UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

NO. 12-1867

UNITED STATES OF AMERICA,
***ex rel.* HEIDI HEINEMAN-GUTA, Relator**

Plaintiff - Appellant

V.

GUIDANT CORPORATION; BOSTON SCIENTIFIC CORPORATION,
individually and as Successor-in-Interest to Guidant Corporation,

Defendants - Appellees

On Appeal from the United States District Court for the District of Massachusetts
C.A. No. 09 CA 11927 RGS
The Honorable Judge Richard G. Stearns

BRIEF OF APPELLANT

WATERS & KRAUS, LLP
Charles S. Siegel, Esquire (Bar No. 105786)
Loren Jacobson, Esquire (Bar No. 102702)
3219 McKinney Avenue
Dallas, Texas 75204
214-357-6244
214-357-7252 (fax)
E-Mail: siegel@waterskraus.com
E-Mail: jacobson@waterskraus.com
COUNSEL FOR APPELLANT

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Cases

Statutes

Rules

Other Authorities

REASONS WHY ORAL ARGUMENT SHOULD BE HEARD

Appellant Heidi Heineman-Guta believes that oral argument should be heard in this appeal because the appeal raises an issue of first impression for this Court and is the subject of a circuit split. Moreover, the issue raised by this appeal can have a profound influence on the incentives provided to would-be False Claims Act relators in the First Circuit and the quality of complaints brought to the government under the Act.

JURISDICTIONAL STATEMENT

This Court has jurisdiction over this appeal because the original suit was filed under the federal False Claims Act, 31 U.S.C. § 3729 *et seq.*, and appeal is taken from an order of dismissal that was entered July 5, 2012. Order, attached hereto at Tab B. A Notice of Appeal was timely filed on July 12, 2012. A.284.

STATEMENT OF THE ISSUE

Did the district court err in finding a second-filed False Claims Act complaint barred under 31 U.S.C. § 3730(b)(5) when the first-filed complaint was legally incapable of serving as a complaint because it did not meet the particularity requirements of Rule 9(b) of the Federal Rules of Civil Procedure?

STATEMENT OF THE CASE

Relator Heidi Heineman-Guta filed the instant suit under seal pursuant to the federal False Claims Act, 31 U.S.C. § 3729 *et seq.*, on November 10, 2009, alleging that Guidant Corporation ("Guidant"), and later Boston Scientific Corporation ("BSC"),[1] proffered kickbacks to physicians to influence them to implant cardiac rhythm management devices and refer patients who would be

[1] Guidant and BSC will be collectively referred to throughout this brief as "defendants" or "appellees." In about April 2006, BSC acquired Guidant. See A.15 – A.16. Heineman-Guta's complaint alleges that not only is BSC a successor-in-interest to Guidant, but that BSC itself continued Guidant's illegal kickback practices for at least as long as Heineman-Guta was employed with the company. See, e.g., A.36 - A.42; A.46 - A.48.

implanted with these devices, in violation of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b. The government investigated the case, and asked for several seal extensions in order to do so.[2] After Judge Stearns refused to further extend the seal, forcing the government to make an intervention decision, in November 2011, the government filed a notice that it was not intervening at the time of unsealing, but would continue its investigation.

After the suit came out from under seal, Heineman-Guta filed and served an amended complaint. A.12 – A.126. Defendants then filed a motion to dismiss pursuant to Rule 12(b)(6) and 9(b), claiming that Heineman-Guta's suit was jurisdictionally barred by the first-to-file provision of 31 U.S.C. § 3730(b)(5) and the public disclosure bar, 31 U.S.C. § 3730(e)(4)(A). A.131 – A.132; A.133 - A.158. Defendants also argued that Heineman-Guta's complaint did not meet the requirements of Fed. R. Civ. P. 9(b). Id.

After briefing and oral argument, on July 5, 2012, Judge Stearns ruled that Heineman-Guta's case was jurisdictionally barred by a suit that was filed under seal in October 2008, and was voluntarily dismissed by the relator and the

[2] The government's requests for seal extensions, Judge Stearns' orders in regards to these extensions, and the government's notice that it was not intervening in the case at the time of unsealing are still under seal and thus are not included in the Appendix in this appeal, but nevertheless are part of the record in the case, and are of course available for the Court to review. The government had asked that its notice that it was not intervening at the time be unsealed, but the Clerk did not unseal the notice or the order unsealing the case. The government's requests for seal extensions are, and should, remain under seal.

government in October 2011. Memorandum and Order, attached hereto at Tab A; see A.140 – A.141. Heineman-Guta timely appealed on July 12, 2012. A.284.

STATEMENT OF THE FACTS

I. Procedural History

Relator Heidi Heineman-Guta was a sales representative in Guidant Corporation's heart failure management group from April 2003 until about December 2007. A.15. On November 10, 2009, she brought the instant suit, alleging that Guidant Corporation ("Guidant"), and later Boston Scientific Corporation ("BSC"), engaged in an illegal kickback scheme in order to influence physicians to implant cardiac devices and refer patients who would be implanted with these devices.

Unbeknownst to Heineman-Guta, prior to her filing suit, in October 2008, two other individuals, Elaine Bennett and Donald Boone, had filed suit under seal in the District of Maryland, also alleging that BSC had engaged in an illegal kickback scheme to induce physicians and hospitals to use its cardiac devices. A.227 – A.254. In September 2011, the government declined to intervene in Bennett and Boone's action. The action was unsealed on October 4, 2011, and was

voluntarily dismissed by Bennett and Boone on October 20, 2011, and by the government on October 25, 2011. A.140 – A.141.[3]

In the meantime, the government was investigating Heineman-Guta's allegations, and had asked for several seal extensions in order to do so. After Judge Stearns refused to extend the seal any longer and forced the government to make an intervention decision, the government filed a notice in November 2011 that it was not intervening in the case at the time, but made clear that it continued to investigate Heineman-Guta's allegations.

II. Heineman-Guta's Allegations

As already stated, Heineman-Guta, who was employed at Guidant and BSC for over four years, alleged in great detail in her amended complaint a scheme by which Guidant and BSC provided kickbacks in various forms to physicians in order to induce them to implant cardiac rhythm management devices or refer patients for implantations.

A. Lavish Trips and Entertainment

The amended complaint alleges that Guidant and BSC instructed its sales representatives to "provide lavish trips and entertainment to physicians in order to

[3] Defendants argued below that another case filed by Bennett having to do with surgical ablation procedures also barred Heineman-Guta's complaint, but Judge Stearns agreed that it was not "a preclusive first-filed complaint because it does not disclose an alleged kickback scheme to promote the sales of cardiac rhythm management products." Memorandum and Order, at p. 6.

encourage them to refer patients for implantation of Guidant cardiac rhythm management devices." A.31. It then provides the details, including date, place, and initials of physicians, for 20 representative instances in which defendants provided kickbacks to doctors, including tickets to a boxing match; a trip to Disneyland; a spa activity for a physician and her friends; tickets for physicians to *The Producers*; stays at the W Hotel in New York City; and wine tasting tours in Napa Valley. A.31-A.33.

The amended complaint also alleges that Guidant/BSC's purpose in providing kickbacks to physicians was to influence them to implant Guidant/BSC devices or refer patients for implantation. For example, relator alleges that Guidant/BSC paid for Dr. A.H.'s stay at the W Hotel because he threatened to shift business away from Guidant. A.32 – A.33. The complaint also references a 2006 Guidant business plan that stated that it would use national and local programs to "woo White Memorial Hospital doctors" to use Guidant devices. A.34. The amended complaint states that a trip to Napa Valley had "no medical or educational purpose," but was provided to physicians as a reward for their referrals for and implants of BSC cardiac devices. A.35; see also A.32.

The amended complaint also alleges that BSC used all-expense paid trips to encourage doctors to use its devices, and required sales reps to develop "Customer Relationship Management Plans," in which they were required to "provide details

on how you plan to either retain the customer and grow their [*sic*] business or conversely win back their [*sic*] support and gain market share." A.35 Resources provided in order to do this included offering the physicians paid trips. Id.

B. Speaker's Fees

The amended complaint alleges that Guidant/BSC paid physicians as speakers to gain their loyalty, paying one high-volume implanting doctor between $1200 and $2500 to speak each of 27 times over the course of two years. A37. The complaint specifically states that Guidant/BSC told sales representatives that a "best practice" for courting skeptical physicians who want to be "compensated" was to provide them with speaking opportunities and referrals. A.44 – A.45.

C. Expensive Meals

The amended complaint also provides specific details about Guidant/BSC's use of lavish meals to encourage physicians to implant Guidant/BSC devices or refer patients for implantation. The complaint lays out the date, place, and participant initials for eight representative lavish dinners, several expensive lunches, and other interactions with physicians, showing the extent to which Guidant/BSC went to bribe physicians to implant their devices. Indeed, some of these meals cost as much as $420/doctor. See A.38 (describing a meal for three physicians at Buddha Bar in New York City that cost $1265.95).

The amended complaint also alleges that these meals were integral to Guidant/BSC's marketing practices. For example, the complaint alleges that BSC's West Coast Area Region Territory Business Plan directed sales reps to have dinners and lunches with cardiologists and referring physicians in order to reach the Plan's goals. A.38. The complaint also references documents that show that BSC provided expensive meals to Dr. H.B. in order to move him from being a "Biotronic Referrer" (Biotronic is a competitor of BSC) to a "Fully Penetrated BSC Preferred," meaning that he would refer patients for implantation solely with BSC devices. A.40 – A.41.

The amended complaint explains that the provision of meals to physicians worked in garnering loyalty. For example, it alleges that after Heineman-Guta set up a meal with a physician at Koi Restaurant in Hollywood, the physician invited her to observe several surgeries and assured her that a couple of her cases would involve BSC cardiac device implants. A.38 – A.39. The complaint also explains that Guidant treated another physician, A.V., to an expensive dinner in July 2007 and provided lunch to his staff the previous day. The complaint references a company document from later in 2007 that indicated that Dr. A.V.'s account was "fully penetrated," meaning that Dr. A.V. was requesting only BSC devices for his patients. A.39.

D. Case Reviews and Referrals

The amended complaint also alleges that Guidant/BSC used "case reviews" to funnel money to referring physicians and to provide patient referrals to implanting physicians (electrophysiologists, or "EPs") in exchange for a commitment to implant Guidant/BSC devices. Under the "case review" program, Guidant/BSC would invite an EP to a dinner program with several cardiologists or other referring physicians in his geographic area to allow the EP to "review" cases to be referred to him. Guidant/BSC picked up the costs of the dinner and paid the referring physicians each a fee for each patient chart brought to the dinner.

The complaint sets forth the dates, places, initials of physicians, and the names of the hospitals with which those physicians were affiliated for 13 representative case review programs. As an example, BSC sponsored a July 2007 case review for Dr. L.P., an EP, at Arnie Morton's Steakhouse in Burbank, CA, in which BSC paid four doctors to bring charts of potential patients for the EP. The dinner for the doctors cost $1066.49, and the EP received two referrals of patients for implantation. A.47.

The amended complaint also explains that defendants made very clear to the EPs what the value of these referrals were: in presentations given to implanting physicians, Guidant reported the amounts Medicare would reimburse for the

implants, and told physicians that the profit margin from Medicare reimbursement was about $12,532. A.44.

Heineman-Guta's complaint alleges that Guidant/BSC's intent in setting up these programs was to influence physicians and references internal Guidant/BSC documents that demonstrate this. The amended complaint alleges, for example, that "many documents" from Guidant/BSC instructed sales reps to give physicians "a choice of dinner or case review" as a means to curry favor and gain commitment to implant Guidant/BSC devices. A.43. The complaint also describes how Heineman-Guta's managers instructed her to set up a certain number of case reviews every month. A.48.

E. Sham Clinical Trials

The amended complaint also describes in detail the ADVANCENT program, which provided payment to physicians for each patient they enrolled in a database. Physicians were asked whether they were interested in a program that would "reimburse" their practice, and were only targeted for the program if the practice had an "implanting champion"—someone loyal to Guidant/BSC. A.49. The amended complaint also describes how a particular physician was enrolled in a Phase IV trial because he was "trying to make as much money as possible" and the company wanted to retain his business. A.50.

F. Placement of Residents in Practices

Finally, Heineman-Guta's amended complaint alleges a scheme under which Guidant/BSC placed residents in established practices in exchange for a commitment that the new physician and his practice implant Guidant/BSC devices. The amended complaint provides dates, places, physician initials and the details of particular meetings where these deals were worked out. A.52 – A.53

G. The Effect of the Kickbacks

In addition to alleging the actual kickback scheme, Heineman-Guta's complaint also alleges in great detail the influence the scheme had on physicians to implant or recommend Guidant/BSC devices. The complaint lays out five representative samples that include the initials of the referring and implanting physicians, the initials of the patients whose implantations occurred due to the scheme, and even dates and places of implantation.

For example, the amended complaint alleges that Dr. M.P., who was treated to a spa activity, tickets to *The Producers*, and a trip to Napa Valley, see A.32 & A.35, referred 11 patients in 2006 for implantation with Guidant devices. A.53. It also alleges that Dr. A.H., whom Guidant/BSC placed as a fellow at Glendale Adventist hospital, A.52, who received meals from Guidant, A.40 – A.41, and whom Guidant/BSC reimbursed $1,395 for his stay at the W Hotel, A.32, implanted "almost exclusively Guidant/BSC devices due to referrals and other

kickbacks given to him by Guidant/BSC." A.54. The amended complaint further identifies three specific patients whom Dr. A.H. implanted with Guidant/BSC devices due to Guidant/BSC's illegal kickback scheme. A.54.

The amended complaint also alleges not only that Medicare paid for the vast majority of these implantations, but that Guidant/BSC *knew* that these procedures would be paid for by Medicare. The amended complaint provides statistical data showing that at least 66.8% of patients who are eligible and receive cardiac implantation are over the age of 65. A.25. The complaint also alleges that Guidant/BSC promoted the lucrative nature of implantation of its devices to physicians by pointing to Medicare reimbursement and the profit margins physicians could make from Medicare, A.44, suggesting not only that Guidant/BSC knew that the majority of reimbursement for these devices came from Medicare, but used this information for promotional means.

The complaint explains that all physicians and hospitals must certify compliance with the AKS, A.21 – A.22, and then identifies specific physicians who implanted Guidant/BSC devices and hospitals where those devices were implanted due to the kickback schemes alleged, see, e.g., A.54 – A.55, meaning that Guidant/BSC caused these physicians and hospitals to make false certifications that were material to the government's decision to pay for the implantation of the companies' cardiac devices.

In sum, based on her four years' of experience at the company and reliance on specific events and internal documents she saw while there, Heineman-Guta has laid out in great detail in her amended complaint Guidant/BSC's kickback scheme that led false and fraudulent claims to be made to Medicare.

III. Bennett and Boone's Allegations

In contrast to Heineman-Guta's allegations, Bennett and Boone's allegations are entirely cursory and speculative, and are based on general knowledge about industry practice, rather than any specific information about how BSC conducted its business.

Bennett only worked at Boston Scientific for three months in 2006, and in the cardiac surgery group, not in the cardiac rhythm management group. A.231 – A.232.[4] Bennett's co-relator Boone worked for Boston Scientific for ten years, but left the company in 1996, twelve years prior to the filing of the complaint. He acknowledged that any information he had came from his experience of industry practice while at other companies, not BSC. A.232.

[4] As explained, in addition to the complaint that Judge Stearns deemed to bar Heineman-Guta's complaint, Ms. Bennett filed another complaint in the Northern District of Illinois, alleging that Boston Scientific illegally marketed its surgical ablation products. See A.190 – A.224. According to one law review article, between 2007 – 2009, Ms. Bennett filed at least five qui tam complaints. See David Freeman Engstrom, Harnessing the Private Attorney General: Evidence from Qui Tam Litigation, 112 COLUM. L. REV. 1244, 1293 (2012).

The complaint contains general information about the False Claims Act, the Anti-Kickback Statute and the Medicare program. A.234 – A.236. There is also a general description of cardiac rhythm devices and the ways in which they work. A.241 – A.243. The complaint then very cursorily sets forth several kickback allegations.

The complaint alleges that BSC provided sham grants to physicians. It states: "In order to provide kickbacks to physicians without arousing suspicion, Defendant encourages doctors to set up tax-exempt educational foundations. Once a doctor has set up a foundation, Defendant then funds these foundations with its own money, characterizing the funds as 'grants.'" A.246. Notably, the complaint says absolutely nothing particular to BSC's conduct with regard to these practices. Instead, it acknowledges that relator Boone does not have any personal, first-hand knowledge about BSC's scheme at all. The complaint states that Boone "has observed that, when a medical device company begins using the 'foundation' method of providing kickbacks, that device company experiences a sudden and dramatic increase in market share . . . . Mr. Boone *believes* that Defendant engages in this practice . . . ." A.247 (emphasis supplied).

The complaint also alleges that BSC provided kickbacks by funding dinner programs for implanting physicians, but besides saying that the company paid for the dinners and also paid honoraria, does not identify or describe even a single

program, a single physician who was targeted, or a single patient who received a device because of the scheme. A.247 – A.248.

In sum, then, unlike Heineman-Guta's complaint, the Bennett-Boone complaint does not identify even one doctor; does not describe even one promotional event such as a dinner, entertainment outing or convention trip; and does not provide even one instance of promotion—of any kind—by either relator. The complaint also does not identify any Guidant or BSC policies, statements, or documents that reflect the kickback scheme. In fact, the complaint makes clear that the allegations are based on relator Boone's experience with *other* companies and industry practice in general, rather than any personal, first-hand experience or observations either Bennett or Boone had while working for Boston Scientific.

IV. The District Court's Ruling

Despite the total lack of any specific information regarding Guidant or BSC's kickback scheme in the Bennett-Boone complaint, Judge Stearns ruled that it barred Heineman-Guta's complaint. In doing so, Judge Stearns rejected the reasoning of the Sixth Circuit in United States ex rel. Walburn v. Lockheed Martin Corp., 431 F.3d 966 (6th Cir. 2005), which held that in order for a first-filed complaint to bar a second-filed complaint it must be legally capable of serving as a complaint and therefore must meet the requirements of Rule 9(b) of the Federal Code of Civil Procedure. Instead, Judge Stearns adopted the D.C. Circuit's opinion

in United States ex rel. Batiste v. SLM Corp, 659 F.3d 1204 (D.C. Cir. 2011), which held that a complaint need not meet the specificity requirements of Rule 9(b) in order to bar a second-filed complaint. Memorandum and Opinion, at p. 9, attached hereto at Tab A. To justify this position, Judge Stearns held that because the "purpose of a qui tam action is to provide the government with sufficient notice that it is the potential victim of fraud worthy of investigation," and a complaint that did not meet Rule 9(b) could do so, even the most perfunctory complaint could serve as a bar under section 3730(b)(5). Id. at 10.

As set forth more fully below, Heineman-Guta contends that Judge Stearns' ruling is error not only because it undermines the purposes underpinning the False Claims Act, but also because it highlights why requiring a complaint to meet Rule 9(b) is important: to say that the Bennett-Boone complaint provided the government with sufficient notice to investigate Guidant and BSC's fraud is problematic—at best—when the complaint is based on nothing more than knowledge regarding "industry practice" and provides not one iota of detail as to what was actually happening at Guidant or BSC. For this reason, Rule 9(b) provides a judicially sound basis for measuring whether a whistleblower has in fact provided the government with enough information to justify and guide an investigation. Judge Stearns' failure to acknowledge this constitutes error. For

these reasons and those set forth in more detail below, his order of dismissal should be reversed and the case should be sent back to the trial court.

SUMMARY OF THE ARGUMENT

The district court erred in holding that a legally infirm complaint that did not meet the particularity requirements of Fed. R. Civ. P. 9(b) nevertheless provided sufficient notice to the government of the allegations in order to bar a second-filed complaint under the False Claims Act's first-to-file rule, 31 U.S.C. § 3730(b)(5). This ruling applies an extremely subjective standard for finding "notice" instead of a well established, judicially sound one, contravenes the purposes underlying the FCA and the first-to-file rule, and should be reversed.

ARGUMENT

I. Standard of Review

This court must review *de novo* the district court's determination that it lacked subject matter jurisdiction over Heineman-Guta's complaint. United States ex rel. Duxbury v. Ortho Biotech Prods., L.P., 579 F.3d 13, 20 (1st Cir. 2009).

II. Judge Stearns Erred in Ruling that the Speculative and Cursory Bennett-Boone Complaint Barred Heineman-Guta's Complaint

The main question raised by this appeal is whether an earlier filed complaint must be legally capable of serving as a complaint in order to bar a second-filed complaint under the first-to-file bar of the False Claims Act ("FCA"). The first-to-

file rule states, "When a person brings an 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). The first-to-file rule "operates to prevent multiplication of FCA suits that could lead to duplicative awards covering the same behavior." United States ex rel. Duxbury v. Ortho Biotech Prods., 551 F. Supp. 2d 100, 103 (D. Mass. 2008) (citing United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc., 149 F.3d 227, 233-34 (3d Cir. 1998)).

Congress enacted the first-to-file rule, among other provisions, in order to "discourage so-called 'parasitic' suits." Duxbury, 551 F. Supp. 2d at 103. But the FCA's jurisdictional scheme serves another purpose as well: the *qui tam* provisions of the law "seek to encourage 'whistleblowers to act as private attorneys-general' in bringing suits for the common good." Walburn, 431 F.3d at 970 (citing United States ex rel. Taxpayers Against Fraud v. General Elec. Co., 41 F.3d 1032, 1041-42 (6th Cir. 1994)). The Court must balance these two purposes in determining whether the legally infirm Bennett-Boone complaint bars Heineman-Guta's fulsome pleading under the first-to-file rule.

In dismissing Heineman-Guta's complaint, Judge Stearns adopted the D.C. Circuit's reasoning in Batiste and held that a first-filed complaint does not have to meet the particularity requirement of Rule 9(b) in order to bar a later-filed

complaint. The main problem with this ruling—and the reasoning in Batiste—is that it assumes that any complaint, no matter how broadly worded, how conclusory, or how devoid of detail, gives the government sufficient notice of the fraud to justify launching an investigation.

A. In Order for an Earlier Complaint to Serve as a Bar Under the First-to-File Rule It Must Provide "Notice" of Fraud to the Government

Every court to evaluate the FCA's first-to-file rule, including this one, has acknowledged that it "is designed to allow recovery when a *qui tam* relator puts the government on notice of potential fraud being worked against the government . . . ." Batiste, 659 F.3d at 1210; Duxbury, 579 F.3d 13 ("'[A] goal behind the first-to-file rule' is to provide incentives to relators to 'promptly alert[] the government to the essential facts of a fraudulent scheme.'" (quoting United States ex rel. Lujan v. Hughes Aircraft Co., 243 F.3d 1181, 1188 (9th Cir. 2001)); United States ex rel. Poteet v. Medtronic, Inc., 552 F.3d 503, 516 (6th Cir. 2009) ("This jurisdictional limit on the courts' power to hear certain duplicative *qui tam* suits further the policies animating the FCA by ensuring that the government has notice of the essential facts of an allegedly fraudulent scheme." (internal citations omitted)); see also United States ex rel. LaCorte v. SmithKline Beecham, 149 F.3d 227, (3d Cir. 1998) (holding that the government must "know[] the essential facts of a fraudulent scheme").

The problem with Judge Stearns' ruling—and the reasoning in Batiste—is that it provides no proper means to measure whether, in fact, a first-filed complaint provides sufficient "notice" to the government of the "essential facts of a fraudulent scheme." In contrast, the Sixth Circuit's analysis in Walburn furthers the purposes of the FCA by providing a judicially sound, well-established standard for evaluating whether sufficient notice has been given—Federal Rule of Civil Procedure 9(b).

B. The Sixth Circuit Has Correctly Ruled that a Complaint Must Meet Rule 9(b) to Bar a Later Filed Complaint Under Section 3730(b)(5)

In Walburn, 431 F.3d at 972, the Sixth Circuit held that a "vague and broadly-worded complaint" that was legally insufficient under Rule 9(b) could not be given pre-emptive effect under § 3730(b)(5). More specifically, the Court was called on to decide whether the "broad and conclusory allegations" of a first-filed complaint barred a second-filed complaint. The court held that if a complaint is not adequate to give sufficient notice to defendants of the allegations of fraud, it could "hardly be said to have given the government notice of the essential facts of a fraudulent scheme, and therefore would not enable the government to uncover related frauds." Id. at 973. For this reason, the court concluded that the second-filed action could not be "based on the facts underlying" the first-filed complaint "when the facts necessary to put the government on notice of the fraud alleged are conspicuously absent from the [first-filed] complaint." Id.

This is likewise the case here. Heineman-Guta's complaint cannot be said to be "based on the facts underlying" the Bennett-Boone complaint when that complaint lacks the facts necessary to put the government on notice of the fraud.

In cases considering whether a False Claims Act complaint meets Rule 9(b), this Court has held in order for a defendant to receive proper notice of the allegations:

> A complaint must specify "the time, place, and content of an alleged false representation." Doyle v. Hasbro, Inc., 103 F.3d 186, 194 (1st Cir.1996) (quoting McGinty v. Beranger Volkswagen, Inc., 633 F.2d 226, 228 (1st Cir.1980), superseded by statute on other grounds, Private Securities Litigation Reform Act of 1995, Pub.L. No. 104-67, 109 Stat. 737). Conclusory allegations and references to "plans and schemes" are not sufficient. Id. (quoting Hayduk v. Lanna, 775 F.2d 441, 444 (1st Cir.1985)).

United States ex rel. Rost v. Pfizer, Inc., 507 F.3d 720, 731 (1st Cir. 2007). Likewise, in order for the government to have sufficient notice of the fraudulent allegations, it should know specifically what fraud the company has engaged in. But, as already discussed, the Bennett-Boone complaint does not provide notice of even one particular incident in which Guidant or Boston Scientific provided a kickback to a physician. There is not one date, not one place, not one time, not one physician mentioned. Moreover, even though the Bennett-Boone complaint alleges that BSC provided kickbacks by funding dinner programs for implanting physicians "who hope to increase their practices' implantation business," A.247, the complaint does not allege that these illegal kickback practices actually led to

any patients being implanted with devices. For these reasons, to say that the Bennett-Boone complaint provided the government with "notice" of BSC's fraudulent conduct sufficient to justify a government investigation is problematic, at best. And for Judge Sterns to rule that Heineman-Guta's complaint was "based on the facts underlying" the incredibly barebones Bennett-Boone complaint constituted error.

C. Rule 9(b) Provides a Clear, Well-Established Standard for Evaluating Whether the Government Has Received Adequate Notice of FCA Violations

Judge Stearns' evaluation of the Bennett-Boone complaint to discern whether the government had been given adequate notice of the allegations also illustrates how problematic it is to rely on a "notice" requirement without also having some established framework for analyzing whether notice has actually been provided. Judge Stearns held:

> For present purposes it is sufficient that this court hold that the Bennett Complaint is pled in sufficient detail to act as a first-filed complaint barring the FAC. Like the FAC, the *Bennett* Complaint disclosed a kickback scheme to promote defendants' cardiac rhythm management products. The *Bennett* Complaint described, inter alia, the same types of kickbacks – grants, honoraria, and lavish meals – as disclosed in the FAC. Although the FAC provides different and somewhat richer details, the *Bennett* Complaint exposed all of the essential facts of the scheme.

Memorandum and Order, at p. 12.

But did the Bennett-Boone complaint really expose "all of the essential facts of the scheme"? It did not show in any way that even a single patient was implanted due to the scheme. It did not point to a single kickback actually provided or describe a single policy or instruction given by BSC to proffer kickbacks. So, what level of detail is required to give the government notice? How broad can the allegations be and still provide notice? How speculative or conclusory can they be? Does the relator have to have any personal knowledge about the fraudulent conduct? Does the relator have to identify any specific misrepresentations or fraudulent activities by the company?

Given how subjective this evaluation of "notice" can be, using Rule 9(b) to evaluate whether a complaint actually does provide notice to the government of fraud, and should therefore bar subsequently filed complaints, provides district courts with a clear standard that is familiar and well established. Indeed, district and appellate courts routinely evaluate whether a complaint provides sufficient "notice" to defendants of allegations of fraud in FCA cases under Rule 9(b), see, e.g., Rost, 507 F.3d at 731, and it is logical for the same standard to be used to evaluate whether a first-filed complaint provides adequate notice to the government of the fraudulent scheme as well.

D. Using Rule 9(b) to Evaluate the Preemptive Effect of a Complaint Comports with the FCA's Legislative History and the Purpose of Section 3730(b)(5)

1. Requiring a First-Filed Complaint to Meet Rule 9(b) Furthers the Purpose of the FCA

Using Rule 9(b) to evaluate whether a first-filed complaint is adequate is also consistent with the FCA's underlying purposes, one of which is to "create incentives for insiders with information that would be particularly valuable to the government." United States ex rel. Campbell v. Redding Med. Ctr., 421 F.3d 817, 824 (9th Cir. 2005). Indeed, although the FCA "reflects a strong congressional policy of encouraging whisteblowers to come forward by rewarding the first to do so," id., it is also meant to incentivize individuals with first-hand knowledge of specific instances of fraud to come forward.

The legislative history of the 1986 amendments to the FCA make clear that those amendments were not made to assure that whistleblowers would give the government mere general notice of fraudulent activity or to require the government to investigate even the most perfunctory claims. Instead, the FCA was amended in order to encourage a "coordinated effort of both the government and the citizenry" in order to "decrease [a] wave of defrauding public funds." S. Rep. No. 99-345, at 1 (1986). The Senate acknowledged that "[d]etecting fraud is usually very difficult without the cooperation of individuals who are either close observers or otherwise involved in the fraudulent activity." Id. at 4.

Thus, it makes little sense to interpret the first-to-file rule in a way to encourage relators to bring the broadest, vaguest, most conclusory allegations—or allegations based not on personal experience, but "industry knowledge." But this is precisely what Judge Stearns' ruling, and the Batiste court's opinion does.

The Walburn court noted that imposing the Rule 9(b) standard in the context of the first-to-file rule was important because it furthered the purpose of the False Claims Act by "deter[ing] would-be relators from making 'overly broad allegations' that fail to adequately alert the government to possible fraud in an effort to preclude future relators from sharing in any bounty eventually recovered." The Ninth Circuit has acknowledged, "[c]onstruing § 3730(b)(5) to create an absolute bar would permit opportunistic plaintiffs with no inside information to displace actual insiders with knowledge of the fraud." Campbell v. Redding Med. Ctr., 421 F.3d at 824. This language is particularly apt here. The Bennett-Boone relators were (1) a serial relator who had worked at BSC for less than four months in a division that did not sell cardiac rhythm management devices, and (2) someone who had left the company twelve years earlier, and explicitly acknowledged that he had no relevant information about BSC, but was basing his information on "industry practice." Heineman-Guta, by contrast, worked for four years in Guidant/BSC's heart failure management group, which actually engaged

in the kickback scheme she alleges. To allow the Bennett-Boone complaint to displace Heineman-Guta's undermines the purposes of the FCA.

2. Requiring a First-Filed Complaint to Meet Rule 9(b) Furthers the Purpose of Section 3730(b)(5)

Requiring a complaint to meet Rule 9(b) in order to bar a later-filed complaint also comports with the purposes of the first-to-file rule itself. In Batiste, the D.C. Circuit acknowledged that the purpose of section 3730(b)(5) is not only "to allow recovery when a qui tam relator puts the government on notice of potential fraud being worked against the government," but also "*to bar copycat actions that provide no additional material information*." 659 F.3d at 1210 (emphasis supplied). But in this case, Judge Stearns allowed a vague first-filed complaint to bar a complaint that clearly was not a "copycat action," as it was filed when the first case was still under seal, and also clearly provided substantial "additional material information." Indeed, Heineman-Guta's complaint describes specific policies and practices that were in place at Guidant and BSC that encouraged the provision of kickbacks, gives the details of particular kickbacks that Guidant and BSC proffered to physicians, and details information from specific company documents to show that the company engaged in a fraudulent scheme. Surely, a description of the *actual* practices of the alleged fraudfeasor constitutes "additional material information," and yet Heineman-Guta's complaint was deemed to be barred by the first-to-file rule. Indeed, this case illustrates how

imposing a vague "notice" requirement on the first-filed complaint undermines the purposes not only of the FCA, but also the first-to-file rule itself.

3. The Requirements of Rule 9(b) Should Be Considered in the First-to-File Analysis to Discourage Opportunistic Filings

In Batiste, the D.C. Circuit Court held that it was unnecessary to "graft" a Rule 9(b) requirement onto the first-to-file rule, because a potential relator will always draft her complaint in order to comply with Rule 9(b) due to concern that her case would be dismissed and she would lose a shot at a monetary award. See 659 F.3d at 1211. In fact, this is not at all true, as one can see from looking at the Bennett-Boone complaint. As discussed, that complaint did not provide any specific details about even one kickback provided by Guidant or BSC, but was based on speculation about what occurred in a division neither relator worked in based on industry practice. Indeed, it seems that Bennett and Boone had little concern about trying to meet Rule 9(b) when they filed their complaint, and quickly dismissed it when the government declined to intervene. Likewise, the first-to-file relator in the Walburn case also seemed to have little concern about meeting Rule 9(b) when drafting and filing that complaint. The Walburn court noted that complaint was "vague and broadly-worded." 431 F.3d at 972.

Some relators do, then, bring broad, conclusory complaints in the hopes that a government investigation will turn something up, without any intent of ever litigating those claims. See Michael Lawrence Kolis, Settling for Less: The

Department of Justice's Command Performance Under the 1986 False Claims Amendments Act, 7 ADMIN. L.J. AM. U. 409, 452-53 (1993) (suggesting that some qui tam relators "file bare bones suits, fully expecting DOJ to intervene, and then sit back and [wait to] collect their rewards when the suits are resolved," and stating that "this contravenes the spirit of the Act because these relators stand to collect a significant portion of any government recovery, while not having made a significant contribution to the anti-fraud effort").

Allowing such claims to bar the cases of relators with actual information about fraud therefore not only may reward opportunistic plaintiffs with no inside information at a cost to actual insiders with knowledge of the fraud; it also provides incentives for would-be relators to file suit as "a pretext to uncover unknown wrongs," United States ex rel. Robinson v. Northrop Corp., 149 F.R.D. 142 (N.D.Ill.1993), unnecessarily requiring the government to expend valuable resources on speculative cases.

Indeed, the Batiste court's interpretation of the first-to-file rule does little to advance one of the FCA's primary goals: discouraging opportunistic behavior or parasitic suits. Rather, under the Batiste court's ruling, since even the most perfunctory complaint could bar a second-filed complaint, it would be in the interest of any individual who sees fraud in her company or division to not only bring suit against the company or division where she may work, but to then bring

numerous, seriatum suits against all other divisions in her company and any other company in the industry, under the assumption that they all do business in the same manner. Incentivizing relators to bring suits based on assumptions and speculation is not good for the government and does not further the purposes of the False Claims Act. The Walburn court's approach does, and Heineman-Guta urges this Court to adopt it.

E. Judge Stearns' Ruling Ignores the Purposes Underpinning the False Claims Act and Section 3730(b)(5)

Judge Stearns' whole-hearted embrace of Batiste therefore does little to further the purposes of the FCA or section 3730(b)(5) because it does not "achieve the golden mean between adequate incentives for whistleblowing insiders with genuinely valuable information and discouragement of opportunistic plaintiffs who have no significant information to contribute of their own." LaCorte, 149 F.3d at 234 (citing United States ex rel. Springfield Terminal Ry. v. Quinn, 14 F.3d 645, 650 (D.C. Cir. 1994)). His ruling should therefore be reversed.

Moreover, Judge Stearns' concerns about passing muster on a complaint not before him have little merit. Judge Stearns, hewing to the Batiste opinion, implied that it was "strange" to ask a court "to evaluate the legal sufficiency of a complaint filed in another jurisdiction, and to make a judgment on an issue that neither the Maryland District Court nor the parties to that case had an opportunity to address." Memorandum and Order, at pp. 11-12. But Judge Stearns did ultimately pass on

whether the Bennett-Boone complaint was "legally sufficient" to bar Heineman-Guta's complaint.

The truth is that the first-to-file rule does require a court to pass muster about whether the first-filed complaint and the second-filed complaint overlap, and whether the notice provided by the first-to-file complaint is sufficient to bar the second-filed complaint, and courts routinely do so. See, e.g., Duxbury, 551 F. Supp. 2d at 111 (holding that resolution of the first-to-file issue "requires the court to compare the allegations" in the first and second-filed complaints). Thus, although the judicial dynamic may be "strange," it is required by the statute. If the worry is that it seems unfair, perhaps because of *res judicata* or collateral estoppel concerns, for a court to deem a complaint not before it not to meet Rule 9(b), procedural methods and the general rules of comity exist to deal with any such concerns. In the instant case, there are no *res judicata* concerns, as the first-filed complaint was voluntarily dismissed. In other words, there was absolutely no risk that either the Bennett-Boone relators or the defendants in that case would be prejudiced by another court ruling on the legal sufficiency of the complaint because the complaint had been voluntarily dismissed prior to the Heineman-Guta complaint coming out from under seal.

In a case in which the first-filed complaint is not dismissed and the first-to-file relator is litigating her case, there are also options to deal with a determination

about whether the first-filed complaint meets Rule 9(b). Specifically, the second-filed case may be stayed while the first-filed case is being litigated, and any motion to dismiss is being considered. Surely, if there is any colorable argument that the first-filed complaint does not meet Rule 9(b), it will be made by the defendant in the first-filed case on a motion to dismiss.[5] In the meantime, the second-filed case can be stayed to await a ruling from the first-filed court. This kind of procedure is used all the time when a ruling in one case will affect another.

In sum, then, there are procedures that courts routinely use when a ruling in one case will affect the outcome of another that can be employed to manage the first-to-file analysis so that no party will be prejudiced in any way. The concern of the Batiste court and Judge Stearns in this regard should not outweigh the problems detailed above in allowing a standard that would permit even a very perfunctory complaint to bar a complaint that properly puts the government on notice of a particular fraud committed.

CONCLUSION

For the reasons set forth above, relator Heidi Heineman-Guta respectfully requests that this Court reverse the district court's July 5, 2012 order of dismissal and remand the case back to the trial court for further proceedings.

[5] This is what happened to the first-filed case in Walburn (although interestingly, the Sixth Circuit did not rely on the dismissal of the first-filed complaint under Rule 9(b) to find it did not bar the second-filed case; the Sixth Circuit engaged in its own Rule 9(b) evaluation, see Walburn, 431 F.3d at 972 n.5).

Dated: November 6, 2012

Respectfully submitted,

WATERS & KRAUS, LLP

/s/ Loren Jacobson
Charles S. Siegel, Esquire
Bar No. 105786
Loren Jacobson, Esquire
Bar No. 102702
3219 McKinney Avenue
Dallas, Texas 75204
214-357-6244
214-357-7252 (fax)
E-Mail: siegel@waterskraus.com
E-Mail: jacobson@waterskraus.com
COUNSEL FOR APPELLANT

CERTIFICATE OF COMPLIANCE WITH RULE 32(a)

Certificate of Compliance with Type-Volume Limitation,
Typeface Requirements, and Type Style Requirements

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 6998 words, excluding the parts of the brief exempted by Fed. R. App. P.32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P.32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2007 in Times New Roman, 14 point font.

DATED: November 6, 2012

/s/ Loren Jacobson
Loren Jacobson

CERTIFICATE OF SERVICE

I hereby certify that two copies of the foregoing Brief of Appellant have been mailed this 6th day of November, 2012, certified mail, return receipt requested to:

Mr. Frederick Robinson
Mr. Mark Emery
Jonathan Franklin
Fulbright & Jaworski, LLP
801 Pennsylvania Ave., N.W.
Washington, D.C. 20004

Andrew J. Danford
Elizabeth C. Mooney
Wilmer Cutler Pickering Hale And Dorr
60 State Street
Boston, MA 02109

Sonya A. Rao
Assistant United States Attorney
United States Attorney's Office
John Joseph Moakley U.S. Courthouse
Suite 9200, One Courthouse Way
Boston, MA 02210

Lisa M. Asiaf
US Attorney's Office
District of Massachusetts
1 Courthouse Way, Suite 9200
Boston, MA 02210

Michael A. Lesser, Esq.
THORNTON & NAUMES, LLP
100 Summer St., 30th Floor
Boston, MA 02110

/s/ Loren Jacobson
Loren Jacobson

ADDENDUM

TABLE OF CONTENTS

TAB A

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 09-11927-RGS

UNITED STATES OF AMERICA et al.[1],
ex rel. HEIDI HEINEMAN-GUTA
v.

GUIDANT CORP. and BOSTON SCIENTIFIC CORP.

MEMORANDUM AND ORDER ON DEFENDANTS' MOTION TO DISMISS AMENDED COMPLAINT

July 5, 2012

STEARNS, D.J.

In this qui tam action, relator Heidi Heineman-Guta, a former employee of defendants Guidant Corp. and Boston Scientific Corp. (BSC)[2], alleges that defendants engaged in a scheme of illegal kickbacks to promote the sales of their cardiac rhythm management devices in violation of the False Claims Act (FCA), 31 U.S.C. § 3729 et seq. Defendants move to dismiss relator's first amended complaint (FAC).

PROCEDURAL HISTORY

In her original Complaint, filed under seal in November of 2009, Heineman-Guta accused defendants of illegally promoting the off-label use of cardiac rhythm

[1] Twenty-three States and the District of Columbia are also named as parties to this action.

[2] Guidant was acquired by BSC in 2006.

management devices and the payment of kickbacks to physicians to induce them to select and recommend the devices for patient implants. The United States, after a preliminary investigation, declined to intervene in October of 2011, and the court ordered the Complaint unsealed. Subsequently, in January of 2012, Heineman-Guta filed the FAC, focusing only on the kickback allegations. The court heard arguments on defendants' motion to dismiss the FAC on July 2, 2012.

ALLEGATIONS

Heineman-Guta worked as an account manager for the heart failure management group at Guidant, later BSC, from April of 2003 until November of 2007. During her tenure, she observed and participated in Guidant/BSC's scheme to induce and reward doctors for referring and implanting Guidant/BSC cardiac rhythm management devices. This scheme included: (1) offering referring and implanting physicians valuable trips, entertainment, and/or grants; (2) treating referring and implanting physicians to lavish meals; (3) making payments, in the guise of honoraria and speaking fees, to referring and implanting physicians for participating in case studies; (4) remunerating loyal referring and implanting physicians for "participation" in sham clinical trials; and/or (5) providing similar benefits and job placement assistance to medical residents and fellows to cultivate future brand loyalty. Identifying various participants by their initials, Heineman-Guta provides numerous examples of specific incidents of kickbacks

in the FAC. She alleges that these kickbacks violated the Anti-Kickback Statute and induced and caused physicians to present false claims or false statements or records in support of claims for reimbursement by Medicare and/or Medicaid in violation of the FCA (Count I), and that defendants conspired to violate the FCA (Count II).

DISCUSSION

"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." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal quotation omitted). While a complaint "does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (internal citations and quotations omitted). "A suit will be dismissed if the complaint does not set forth 'factual allegations, either direct or inferential, respecting each material element necessary to sustain recovery under some actionable legal theory.'" *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 384 (1st Cir. 2011), quoting *Gagliardi v. Sullivan*, 513 F.3d 301, 305 (1st Cir. 2008).

Heineman-Guta's claims are based on 31 U.S.C. § 3729(a)(1) and (a)(2).[3] Subsection (a)(1) prohibits the knowing presentment of a false claim for payment to the government, or (as alleged here) causing such a presentment to be made. Subsection (a)(2) prohibits the creation or use of false records and statements as part of a scheme to persuade the government to pay a false claim.

Defendants argue that Heineman-Guta's claims must be dismissed for lack of subject matter jurisdiction based on the first-to-file bar.[4] "When a person brings an action under this subsection, no other 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). Courts have uniformly interpreted § 3730(b)(5) to "bar a later allegation if it states all the essential facts of a previously-filed claim or the same elements of a fraud described in an earlier suit." *United States ex. rel. Duxbury v. Ortho Biotech*

---

[3] These and other provisions of the FCA were significantly amended by the Fraud Enforcement and Recovery Act of 2009 (FERA), Pub. L. No. 111-21, 123 Stat. 1617 (2009). Most FERA amendments took effect on May 20, 2009. The amendment to Section 3729(a)(2) applies retroactively to claims pending on or after June 7, 2008. See *United States ex rel. Carpenter v. Abbott Labs., Inc.*, 723 F. Supp. 2d 395, 401-403 (D. Mass. 2010) (analyzing FERA's effective date and retroactivity provisions). All of Heineman-Guta's allegations involve events occurring between 2003 and 2007, before FERA's effective date and prior to the retroactive application of Section 3729(a)(2). Accordingly, the pre-FERA version of the FCA applies in this case.

[4] The United States filed a "statement of interest" regarding defendants' motion to dismiss, but took no position on the contention that the suit is barred because of the first-to-file rule.

Prods., L.P., 579 F.3d 13, 32 (1st Cir. 2009), quoting *United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc.*, 149 F.3d 227, 232-233 (3d Cir. 1998) (quotation marks omitted). The first-to-file rule is intended to "provide incentives to relators to promptly alert the government to the essential facts of a fraudulent scheme," *Duxbury*, 579 F.3d at 24, citing *United States ex rel. Lujan v. Hughes Aircraft Co.*, 243 F.3d 1181, 1188 (9th Cir. 2001), and to prevent parasitic repeat claims based on allegations already known to the government. *Duxbury*, 579 F.3d at 23-24 (citation omitted). This is a jurisdictional rule that is "exception-free." *Id.* at 33, citing *Lujan*, 243 F.3d at 1187.

Defendants rely on two earlier-filed complaints as barring Heineman-Guta's claims: *United States ex rel. George v. Boston Scientific Corp.*, No. H-07-02467 (S.D. Tex. 2007) (*George* Complaint), filed on November 6, 2006[5]; and *United States ex rel. Bennett v. Boston Scientific Corp.*, No. 1:08-cv-02733 (D. Md. 2008) (*Bennett* Complaint), filed on October 16, 2008. Defendants assert that these two complaints disclosed the "essential elements" of the alleged fraud in Heineman-Guta's complaint, namely, the provision of trips, entertainment, meals, grants, honoraria, and other remuneration as kickbacks to physicians to increase defendants' market share in

[5] The *George* Complaint was initially filed in the Northern District of Illinois in 2006, and was transferred to the Southern District of Texas in 2007.

cardiac rhythm management devices.

The *George* Complaint alleged that defendants "promoted the FlexView microwave surgical-ablation system for an off-label use and that these promotional activities caused physicians and hospitals to submit false claims for reimbursement from Medicare or Medicaid." *United States ex rel. Bennett*[6] *v. Boston Scientific Corp.*, 2011 WL 1231577 (S.D. Tex. Mar. 31, 2011). Heineman-Guta argues, and the court agrees, that the *George* Complaint is not a preclusive first-filed complaint because it does not disclose an alleged kickback scheme to promote the sales of cardiac rhythm management products.[7]

The *Bennett* Complaint, on the other hand, alleged, that

> [s]ince at least 2003, and continuing through [at least 2008], Boston Scientific Corporation (and, prior to being acquired by Boston Scientific, Guidant Corporation) has engaged in an illegal kickback scheme within its Cardiac Rhythm Management ("CRM") division designed to induce physicians and hospitals to use Boston Scientific pacemakers, internal cardiac defibrillators ("ICD's"), cardiac resynchronization therapy ("CRT's"), and cardiac resynchronization therapy with defibrillators ("CRTD's"), thereby increasing the Company's market share of these devices.

---

[6] The relator in *George* and *Bennett* is the same person, whose name changed from George to Bennett after the filing of the first complaint.

[7] Although the *George* Complaint also alleged kickbacks, they are "in the form of free advertising, press, and referral services" relating to the off-label promotion of a different line of products. *George* Compl. ¶ 10.

Bennett Compl. ¶ 3. This alleged scheme included

> inter alia, (1) provid[ing] doctors and hospitals with kickbacks in the form of follow-up medical services in exchange for the providers' use of BSC's cardiac rhythm devices; (2) induc[ing] doctors and hospitals to bill for medical services and procedures they do not perform; (3) requir[ing] BSC sales personnel to provide medical care in the absence of a licensed physician or staff member; and (4) improperly conducting Medicare billing for physicians and hospitals through non-licensed, non-medical staff; (5) provid[ing] monetary "grants" to foundations set up by physicians and physician groups in return for favored status by such physicians; and (6) sponsor[ing] dinner meetings for implanting physicians to invite potential "referring physicians" to, in order for the implanting physician to increase the number of patients he receives for implants from those referring physicians. In most cases, the benefitting implanting physician also receives an "honorarium" for speaking about his or her expertise at the program.

Id. ¶ 4.

Heineman-Guta does not deny that the *Bennett* Complaint disclosed a scheme nearly identical to the one alleged in the FAC, but asserts that it does not qualify as a first-filed bar under an exception to the first-to-file rule established by the Sixth Circuit.[8]

---

[8] Heineman-Guta also relies on *Campbell v. Redding Med. Ctr.*, 421 F.3d 817, 825 (9th Cir. 2005), for the proposition that a jurisdictionally barred earlier-filed complaint cannot bar a later-filed complaint. However, the Ninth Circuit's holding was much narrower than that of the Sixth Circuit. *Campbell* dealt with the situation where the earlier-filed complaint was barred by the public disclosure rule, and was asserted against a later-filed complaint by the original source. The Ninth Circuit held that "*in a public disclosure case*, the first-to-file rule of § 3730(b)(5) bars only subsequent complaints filed after a complaint that fulfills the jurisdictional prerequisites of § 3730(e)(4)." *Campbell*, 421 F.3d at 825 (emphasis added). That is not the situation

> One important caveat to this first-to-file rule . . . is that, in order to preclude later-filed qui tam actions, the allegedly first-filed qui tam complaint must not itself be jurisdictionally or otherwise barred. *See Walburn* [*v. Lockheed Martin Corp.*], 431 F.3d [966,] 972 [(6th Cir. 2005)] (finding that an earlier filed complaint's failure to comply with Rule 9(b) rendered it legally infirm from its inception, and thus unable to preempt a later-filed action); *Campbell v. Redding Med. Ctr.*, 421 F.3d 817, 825 (9th Cir. 2005) (holding that "the first-to-file rule of § 3730(b)(5) bars only subsequent complaints filed after a complaint that fulfills the jurisdictional prerequisites of § 3730(e)(4)"). Indeed, if the first complaint is either jurisdictionally precluded, *see* 31 U.S.C. § 3730(e), or legally incapable of serving as a complaint, *see* Fed. R. Civ. P. 9(b); *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 501 F.3d 493, 504 (6th Cir. 2007) . . . then it does not properly qualify as a "pending action" brought under the FCA, 31 U.S.C. § 3730(b)(5). However, if the first-filed qui tam action has been dismissed on its merits or on some other grounds not related to its viability as a federal action, it can still preclude a later-filed, but possibly more meritorious, qui tam complaint under the first-to-file rule. *See Lujan*, 243 F.3d at 1188.

United States ex rel. Poteet v. Medtronic, Inc., 552 F.3d 503, 516-517 (6th Cir. 2009).

Heineman-Guta contends, as did the plaintiff in *Walburn,* that the *Bennett* Complaint was "legally incapable of serving as a complaint" because it lacked the particularity required by Fed. R. Civ. P. 9(b),[9] and therefore cannot act as a jurisdictional bar to the prosecution of the FAC.

---

in this case.

[9] Rule 9(b) requires that "[i]n alleging fraud . . . a party must state with particularity the circumstances constituting fraud . . . ." Heineman-Guta argues that, unlike her FAC, the *Bennett* Complaint failed the Rule 9(b) test because it did not provide any examples of specific incidents of kickbacks.

This court has previously "share[d] the skepticism expressed by Judge McKeague in his concurring opinion in *Poteet,* whether the [dismissal on the merits element] of the first-to-file requirements found by the Sixth Circuit . . . is an accurate (or wise) interpretation of the qui tam statute." *United States ex rel. Poteet v. Lenke*, 604 F. Supp. 2d 313, 323 (D. Mass. 2009) (*Lenke*). However, in *Lenke*, it was unnecessary for this court to decide the issue because the *Lenke* complaint was barred by the wholly separate public disclosure rule. Since then, the D.C. Circuit has refused to follow *Poteet* where an earlier-filed complaint is alleged to trip over Rule 9(b), and therefore cannot serve as a bar.

> We are unconvinced. Nothing in the language of Section 3730(b)(5) incorporates the particularity requirement of Rule 9(b), which militates against reading such a requirement into the statute. The statutory text imposes a bar on complaints related to earlier-filed, "pending" actions. The command is simple: as long as a first-filed complaint remains pending, no related complaint may be filed. Further, Rule 9(b) is designed to protect defendants in fraud cases from frivolous accusations and allow them to prepare an appropriate response. Section 3730(b) is designed to allow recovery when a qui tam relator puts the government on notice of potential fraud being worked against the government, but to bar copycat actions that provide no additional material information. As the district court found, a complaint may provide the government sufficient information to launch an investigation of a fraudulent scheme even if the complaint does not meet the particularity standards of Rule 9(b). [*United States ex rel.*] *Batiste* [*v. SLM Corp.*], 740 F.Supp. 2d [98,] 104 [(D.D.C. 2010) (*Batiste I*)]. Imposing the heightened pleading standard, moreover, would create a strange judicial dynamic, potentially requiring one district court to determine the sufficiency of a complaint filed in another district court, and possibly creating a situation in which the two district courts

disagree on a complaint's sufficiency.

United States ex rel. Batiste v. SLM Corp., 659 F.3d 1204, 1210 (D.C. Cir. 2011) (*Batiste II*).

This court agrees with the reasoning of the D.C. Court of Appeals and the D.C. District Court.[10] The purpose of a qui tam action is to provide the government with sufficient notice that it is the potential victim of a fraud worthy of investigation.

> [I]t is entirely plausible that a complaint may provide sufficient information to cause the government to launch its own investigation of a fraudulent scheme without providing enough information under Rule 9(b) to protect the defendant's interests. In other words, there might be a situation where there is sufficient notice for the government, but not for the defendant. In that event, it would be proper to dismiss the complaint against the defendant for purposes of Rule 9(b) but to allow the preemption of any subsequent related actions for purposes of the "first-to-file" rule. After all, once the whistle has sounded, the government has little need for additional whistle-blowers.

[10] The First Circuit has yet to rule on the issue.

Batiste I, 740 F. Supp. 2d at 104.[11, 12]

Furthermore, this case well demonstrates the "strange judicial dynamic" that concerned the D.C. Circuit. *See Batiste II*, 659 F.3d at 1210. As defendants note, the *Bennett* Complaint was not dismissed by the District of Maryland for failing to meet Rule 9(b)'s requirements, but was voluntarily dismissed. Heineman-Guta is asking this court to evaluate the legal sufficiency of a complaint filed in another jurisdiction, and to make a judgment on an issue that neither the Maryland District Court nor the parties

---

[11] The holding of the D.C. Circuit and the D.C. District Court is faithful to the purpose of the qui tam statute. It is highly unlikely that prosecutors – the audience to which the qui tam notice is directed – would decline to investigate serious allegations of fraud against the government merely because a complaint failed to meet the particularity requirement of Rule 9(b), or for that matter, that they would even think it desirable to conduct a Rule 9(b) screening of a qui tam complaint before undertaking an investigation of its allegations. Moreover, in the FCA context, where the complaint is typically sealed, prosecutors must decide whether to initiate an investigation before having the benefit (such as it might be) of a judicial determination of the complaint's sufficiency under Rule 9(b).

[12] The court can imagine, as suggested by counsel for Heineman-Guta at oral argument, the possibility of a first-filed complaint that is so spurious or vacuous as to provide no real notice of fraud to the government, and therefore not serve to bar later-filed complaints of genuine substance. It is also possible to imagine a complaint so rich in details that later prove to be false that it would survive a Rule 9(b) analysis under a motion to dismiss standard while leading prosecutors down a rabbit hole. Because the *Bennett* Complaint is not either of these hypothetical cases, it is not necessary to attempt to ascertain a limiting principle distinguishing complaints that are sufficiently pled to act as a first-filed qui tam bar from complaints that are not. If one had to be identified, defendants' suggestion of a quasi-res judicata rule might make the most sense. However, for present purposes, it is enough to say that Rule 9(b) does not, and was never intended to, serve as a qui tam barring device.

to that case had the opportunity to address.

For present purposes it is sufficient that this court hold that the *Bennett* Complaint is pled in sufficient detail to act as a first-filed complaint barring the FAC. Like the FAC, the *Bennett* Complaint disclosed a kickback scheme to promote defendants' cardiac rhythm management products. The *Bennett* Complaint described, inter alia, the same types of kickbacks – grants, honoraria, and lavish meals – as disclosed in the FAC. Although the FAC provides different and somewhat richer details, the *Bennett* Complaint exposed all of the essential facts of the scheme, and thus acts as a bar precluding the filing of the FAC.[13] *See Duxbury,* 579 F.3d at 32 ("Under this 'essential facts' standard, § 3730(b)(5) can still bar a later claim 'even if that claim incorporates somewhat different details.'") (citation omitted).

CONCLUSION

For the foregoing reasons, defendants' motion to dismiss is ALLOWED. The Clerk is directed to enter an order of dismissal for lack of subject matter jurisdiction and close the case.

[13] Defendants contend that dismissal is also warranted on several alternative grounds. However, because the *Bennett* Complaint serves as an absolute bar, it is unnecessary to address defendants' other arguments.

SO ORDERED.

/s/ Richard G. Stearns

UNITED STATES DISTRICT JUDGE

TAB B

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

USA
Plaintiff

V.

CIVIL ACTION

NO. 09-11927 RGS

Guidant Corp
Defendant

ORDER OF DISMISSAL

STEARNS, D. J.

In accordance with the Court's Memorandum and Order dated 7/5/12 granting defendant's motion to dismiss, it is hereby ORDERED that the above-entitled action be and hereby is dismissed.

By the Court,

7/5/12
Date

/s/ Elaine Flaherty
Deputy Clerk

(Dismissal Memo.wpd - 12/98)