

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, 2006⁵; 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