; loss of consortium; medical monitoring; unjust enrichment; and punitive damages). *In re: Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, 05-md-1708 (DWF/AJB) (Doc. No. 2077); *Allen v. Guidant*, 06-cv-1826 (DWF/AJB) (Doc. No. 3).

05-md-1708 (DWF/AJB) (Doc. No. 3823). Relator was one of the plaintiffs who settled his claims pursuant to the MSA. (*Id.*, Ex. A.)

DISCUSSION

I. Legal Standard

In deciding a motion to dismiss pursuant to Rule 12(b)(6), a court assumes all facts in the complaint to be true and construes all reasonable inferences from those facts in the light most favorable to the complainant. *Morton v. Becker*, 793 F.2d 185, 187 (8th Cir. 1986). In doing so, however, a court need not accept as true wholly conclusory allegations, *Hanten v. Sch. Dist. of Riverview Gardens*, 183 F.3d 799, 805 (8th Cir. 1999), or legal conclusions drawn by the pleader from the facts alleged, *Westcott v. City of Omaha*, 901 F.2d 1486, 1488 (8th Cir. 1990). A court may consider the complaint, matters of public record, orders, materials embraced by the complaint, and exhibits attached to the complaint in deciding a motion to dismiss under Rule 12(b)(6). *Porous Media Corp. v. Pall Corp.*, 186 F.3d 1077, 1079 (8th Cir. 1999).

To survive a motion to dismiss, a complaint must contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 545 (2007). Although a complaint need not contain "detailed factual allegations," it must contain facts with enough specificity "to raise a right to relief above the speculative level." *Id.* at 555. As the United States Supreme Court recently reiterated, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements," will not pass muster under *Twombly*. *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (citing *Twombly*, 550 U.S. at 555). In sum, this standard "calls for enough fact[s] to raise

a reasonable expectation that discovery will reveal evidence of [the claim]." *Twombly*, 550 U.S. at 556.

II. Motion to Dismiss

Defendants have moved to dismiss Relator's claims, arguing that: (1) the government's complaint supersedes Relator's complaint; (2) this Court does not have jurisdiction under the FCA over Relator's claims because they are based on publicly disclosed information and Relator is not an original source; (3) Relator fails to plead fraud with particularity; and (4) Relator lacks standing to assert his common law claims.

A. Superseding Complaint

The FCA provides that if the government chooses to intervene in an action, the relator has "the right to continue as a party to the action, subject to the limitations set forth in paragraph (2)." 31 U.S.C. § 3730(c)(1). Subsection (c)(2) of the Act describes when the government can: dismiss the action; settle the action; or restrict the relator's participation in the action.[10] *Id.* § 3730(c)(2). "The only limitations on the relator's

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[10] 31 U.S.C. § 3730(c)(2) states:

> (A) The Government may dismiss the action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion.
> (B) The Government may settle the action with the defendant notwithstanding the objections of the person initiating the action if the court determines, after a hearing, that the proposed settlement is fair, adequate, and reasonable under all the circumstances. Upon a showing of good cause, such hearing may be held in camera.
> (C) Upon a showing by the Government that unrestricted participation during the course of the litigation by the person initiating the action would interfere with or unduly delay the Government's prosecution of the case, or

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participation in the case are contained in § 3730(c)(2)." *United States ex rel. O'Keefe v. McDonnell Douglas Corp.*, 918 F. Supp. 1338, 1347 (E.D. Mo. 1996).

If the government's claims are duplicative of those of the relator, the government's claims become the operative claims when the government intervenes. *United States ex rel. Feldman v. City of N.Y.*, No. 09 Civ. 8381, 2011 WL 3862844, at *5 (S.D.N.Y. Sept. 1, 2011). "However, if the Government only partially intervenes in an action, a relator may retain standing to prosecute those aspects of his or her complaint as to which the Government has not intervened." *Id*; *see also O'Keefe*, 918 F. Supp at 1346-47 (permitting the relator to pursue FCA claims not adopted by the government).

In this case, Relator's complaint pertains to defective Prizm 1861 devices manufactured *after* April 16, 2002. (Rel. Am. Compl. ¶¶ 116-36.) The government's allegations with respect to the Prizm 1861 relate only to devices manufactured *before* April 16, 2002. (Int. Compl. ¶¶ 50-81.) Thus, the government has only partially

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> would be repetitious, irrelevant, or for purposes of harassment, the court may, in its discretion, impose limitations on the person's participation, such as--
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> (i) limiting the number of witnesses the person may call;
> (ii) limiting the length of the testimony of such witnesses;
> (iii) limiting the person's cross-examination of witnesses; or
> (iv) otherwise limiting the participation by the person in the litigation.
>
> (D) Upon a showing by the defendant that unrestricted participation during the course of the litigation by the person initiating the action would be for purposes of harassment or would cause the defendant undue burden or unnecessary expense, the court may limit the participation by the person in the litigation.

31 U.S.C. § 3730(c)(2).

intervened in this action as it relates to the Prizm 1861. Moreover, the government has not sought to dismiss or settle Relator's claims or to limit Relator's participation in the action. The Court concludes that the government's complaint does not supersede Relator's complaint. At a minimum, Relator retains standing to prosecute his FCA claim.

B. False Claims Act

1. Public Disclosure Bar

Defendants argue that this Court does not have jurisdiction over Relator's FCA claim because his claim is based on publicly disclosed information and Relator does not qualify as an original source.

31 U.S.C. § 3730(e)(4), as it existed at the time Relator filed his original complaint in July 2008, provided:

> (A) No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.
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> (B) For purposes of this paragraph, "original source" means an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information.

31 U.S.C. § 3730(e)(4) (2006) (amended 2010).[11] For purposes of the present motion, the Court considers the statute as it existed at the time this action was initiated in 2008.

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[11] 31 U.S.C. § 3730(e)(4), as amended in 2010, now provides:

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See, e.g., United States ex rel. Estate of Cunningham v. Millennium Labs. of Cal., Civ. No. 09-12209-JLT, 2012 WL 259572, at *3 (D. Mass. Jan. 30, 2012), citing *Mullan v. Torrance*, 22 U.S. 537, 539 (1824) ("It is quite clear, that the jurisdiction of the Courts depends upon the state of things at the time of the action brought . . . .").

A court must consider three questions when determining whether a particular qui tam action under the FCA is barred as a result of public disclosures: "(1) Have allegations made by the relator been 'publicly disclosed' before the qui tam suit was brought? (2) If so, is the qui tam suit 'based upon' the public disclosure? and (3) If so, was the relator an 'original source' of the information on which the allegations were based?" *Minnesota Ass'n of Nurse Anesthetists v. Allina Health Sys. Corp.*, 276 F.3d 1032, 1042 (8th Cir. 2002). If the Court answers either of the first two questions in the

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> (A) The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed--
> (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;
> (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or
> (iii) from the news media, unless . . . the person bringing the action is an original source of the information.
> (B) For purposes of this paragraph, "original source" means an individual who either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) [sic] who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.

Patient Protection and Affordable Care Act, Pub. L. No. 111–148, § 10104(j)(2), 124 Stat. 119, 901 (2010) (codified as amended at 31 U.S.C. § 3730(e)(4) (Supp. 2010) (effective July 22, 2010)).

negative, or the third question in the affirmative, the Court has jurisdiction over the action. *Id*.

Defendants first assert that the allegations made by Relator in this case were "publicly disclosed" before the qui tam suit was filed. Defendants claim that Relator relied upon media reports and other public materials as the source of his claims. Defendants identify three articles from the New York Times (Doc. No. 80, Exs. A-C), Relator's state court personal injury case (*Id.* Ex. E),[12] and the MDL Master Complaint (*Id.* Ex. F) as the public documents upon which Relator has based this action.

In order to bar an FCA claim, the public disclosure must reveal "the critical elements of the fraudulent transaction themselves." *United States ex rel. Hixson v. Health Mgmt. Sys., Inc.*, 613 F.3d 1186, 1188 (8th Cir. 2010); *see also Minn. Ass'n of Nurse Anesthetists*, 276 F.3d at 1044 ("[A] public disclosure must reveal both the true state of facts and that the defendant represented the facts to be something other than what they were."). Even assuming, without deciding, that Relator's claims are in some way based upon the public disclosures identified by Defendants,[13] the Court concludes that Relator is an original source of the information on which the allegations are based.

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[12] Relator's personal injury action was removed to federal court and subsequently adopted by the MDL. *In re: Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, 05-md-1708 (DWF) (Doc. No. 2077); *Allen v. Guidant*, 06-cv-1826 (DWF) (Doc. No. 3).

[13] The Court notes that the New York Times articles identified by Defendants do not disclose defects in Prizm 1861 devices manufactured after April 16, 2002. (Doc. No. 80, Exs. A-C.)

To qualify as an original source, "the relator's knowledge of the information must be (1) direct and (2) independent, and (3) the relator must have voluntarily provided the information to the Government before filing suit." *Minn. Ass'n of Nurse Anesthetists*, 276 F.3d at 1042-43. The FCA "seeks to encourage persons with first-hand knowledge of fraudulent misconduct . . . or those who are either close observers or otherwise involved in the fraudulent activity to come forward." *United States ex rel. Barth v. Ridgedale Elec., Inc.*, 44 F.3d 699, 703 (8th Cir. 1995) (internal citations and quotations omitted); *see United States ex rel. Kinney v. Stoltz*, 327 F.3d 671, 674 (8th Cir. 2003). An individual who receives second-hand information from a person having direct knowledge of the asserted fraud does not have direct knowledge himself. *Barth*, 44 F.3d at 703. A relator need not to have personal knowledge of all of the elements of a claim, however, to qualify as an original source. *Minn. Ass'n of Nurse Anesthetists*, 276 F.3d at 1050.

Relator experienced malfunctions with his own Prizm 1861 device, which was manufactured on June 13, 2002, on at least two occasions. (Rel. Am. Compl. ¶¶ 65-69.) On December 2, 2002, Relator's device malfunctioned, rendering him unconscious and causing myocardial damage. (*Id.* ¶¶ 66-67.) His device malfunctioned again in 2003, causing him to fall down a flight of stairs. (*Id.* ¶ 69.) Relator's claims in this case arise from purported defects in Prizm 1861 devices manufactured after April 16, 2002. (*Id.* ¶¶ 116-36.) Thus, Relator has personal knowledge of the propensity for Prizm 1861 devices—specifically those manufactured after April 16, 2002—to malfunction. Through

his personal experiences with his Prizm 1861, Relator has direct and independent knowledge of the information on which his FCA claim is based.

Additionally, Relator voluntarily reported the relevant information to the government before filing his complaint. (*Id.* ¶¶ 99-102.) Therefore, the Court concludes that the public disclosure bar does not prohibit Relator's FCA claim from proceeding, and this Court is not divested of jurisdiction pursuant to 31 U.S.C. § 3730(e)(4).

2. Rule 9(b) Pleading Requirements

In the alternative, Defendants argue that Relator's FCA claim fails to meet the requirements of Rule 9(b) of the Federal Rules of Civil Procedure.

A defendant who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim" is liable under the FCA. 31 U.S.C. § 3729(A)(1)(a)-(b). When a party asserts a violation of the FCA, the complaint must satisfy the heightened pleading requirements of Rule 9(b). *United States ex rel. Roop v. Hypoguard USA, Inc.*, 559 F.3d 818, 822 (8th Cir. 2009). The party must "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). To meet these requirements, the complaint must 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, who engaged in them, and what was obtained as a result." *United States ex rel. Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552, 556 (8th Cir. 2006). In other words, the complaint must state the who, what, where, when, and how of the alleged FCA violation. *Id.* "[C]onclusory allegations that a

defendant's conduct was fraudulent and deceptive are not sufficient to satisfy the rule." *Drobnak v. Anderson Corp.*, 561 F.3d 778, 783 (8th Cir. 2009).

Applying these standards, the Court finds that Relator has pleaded a violation of the FCA with sufficient particularity to meet the requirements of Rule 9(b). Relator alleges the time, place, and content of Defendants' fraudulent acts and false representations: namely, that Guidant knew about arcing problems in the Prizm 1861 devices manufactured after April 16, 2002, that Guidant did not effectively repair the devices, that Guidant submitted false reports (or failed to submit reports as required) to the FDA on particular dates, and that Guidant thus falsely represented to Medicare and the Veteran's Administration that Prizm 1861 units, manufactured between April 16, 2002 and October 5, 2007, were free from any known defects. (Rel. Am. Compl. ¶¶ 38-64, 110-29.) Relator also details his own experience with his defective device and further describes specific representations made by Guidant personnel (identified by name) about the supposed safety of his device.[14] (*Id.* ¶¶ 65-97.) Having carefully reviewed Relator's complaint, the Court concludes that Relator's FCA claim satisfies Rule 9(b).

[14] In particular, Relator asserts that, when he attempted to replace his Prizm 1861 device in 2005, James Davis, a Guidant salesperson, told Relator's surgeon that his device was not defective. (Rel. Am. Compl. ¶ 73.) Relator also corresponded with Daniel Tich, a manager in Product Performance Communications at Guidant, from August 2005 to March 2006, who maintained that Relator's device was not subject to the recall, that no Prizm 1861 devices manufactured after April 2002 had experienced an electrical short circuit problem, and that Guidant had received approval for the November 2002 change to the Prizm 1861. (*Id.* ¶¶ 82-94.)

C. Common Law Claims

Defendants assert that Relator's common law claims of unjust enrichment and payment by mistake of fact must also be dismissed. "No common law right to maintain Qui tam actions exists and authority to file such actions must be found in legislation." *United States ex rel. Burnette v. Driving Hawk*, 587 F.2d 23, 24 (8th Cir. 1978); *see also Stalley v. Catholic Health Initiatives*, 509 F.3d 517, 521-22 (8th Cir. 2007) ("There presently is no common-law right to bring a qui tam action, which is strictly a creature of statute.").

Under the FCA, a private citizen may bring a civil action for a violation of the Act on behalf of both the federal government and himself.[15] 31 U.S.C. § 3730(b)(1); *see Vermont Agency of Natural Res. v. United States ex rel. Stevens*, 529 U.S. 765, 773 (2000) ("The FCA can reasonably be regarded as effecting a partial assignment of the Government's damages claim."). In such a case, the government's injury in fact suffices to confer standing upon the relator to assert the FCA violation. *See Vermont Agency of Natural Res.*, 529 U.S. at 773-74. Nevertheless, a "relator in a *qui tam* FCA action does not have standing to assert common law claims based upon injury sustained by the United States." *United States ex rel. Rockefeller v. Westinghouse Elec. Co.*, 274 F. Supp. 2d 10,

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[15] 31 U.S.C. § 3730(b)(1) provides:

> A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government. The action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting.

31 U.S.C. § 3730(b)(1).

14 (D.D.C. 2003) (dismissing relator's claims for common law fraud, payment by mistake, and unjust enrichment); *see United States ex rel. Phipps v. Comprehensive Cmty. Dev. Corp.*, 152 F. Supp. 2d 443, 452 (S.D.N.Y. 2001) (holding that relator lacked standing to assert claims for unjust enrichment, fraud, and mistake of fact on behalf of the government); *United States v. Eastman Kodak Co.*, 98 F. Supp. 2d 141, 149 (D. Mass. 2000) (dismissing common law claims and noting that relator failed to claim he suffered an injury in fact); *United States ex rel. Long v. SCS Bus. & Tech. Inst.*, 999 F. Supp. 78, 92 (D.D.C. 1998) (holding that relator did not have standing to bring unjust enrichment claim), *rev'd on other grounds*, 173 F.3d 870 (D.C. Cir. 1999).

Relator's claims of unjust enrichment and payment by mistake of fact allege injuries sustained by the United States. (Rel. Am. Compl. ¶¶ 137-45.) Relator does not allege that he personally suffered an injury in fact as a result of Guidant's wrongful conduct with respect to those claims. (*Id.*) The Court concludes that Relator does not have standing under the FCA to bring common law claims on behalf of the government. Consequently, Relator's claims of unjust enrichment and payment by mistake of fact are rightfully dismissed.

ORDER

Based upon the foregoing, **IT IS HEREBY ORDERED** that Defendants' Motion to Dismiss Relator's claims (Doc. No. [77]) is **GRANTED IN PART** and **DENIED IN PART** as follows:

1. To the extent Defendants seek dismissal of Relator's common law claims, the motion is **GRANTED**. Count Two (Unjust Enrichment) and Count Three (Payment

by Mistake of Fact) of Relator's Amended Complaint (Doc. No. [15]) are **DISMISSED WITH PREJUDICE**.

2. To the extent Defendants seek dismissal of Count One of Relator's Amended Complaint (Violation of the False Claims Act) (Doc. No. [15]), the motion is **DENIED**.

Dated: March 14, 2012

s/Donovan W. Frank
DONOVAN W. FRANK
United States District Judge