UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

UNITED STATES OF AMERICA *ex rel.* ROBERT A. FRY,	)	
Plaintiffs,	)	
v.	)	**Civil Action No. 3:03-0842**
	)	**JUDGE TRAUGER**
GUIDANT CORPORATION, its predecessor Cardiac Pacemakers, Inc., a division of Eli Lilly and Company, MEDTRONIC, INC., and unknown entities and individuals,	)	
Defendants.	)	
AND	)	
STATE OF TENNESSEE, CALIFORNIA) And FLORIDA *ex rel.* ROBERT A. FRY	)	
Plaintiffs,	)	
v.	)	
GUIDANT CORPORATION, its predecessor Cardiac Pacemakers, Inc., a division of Eli Lilly and Company, and unknown entities and individuals,	)	
Defendants.	)	

MEMORANDUM

Currently before the court in this pending *qui tam* action are the Motions to Dismiss filed separately by the defendants Guidant Corporation and Medtronic Inc. (Docket Nos. 40, 73), to which the plaintiff, relator Robert A. Fry, has responded (Docket Nos. 81, 88), and the defendants have replied (Docket Nos. 85, 89). Also before the court is the plaintiff's Motion for Leave to File a Second Amended Complaint Adding a Relator Party (Docket No. 78), to which the defendants have responded (Docket Nos. 86, 87), and the plaintiff has replied (Docket Nos. 90, 91).

For the reasons stated herein, the plaintiff's Motion for Leave to File a Second Amended Complaint Adding a Relator Party will be granted in part and denied in part. Defendant Guidant's Motion to Dismiss will be denied, and defendant Medtronic's Motion to Dismiss will be granted.

BACKGROUND

I. Facts[1]

Defendants Guidant Corporation ("Guidant") and Medtronic Inc. ("Medtronic"), Indiana and Minnesota corporations respectively, manufacture and sell implant medical devices ("IMDs"), such as defibrillators and pacemakers, to doctors and hospitals throughout the United States.[2] Relator Robert A. Fry was a salesman for Guidant in Tennessee and Kentucky from April 1981 until March 1997, when he left the company.

[1] The following facts have been drawn from the First Amended Complaint. (Docket No. 14)
[2] The First Amended Complaint specifically identifies Saint Thomas Hospital in Nashville, Tennessee, Hamilton County Authority d/b/a Erlanger Health Systems Hospital in Chattanooga Tennessee, and Veterans Administration Hospitals in Nashville, Tennessee, and across the country, as such hospitals.

At least since 1981, IMDs were shipped to various hospitals in sealed, contamination-free containers and stored in hospital material supply rooms to be made available for implantation by the requesting doctor. Each Guidant and Medtronic IMD was accompanied by a limited warranty on replacement IMDs that arrived at the hospital inside the sealed device container.[3] During implant procedures, for which the IMD salesperson was typically present, "[i]t was Fry's practice, and to his knowledge, information and belief, the practice of other Guidant salesmen in Tennessee, Florida, and California and other states, to open and remove the IMD from the sealed container and dispose of the container in the operating room garbage can. The warranty, which contained the information on credits available to the hospitals, was in the container and was thrown in the garbage can." (First Amended Complaint, ¶ 15) Fry further alleges, on information and belief, that Medtronic salespersons similarly concealed from provider hospitals warranties that explained credits available for replacement IMDs.

Hospitals, unaware that the warranty and upgrade credits could substantially reduce the cost of replacement IMDs, made no attempt to collect on the warranties and, instead, purportedly passed the cost on to Medicare and/or Medicaid by submitting the higher cost of replacement in its Cost Reports (now or formally Form 2552).[4] As a result, Fry alleges that federal Medicare and Medicaid and state Medicaid programs returned to the provider hospitals higher sums than if the appropriate credits had been given, that defendants were paid the full cost of replacement (absent any credits), and that defendants improperly retained the credits as profit.

[3] The First Amended Complaint also alleges that "upgrade" credits were available if implanted devices were replaced with an upgraded IMD within a specified period of time.
[4] For example, Fry and other Guidant sales agents were instructed at a training session that 78% of pacemakers are implanted to patients on Medicare.

II. Procedural History

On September 11, 2003, Fry filed a *qui tam* action on behalf of the United States of America[5] against Guidant Corporation, its predecessor Cardiac Pacemakers, Inc., and unknown entities and individuals, alleging that these defendants, in violation of the False Claims Act, 31 U.S.C. § 3729, *et seq*., knowingly engaged in a fraudulent systematic scheme to defraud the Medicare program by concealing the existence of rebates and/or credits for replacement IMDs, which, in turn, caused the U.S. Department of Health and Human Services to pay greater cost adjustment amounts to hospitals throughout Tennessee and the United States. (Docket No. 1, hereinafter "Original Complaint") Pursuant to the statutory scheme set forth in the False Claims Act, the Original Complaint was filed under seal and served upon the United States, remaining under seal while the United States investigated the allegations therein and decided whether or not to intervene in the action.[6]

[5] A *qui tam* action is one "brought by an informer, under a statute which establishes a penalty for the commission or omission of a certain act…, part of the penalty to go to any person who brings such action and the remainder to the state or some other institution." *McKenzie v. BellSouth Telecomm., Inc*., 123 F.3d 935, 936 n. 1 (6th Cir. 1997) (quoting Black's Law Dictionary 1251 (6th ed. 1990)).

[6] Pursuant to § 3730(b)(2) of the FCA, a *qui tam* plaintiff must disclose to the government the information on which his or her claim is based. 31 U.S.C. § 3730(b)(2). If the government declines to intervene, the *qui tam* plaintiff may serve the complaint on the defendant and proceed with the action on his own. 31 U.S.C. § 3730(b)(4)(B). If the action is successful, private plaintiffs suing on behalf of the government receive a portion of the recovered funds as incentive to bring such claims. 31 U.S.C. § 3730(d).

On July 22, 2004, Fry filed an Amended Complaint adding Medtronic Inc. as a defendant. (Docket No. 14, hereinafter "First Amended Complaint") In addition, the First Amended Complaint asserts claims under the federal Anti-Kickback Statute, 42 U.S.C. §§ 1320a-7b(b), and claims under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.* against both Guidant and Medtronic, as well as claims under the California False Claims Act, Cal. Gov't Code § 12650 *et seq*., and the Florida False Claims Act, Fl. Stat. § 68.081 *et seq*., solely against defendant Guidant. *Id*. The First Amended Complaint was filed without leave of court pursuant to Federal Rule of Civil Procedure 15(a).

On December 15, 2005, the court issued an order disclosing that the State of Tennessee had elected not to intervene and ordering the Original Complaint unsealed and served upon defendants. Thereafter, by Order dated January 17, 2005, the First Amended Complaint was unsealed and served. The United States and the states of Florida and California have declined to intervene.

On February 1, 2006, defendant Guidant moved to dismiss with prejudice Relator Fry's FCA and related state law claims, based upon the First Amended Complaint's purported failure to satisfy the pleading requirements of Rule 9(b), failure to state a claim pursuant to Rule 12(b)(6), and failure to comply with the applicable six-year statute of limitations. (Docket No. 4). Guidant also moved to dismiss the Anti-Kickback claim based on an alleged lack of standing. *Id*. On February 22, 2006, Medtronic filed a substantially similar Motion to Dismiss. (Docket No. 73) In addition to the grounds for dismissal urged by Guidant, Medtronic also asserts that it was improperly joined in this action.

Relator Fry, on February 24, 2006, contemporaneously filed a Response in Opposition to

Defendant Guidant Corp's Motion to Dismiss (Docket No. 81) and a Motion for Leave to File a Second Amended Complaint (Docket No. 78). In his Motion for Leave to Amend, Fry seeks permission, pursuant to Rules 15 and 20, to file a Second Amended Complaint in order to: "(a) delete the claim for violation of the Anti-Kickback Statute; (b) plead his allegation with greater particularity; and (c) add as a second relator a Guidant salesman with personal knowledge of the allegations asserted herein, who can both confirm and supplement the allegations made by the original relator." (Docket No. 79 p. 3)

In addition to adding Timothy McDonald, a Guidant salesman who served as a sales agent for Guidant IMD products in Tennessee, Georgia, and Alabama from 1987 until 2006, as a second relator, the proposed Second Amended Complaint includes five examples of purportedly false Medicare claims submitted in relation to the replacement or upgrading of Guidant IMDs in five specific patients and sets forth additional evidence of the alleged fraudulent scheme based on documents Guidant submitted to the Tennessee Attorney General- and subsequently disclosed to relator Fry- in connection with this suit. The proposed Complaint also alleges, for the first time, that the administrative processes for defendants' warranty credit programs were designed with strong disincentives for IMD salespeople to provide credits to hospitals. For example, the Second Amended Complaint avers that Medtronic's method of calculating commissions of their sales personnel results in higher commissions where no credit issues and lower commissions where one is in fact extended, and that defendants' requirement that replaced devices be physically returned to them before a credit will issue aims to suppress the availability of warranty and replacement

credits. Finally, the Second Amended Complaint points out the existence of a previously filed *qui tam* action against defendant Medtronic:

> [I]n 1994, at an early point in Medtronic's scheme, a Medtronic sales agent in Kansas expressed to his superiors and supervisors his concern that Medtronic personnel were acting to suppress the extension of warranty credits to hospitals. Medtronic terminated the complaining employee and in 2001 settled his subsequent lawsuit, which brought two complaints, one in *qui tam* and another for wrongful discharge, under a confidentiality agreement that precludes the former employee from sharing any information or participating in any actions against the company. Since that time, Medtronic has continued to suppress warranty, warranty replacement and recall credits otherwise available to hospitals.

(Docket No. 78 at ¶ 43)

In his Response in Opposition to Guidant's Motion to Dismiss, Fry "[c]onced[es] some deficiencies in the First Amended Complaint" and, thus, "addresses the Motion to Dismiss with reference to the allegations in the Second Amended Complaint." (Docket No. 81 p. 3) Similarly, in his March 13, 2006 Memorandum in Opposition to Defendant Medtronic's Motion to Dismiss (Docket No. 88), Fry asks the court to review Medtronic's motion in light of the expanded allegations contained in the proposed Second Amended Complaint. Because Fry's opposition to the defendants' Motions to Dismiss relies in large part on allegations contained in the proposed Second Amended Complaint, the court will first consider whether Fry should be granted leave to file the Second Amended Complaint.

ANALYSIS

The *qui tam* provisions of the False Claims Act permit private individuals to bring civil actions on behalf of the United States against persons who have committed a fraud upon the government. *McKenzie v. BellSouth Telecommunications, Inc.*, 123 F.3d 935, 938 (6th Cir. 1997).

As an incentive to bring such claims, private plaintiffs suing on behalf of the government receive a portion of the funds recovered in a successful suit. *See* 31 U.S.C. § 3730(d). However, while the *qui tam* provisions "seek to encourage 'whistleblowers to act as private attorneys-general' in bringing suits for the common good," *Walburn Lockheed Martin Corp*., 431 F.3d 966, 970 (6th Cir. 2005) (quoting *United States ex rel. Taxpayers Against Fraud v. General Elec. Co*., 41 F.3d 1032, 1041-42 (6th Cir. 1994)), they also "seek to discourage opportunistic plaintiffs from bringing parasitic lawsuits whereby would-be relators merely feed off a previous disclosure of fraud." *Id*. (citing *United States ex rel. Jones v. Horizon Healthcare Corp*., 160 F.3d 326, 335 (6th Cir. 1998)). In order to serve this latter interest, Congress put some notable restrictions on a relator's ability to proceed with a *qui tam* suit. *Bledsoe v. Community Health Sys. Inc*., 342 F.3d 634, 640 (6th Cir. 2003); *see also McKenzie*, 123 F.3d at 938 ("Congress has placed some jurisdictional limits on qui tam actions… in the interest of avoiding parasitic suits."). The defendants assert that two such restrictions, the first-to-file bar of 31 U.S.C. § 3730(b)(5) and the public disclosure bar of 31 U.S.C. § 3730(e)(4)(A), apply to the proposed amendments contained in relator Fry's allegedly curative Second Amended Complaint. As the proposed amendments would be "futile" based on these jurisdictional bars, the defendants request that Fry's Motion for Leave to Amend be denied and their Motions to Dismiss be granted.

I. Amending to Add a Second Relator

As stated above, the proposed Second Amended Complaint includes as a second relator Timothy McDonald, a Guidant salesman who served as a sales agent for Guidant IMD products from 1987 until 2006 and observed and assisted in approximately 3,000 IMD implant procedures.

According to the proposed amendments, McDonald witnessed numerous instances of defendants' warranties schemes in action, including, but not limited to, the series of warranty-applicable IMD sales involving four patients identified in the Second Amended Complaint as Patients B, C, D, and E. (Second Amended Complaint ¶ 59) The facts surrounding the IMD implants, subsequent replacements, and related false Medicare claims are specifically detailed in the Second Amended Complaint under the heading "Specific Examples of Defendant's Respective Schemes in Action." (*Id*. at ¶¶ 59-71)

Defendants first argue that McDonald's claims are barred in their entirety because he was not the "first to file." Section 3730(b)(5), colloquially known as the "first-to-file bar," provides:

> When a person brings a [qui tam] action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.

31 U.S.C. § 3730(b)(5). It is well-settled that Section 3730(b)(5) "unambiguously establishes a first-to-file bar, preventing successive plaintiffs from bringing related actions based on the same underlying facts." *Walburn* 431 F.3d at 971 (quoting *United States ex rel. Lujan v. Hughes Aircraft Co.*, 243 F.3d 1181, 1187 (9th Cir. 2001)). According to the defendants, because the four new claims identified by relator McDonald are, by Fry's own characterization, just simply details of the fraudulent scheme already alleged by Fry in his Original and First Amended Complaints, McDonald is jurisdictionally barred by the first-to-file bar from joining in this action as a second relator.

Defendants correctly point out that Fry characterizes McDonald as a relator who can "both confirm and supplement the allegations made by the original Relator" and who "makes the same and additional allegations concerning the same Guidant and Medtronic schemes to suppress the

existence and availability of warranty and/or replacement credits…." (Docket No. 79 at pp. 3, 4) However, Fry counters that the first-to-file bar does not apply to block the addition of McDonald as a second relator in the proposed Second Amended Complaint, because McDonald seeks neither to "intervene" nor to "bring a related action" within the meaning of Section 3730(b)(5). Rather, Fry argues that McDonald may be added as a party via amendment pursuant to Federal Rule of Civil Procedure 15(a) and the rationale set forth in *United States ex rel. Precision Co. v. Koch Indus., Inc*., 31 F.3d 1015 (10th Cir. 1994).[7]

In *Koch*, the Tenth Circuit held that the first-to-file bar did not prevent two stockholder relators from entering into an existing lawsuit brought originally by the corporation via an amended complaint, as they were not "intervenors" within the plain language of Section 3730(b)(5). In so finding, the Court ruled that the term "intervene," as used in Section 3730(b)(5), should be interpreted in its narrow, Rule 24 plain legal meaning and rejected the defendant's argument that the term should be given greater breadth so as to include any form of joinder:

> Our judgment tells us the statute implies intervention of the types set forth in Rule 24(b)(2), and the addition of parties does not constitute intervention. Indeed, the legislative history of § 3730(b)(5) implies this view. As the Senate noted, the section was adopted to prevent "multiple separate suits based on identical facts and circumstances." Rule 24(b)(2) intervention is nothing more than a joinder of claims or issues which fall within that very description.

[7] In his Brief in Support of Relator's Motion for Leave to File a Second Amended Complaint Adding a Relator Party (Docket No. 79), Fry also argues that McDonald may be permissively added as a second relator party to this action pursuant to Federal Rule of Civil Procedure 20(a), since "McDonald's claims and contentions arise out of the same series of transactions and occurrences and share questions of fact and law as those brought by relator Fry" (*Id*. at p. 4). Rule 20, however, must be read in conjunction with Rule 82, which prohibits the Federal Rules of Civil Procedure from being "construed to extend or limit the jurisdiction of the United States district courts or the venue of actions therein." Fed. R. Civ. P. 82; *see also Square D Co. v. United Elec., Radio and Mach. Workers of America*, 123 F. Supp. 776 (E.D. Mich. 1954). Thus, Rule 20 cannot be used to circumvent the jurisdictional bars imposed by the FCA.

> Indeed, we have already noted that Rule 24 permits unrelated persons who are strangers to the existing action to become parties if their interests are appropriately related. An intervenor need not have a relation to the original plaintiff if the claims or interests of the two parties are related or share a common question of law or facts. Rule 24(b)(2) permits intervention by a party asserting a "question of law or fact in common" with the original plaintiff. Because Rule 24(b)(2) existed long before the enactment of § 3739(b)(5), we must presume Congress was aware of the accepted meaning of "permissive intervention" and intended to employ that meaning when the statute was written.
>
> Thus, when § 3730(b)(5) speaks of intervention, it means to prohibit parties unrelated to the original plaintiff from joining the suit to assert a claim based on the same facts relied upon by the original plaintiff.

31 F.3d at 1017-1018 (internal citations and quotations omitted). Because the stockholders were related to the original relator corporation, their addition to the suit as relator parties was permitted. *Id*.

While the Tenth Circuit has essentially carved out a limited exception to Section 3730(b)(5) for the intervention of new relator parties, as long as they are "related" to the original plaintiff, the Fourth and Ninth Circuits have explicitly rejected the notion of reading exceptions into the statute's plain language. *See United States ex rel. Lujan v. Hughes Aircraft Co.*, 243 F.3d 1181, 1187 (9th Cir. 2001) ("Unlike § 3730(e)(4) (the public disclosure jurisdictional bar), § 3730(b)(5)'s plain language does not contain exceptions.... We reject Lujan's contentions because they would require this court to read exceptions into the statute's plain language."); *United States ex rel. LaCorte v. Wagner*, 185 F.3d 188, 191 (4th Cir. 1999) (holding that FCA provision § 3730(c)(5) does not create exceptions to the categorical bar of § 3730(b)(5) against private party intervention.) According to the Fourth Circuit, Section 3730(b)(5), on its face and without exception, precludes any person other than the government from intervening in an action, as "[t]his provision states without qualification that persons other than the government may not intervene in qui tam actions."

Id. The Court further observed that, "[b]y drafting the statute in such unequivocal language, Congress made the strongest possible statement against private party intervention in qui tam suits." *Id*.

In this instance, the court agrees with the straightforward, exception-free interpretation of Section 3730(b)(5) adopted by the Fourth and Ninth Circuits. Fry's arguments that McDonald may be added as an additional relator because he is "related" to Fry, has not filed a formal motion to "intervene," and does not seek to bring a separate "related action" are not, therefore, well-taken. To find otherwise would permit any potential relator to circumvent the first-to-file doctrine by seeking entrance to the action via amended complaint, thereby undermining a central purpose of Section 3730(b)(5)- the preclusion of plaintiffs with merely duplicative claims. *See Walburn*, 431 F.3d at 970 ("[T]he [FCA] provisions seek to discourage opportunistic plaintiffs from bringing parasitic lawsuits whereby would-be relators merely feed off a previous disclosure of fraud."). As the Sixth Circuit has noted, "[t]he first-to-file bar furthers the policy of the False Claims Act in that '[t]he first-filed claim provides the government notice of the essential facts of an alleged fraud, while the first-to-file bar stops repetitive claims.'" *Walburn*, 431 F.3d at 971 (citing *Lujan*, 243 F.3d at 1187). "[S]uch duplicative claims do not help reduce fraud or return funds to the federal fisc, since once the government knows the essential facts of a fraudulent scheme, it has enough information to discover related frauds." *United States ex rel. LaCorte v. Smithkline Beecham Clinical Labs. Inc*., 149 F.3d 227, 234 (3rd Cir. 1998) (cited in *Walburn*, 431 F.3d at 971).

This important policy rationale applies equally to the facts at hand. While facts discovered during relator Fry's independent investigation- through McDonald or otherwise- may be used in support of Fry's allegations of fraud, Section 3730(b)(5) strictly forbids private parties, such as

McDonald, from being added as additional party relators with claims based on the same underlying facts ("intervening") *after* a qui tam action has been filed and the government has already been made aware of the essential facts of the alleged fraud.

Thus, plaintiff's Motion for Leave to File a Second Amended Complaint will be denied to the extent that it seeks to add McDonald as a second relator.[8] However, as detailed below, the Motion will be granted to the extent that it seeks to plead the allegations of fraud against defendant Guidant with greater particularity. As a result, Guidant's Motion to Dismiss based on a failure to comply with Rule 9(b) will be denied, as will all other claims for dismissal asserted by defendant Guidant.

Because, however, the claims against Medtronic are jurisdictionally barred by the first-to-file and public disclosure bars, even assuming compliance with Rule 9(b), the Motion to Dismiss filed by defendant Medtronic will be granted. *See infra* pp. 16-17.

II. Amending to Plead with Greater Particularity

The parties agree that a Complaint alleging violations of the FCA must comply with Federal Rule of Civil Procedure 9(b), which mandates that in "all averments of fraud… the circumstances constituting fraud or mistake shall be stated with particularity." *Bledsoe* 342 F.3d at 460. *See also Yuhasz v. Brush Wellman, Inc.*, 341 F.3d 559, 563 ((“The heightened pleading

[8]Contrary to defendants' assertions, however, the addition of McDonald as a second relator is not necessary to survive dismissal based on statute of limitations grounds because he, unlike Fry, was employed by defendant Guidant within six years of the filing of this action on September 11, 2003. While the FCA bars claims that are brought more than six years after the date on which the defendant's violation of the statute is alleged to have occurred, 31 U.S.C. § 3731(b), there is, quite simply, no statute of limitations requirement that a relator be employed by the defendant less than six years from the filing of the action.

standard set forth in Rule 9(b) applies to complaints brought under the FCA.") In the Sixth Circuit, Rule 9(b) is read as requiring plaintiffs, at a minimum, to "allege the time, place and content of the alleged misrepresentation on which he or she relied; the fraudulent scheme; the fraudulent intent of the defendants; and the injury resulting from the fraud." *Yushasz* 341 F.3d at 563 (quoting *Coffey v. Foamex L.P.*, 2 F.3d 157, 161-62 (6th Cir. 1993) (internal quotations omitted)). "Essentially, the amended complaint should provide fair notice to Defendants and enable them to 'prepare an informed pleading responsive to the specific allegations of fraud.'" *Bledsoe,* 342 F.3d at 643 (quoting *Advocacy Org. for Patients & Providers v. Auto Club Ins. Ass'n*, 176 F.3d 315, 322 (6th Cir. 1999)). Fry does not dispute defendants' contention that the First Amended Complaint fails to plead the allegations of fraud with sufficient particularity so as to satisfy Rule 9(b). Rather, Fry seeks leave to file a Second Amended Complaint in order to plead with greater specificity and meet the heightened requirement.

It is well-established that "federal courts must be liberal in allowing parties to amend their complaints." *Coffey*, 2 F.3d at 162. Thus, "[w]here a more carefully drafted complaint might state a claim, a plaintiff must be given at least one chance to amend the complaint before the district court dismisses the action with prejudice." *Bledsoe*, 342 F.3d at 644 (quoting *EEOC v. Ohio Edison Co.*, 7 F.3d 541, 546 (6th Cir. 1993)). Indeed, the Sixth Circuit has often permitted a *qui tam* plaintiff leave to amend his complaint to plead with greater particularity so as to satisfy the requirements of Rule 9(b). *C.f. Bledsoe*, 342 F.3d at 645; *and Yushasz,* 341 F.3d at 1333. "Denial may be appropriate, however, where there is 'undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of the

amendment, etc.'" *Morse v. McWhorter*, 290 F.3d 795, 800 (6th Cir. 2002) (quoting *Foman v. Davis*, 371 U.S. 178, 182 (1962)).

In order to cure the conceded deficiencies in the First Amended Complaint, the proposed Second Amended Complaint contains five specific examples of purportedly false Medicare claims submitted in relation to the replacement or upgrading of Guidant IMDs in five patients, identified as patients "A" through "E." (Second Amended Complaint at ¶¶ 54-71) It also sets forth additional evidence of the alleged fraudulent scheme based on documents Guidant submitted to the Tennessee Attorney General- and subsequently disclosed to relator Fry- in connection with this suit. (*Id*. at ¶¶ 76-85) Defendant Guidant does not argue that the Second Amended Complaint on its face fails to comply with Rule 9(b) but, instead, asserts that the proposed amendments are barred by the FCA's first-to-file and public disclosure rules. Specifically, defendant Guidant alleges that the four patient examples (relating to Patients "B" through "E") provided by McDonald in Paragraphs 59 through 71 of the Second Amended Complaint are barred by both rules and that the public disclosure operates to bar the example of fraud related to Patient "A" (*Id*. at ¶¶ 54-59) as well as the additional examples of false claims based on information taken from the Guidant discovery documents (*Id*. at ¶¶ 79-85).

Neither the release of the Guidant documents nor the information provided by Patient A to relator Fry, however, constitutes a "public disclosure" for purposes of the FCA jurisdictional limitations. Section 3730(e)(4)(A), referred to as the "public disclosure bar," provides that:

> No court shall have jurisdiction over a [qui tam] action based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing … unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

31 U.S.C. § 3730(e)(4)(A). In determining whether the jurisdictional bar of Section 3730(e)(4)(A) applies, a court must first consider whether there was a public disclosure. While the Third Circuit has held that information revealed through discovery in one civil litigation is "publicly disclosed" for purposes of a subsequent *qui tam* action, *United States exx rel. Stinson v. Prudential Insurance Co*., 944 F.2d 1149, 1157-60 (3rd Cir. 1991), the Ninth Circuit prudently declined to extend this holding to discovery conducted in the course of the *qui tam* case itself. *Wang v. FMC Corp*., 975 F.2d 1413, 1416 (9th Cir. 1992) As the *Wang* Court explained:

> Evidence publicly disclosed for the first time during the discovery phase of a *qui tam* suit is not barred from use in that same suit by section 3730(e)(4)(A). If it were, *qui tam* plaintiffs would have little choice but to waive their right to discovery for fear of disclosing information that would bar the claims for which they might wish discovery in the first place.

Id. Though the Guidant documents at issue were not disclosed during formal discovery, which has not yet occurred, the reasoning articulated in *Wang* applies. Like the documents there, the Guidant documents would not have made their way to the public absent the filing of the *qui tam* case at bar. These documents do not, therefore, qualify as "public disclosures" for purposes of the public disclosure bar.

With respect to Patient A, defendants argue only that relator is not the "original source" of Patient A's claim. Yet, one need only be an "original source" of information if the information has already been publicly disclosed. *See Walburn*, 431 F.3d at 974 (a court must only examine whether the relator is an "original source" in the event that there has been a public disclosure). As there has been no such showing with respect to the allegations surrounding Patient A, Paragraphs 54 to 59 are not barred by the public disclosure bar.

Thus, even assuming that the four patient examples provided by Timothy McDonald were barred from consideration,[9] the Second Amended Complaint contains sufficient particularity with respect to the fraud claims asserted against defendant Guidant based on the examples set forth in Paragraphs 54-59 and Paragraphs 79-85. While the Second Amended Complaint generally alleges that, over the course of more than twenty years, Guidant participated, through unidentified employees, in a systematic, fraudulent scheme to conceal warranties from identified hospitals, the aforementioned paragraphs provide specific examples of such concealment and the resulting false claims. Under these facts, the court finds that the proposed Second Amended Complaint adequately describes defendant Guidant's allegedly fraudulent scheme to defraud the United States of Medicare and Medicaid funds so as to ensure that defendant Guidant has received notice of the charges against it.[10]

Even assuming, however, that the Second Amended Complaint pleads with sufficient particularity the fraud claims asserted against defendant Medtronic, all such claims are

[9] While McDonald may not be added as a second *qui tam* relator pursuant to the FCA jurisdictional bars, the defendants have not pointed to, nor has the court found, any associated restriction on original relator Fry's ability to plead, as support for his allegations of fraud, facts independently discovered through his investigative communications with McDonald.

[10] Contrary to defendants' assertions, Fry need not plead every instance of fraud in every location or state alleged in order to comply with Rule 9(b), *United States ex rel. Pogue v. American Healthcorp, Inc.*, 977 F.Supp. 1329, 1333 (M.D. Tenn. 1997), or allege a false "statement" or breach of rule, regulation or standard in order to state a cause of action for fraud under the FCA. *See U.S. ex rel. A+ Homecare, Inc. v. Medshares Management Group., Inc.*, 400 F.3d 428, 443 (6th Cir. 2005) ("the FCA imposes liability only for false statements *or conduct*….") (emphasis added); *Kaminski v. Teledyne Indus. Inc.*, No. 96-3620, 121 F.3d 708, at **3 (6th Cir. 1997) ("the FCA is a broadly remedial statute, which reaches beyond 'claims' which might be legally enforced, to all fraudulent attempts to cause the Government to pay out sums of money") (internal quotations omitted). Nor is Fry required, in order to establish FCA causation, to claim that defendants "played some role in how the hospitals prepared and submitted their claims" (Docket No 41 at p. 14). Fry alleges sufficient facts from which a reasonable juror could infer that the defendants' fraudulent course of conduct in concealing warranties and upgrade credits was causally connected to the Medicare claims submitted by participating hospitals.

jurisdictionally barred pursuant to the public disclosure bar.[11] As outlined above, the Second Amended Complaint reveals the existence of a previously filed *qui tam* action against defendant Medtronic:

> [I]n 1994, at an early point in Medtronic's scheme, a Medtronic sales agent in Kansas expressed to his superiors and supervisors his concern that Medtronic personnel were acting to suppress the extension of warranty credits to hospitals. Medtronic terminated the complaining employee and in 2001 settled his subsequent lawsuit, which brought two complaints, one in *qui tam* and another for wrongful discharge, under a confidentiality agreement that precludes the former employee from sharing any information or participating in any actions against the company. Since that time, Medtronic has continued to suppress warranty, warranty replacement and recall credits otherwise available to hospitals.

(Docket No. 78 at ¶ 43) This case is later identified by relator Fry as *United States ex rel. J.L Regan v. Medtronic, Inc.*, D. Kan. Case No. 95-1236-MLB (May 8, 1995). Fry does not dispute that a complaint filed in another court constitutes a "public disclosure" within the meaning of the FCA's public disclosure bar. *See Bledsoe*, 342 F.3d at 645 ("There is little doubt that a complaint filed in state court qualified as a public disclosure."). Rather, Fry contends that "because this case is not based upon the facts advanced in *Regan*, but rather by the facts derived from the present relator's own investigation and original-source knowledge," it is not barred pursuant to Section 3730(e)(4)(A). In other words, Fry contends that he qualifies as an "original source."

[11] The court also notes that Medtronic was improperly joined in this action to start, as an allegation that multiple defendants engaged in similar conduct is not, without more, sufficient to establish proper joinder pursuant to Rule 20(a). *See Michaels Bldg. Co. v. Ameritrust Co.*, 848 F.2d 674, 688 (6th Cir. 1988). Perhaps in acknowledgement thereof, Fry requests that the claims as to Medtronic be severed and that he be allowed to replead separately against Medtronic. For the reasons discussed above, however, such repleading would be futile.

However, in order to qualify as an "original source" in this circuit, a relator must "inform the government of the alleged fraud before the information has been publicly disclosed." *McKenzie*, 123 F.3d at 942. As no such showing has or can be made in the case at bar, the claims against Medtronic will be dismissed in full for lack of subject matter jurisdiction.

III. Amending to Dismiss Anti-Kickback Claim

As relator Fry concedes appropriate dismissal of this claim by seeking its withdrawal, leave to file a Second Amended Complaint reflecting such a removal will be granted.

CONCLUSION

For these reasons, defendant Medtronic's Motion to Dismiss will be granted and all claims against Medtronic will be dismissed. Defendant Guidant's Motion to Dismiss will be denied, and Fry's Motion for Leave to File a Second Amended Complaint will be granted in part and denied in part. The Motion will be granted to permit Fry to file a Second Amended Complaint for the purpose of pleading his allegations of fraud against defendant Guidant with greater particularity, as well as to remove his claim based on the Anti-Kickback statute. The Motion will be denied to the extent that Fry seeks to add Timothy McDonald as a second relator or to assert claims against defendant Medtronic.

The Second Amended Complaint shall be amended to reflect the findings herein.

An appropriate order will issue.

ALETA A. TRAUGER
U.S. District Judge