IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

UNITED STATES OF AMERICA ex rel. ROSE MARIE DE SOUZA, et al.,	)	
Plaintiffs,	)	
v.	)	Civ. No. 12-756-SLR
ASTRAZENECA PLC, ASTRAZENECA PHARMACEUTICALS LP,	)	
Defendants.	)	

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MEMORANDUM OPINION

Dated: November 5, 2014
Wilmington, Delaware

ROBINSON, District Judge

I. INTRODUCTION

On February 15, 2010, relator RoseMarie De Souza ("De Souza") filed this qui tam action against defendants AstraZeneca PLC and AstraZeneca Pharmaceuticals LP's ("collectively AstraZeneca") alleging False Claims Act ("FCA") violations relating to the promotion of Crestor® ("the original De Souza complaint"). (D.I. 1) On February 26, 2010, De Souza amended her complaint ("the De Souza complaint"). (D.I. 4) De Souza's motion to file a second amended complaint was granted and such second amended complaint was filed on December 13, 2011. (D.I 48, 49, 50) On March 4, 2013, the government declined to intervene. (D.I. 63, 64) Presently before the court is AstraZeneca's motion for to dismiss for lack of subject matter jurisdiction. (D.I. 83) The court has jurisdiction pursuant to the FCA, 31 U.S.C. § 3732(a).

II. STANDARD OF REVIEW

Not only may the lack of subject matter jurisdiction be raised at any time, it cannot be waived and the court is obliged to address the issue on its own motion. *See Moodie v. Fed. Reserve Bank of NY*, 58 F.3d 879, 882 (2d Cir. 1995). Once jurisdiction is challenged, the party asserting subject matter jurisdiction has the burden of proving its existence. *See Carpet Group Int'l v. Oriental Rug Importers Ass'n, Inc.*, 227 F.3d 62, 69 (3d Cir. 2000).

Under Rule 12(b)(1), the court's jurisdiction may be challenged either facially (based on the legal sufficiency of the claim) or factually (based on the sufficiency of jurisdictional fact). *See* 2 James W. Moore, Moore's Federal Practice § 12.30[4] (3d ed. 1997). Under a facial challenge to jurisdiction, the court must accept as true the

allegations contained in the complaint. *See id.* Dismissal for a facial challenge to jurisdiction is "proper only when the claim 'clearly appears to be immaterial and made solely for the purpose of obtaining jurisdiction or . . . is wholly insubstantial and frivolous.'" *Kehr Packages, Inc. v. Fidelcor, Inc.*, 926 F.2d 1406, 1408-09 (3d Cir. 1991) (quoting *Bell v. Hood*, 327 U.S. 678, 682 (1946)).

Under a factual attack, however, the court is not "confine[d] to allegations in the . . . complaint, but [can] consider affidavits, depositions, and testimony to resolve factual issues bearing on jurisdiction." *Gotha v. United States*, 115 F.3d 176, 179 (3d Cir. 1997); *see also Mortensen v. First Fed. Sav. & Loan Ass'n*, 549 F.2d 884, 891-92 (3d Cir. 1977). In such a situation, "no presumptive truthfulness attaches to plaintiff's allegations, and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims." *Carpet Group*, 227 F.3d at 69 (quoting *Mortensen*, 549 F.2d at 891).

III. BACKGROUND

A. Parties

De Souza is a citizen of the United States and resident of the State of Florida. De Souza worked for AstraZeneca as a sales representative from October 2000 until her termination in February 2010. (D.I. 4 at ¶¶ 3, 39, 55-55) Defendant AstraZeneca PLC is a public limited company organized in the United Kingdom, with a principal place of business in London, United Kingdom. Defendant AstraZeneca Pharmaceuticals, LP is a limited partnership organized in Delaware with a principal place of business in Wilmington, Delaware. (*Id.* at ¶¶ 6-7)

B. Factual Allegations

The De Souza complaint[1] alleges the following pertinent facts. Crestor® was initially approved for use in the United States in 2003, to lower cholesterol. On February 8, 2010, AstraZeneca announced that the Food and Drug Administration ("FDA") had approved Crestor® to reduce the risk of stroke and heart attack in patients with an increased risk of cardiovascular disease. Crestor® competes with Lipitor® (manufactured by Pfizer) and Zocor® (manufactured by Merck). (D.I. 4 at ¶¶ 38-39) In 2006, AstraZeneca directed its sales representatives to promote the results of a Crestor® drug study, the ASTEROID[2] study. AstraZeneca held a teleconference with its sales representatives to explain the ASTEROID study and emphasize the study results that Crestor® caused regression of atherosclerosis in certain patients' arteries (an indication never approved by the FDA). The sales representatives were sent a summary of the ASTEROID study, which could be easily shared with doctors, even though AstraZeneca's written policy instructed their sales representatives not to discuss off-label results with doctors. (*Id.* at ¶¶ 40-41)

On or about November 8-11, 2008, another Crestor® drug study (the JUPITER[3] study) was presented to attendees at an American Heart Association conference. The

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[1]The court summarizes the first amended complaint rather than the second amended complaint, as De Souza's arguments are referenced to the first amended complaint. Moreover, the second amended complaint provides additional factual details and adds state causes of action for Colorado, Iowa, Maryland and Minnesota.

[2]A Study To Evaluate the Effect of Rosuvastatin On Intravascular Ultrasound-Derived Coronary Atheroma Burden.

[3]Justification for the Use of Statins in Prevention: An Intervention Trial Evaluating Rosuvastatin.

JUPITER study contends, and AstraZeneca later promoted, that Crestor® can achieve results such as reducing the mortality rates in certain patients (a result never confirmed by the FDA) and reducing the risk of cardiovascular problems, including heart attacks and strokes, in certain patients (a result not confirmed by the FDA at that time). AstraZeneca held a teleconference to go over the JUPITER study with its sales representatives and distributed two sets of information in purple and yellow envelopes.[4] The envelopes were used at least from November 2008 to February 2009. In January and February 2009, AstraZeneca instructed sales representatives to discard the envelopes and cease distributing them. (*Id.* at ¶¶ 41-49)

AstraZeneca paid medical professionals to promote Crestor® and the results of the JUPITER study at speaking engagements. It trained and compensated the speakers. AstraZeneca's speaker program was a poorly disguised kickback. (*Id.* at ¶¶ 56-58)

After settling fraud allegations with the government in 2003 related to a drug, Zoladex, AstraZeneca entered into a Corporate Integrity Agreement ("Zoladex CIA") with the Office of the Inspector General for the Department of Health and Human Services. (*Id.* at ¶¶ 62-67) On or around October 2009, AstraZeneca entered into another settlement regarding physician involvement in clinical trials for Seroquel and off-label promotion of the drug Seroquel. The settlement should have included another

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[4]The sales representatives were told to deliver a purple, unmarked, sealed envelope containing a summary of the JUPITER Study prepared by AstraZeneca to certain top-prescribing doctors. The sales representatives were also given a yellow, unmarked, sealed envelope containing a reprint of the JUPITER study to distribute to doctors with or without solicitation.

Corporate Integrity Agreement ("Seroquel CIA"). (*Id.* at ¶¶ 68-73) AstraZeneca violated the FCA by impliedly or expressly certifying compliance with the Zoladex CIA and Seroquel CIA, when it was marketing off-label uses of Crestor® and offering kickbacks to induce physicians to prescribe high volumes of Crestor®. (*Id.* at ¶¶ 67, 73, 88-89)

AstraZeneca made millions of dollars in sales of Crestor® through various benefit programs. It violated the Federal Food, Drug, and Cosmetic Act by distributing misbranded Crestor®, because the "labeling was false or misleading, [the] labeling did not bear adequate directions for use, and/or [the] labeling did not bear adequate warnings against unsafe dosage or methods of administration or application." AstraZeneca's conduct violated federal laws prohibiting manufacturers from promoting off-label uses of drugs and the Anti-Kickback Statute by providing kickbacks to doctors. (*Id.* at ¶¶ 82-86)

In October 2009, AstraZeneca met with De Souza regarding the distribution of the envelopes and her call-notes (sales representative follow-up notes after meeting with doctors). On February 2, 2010, De Souza was accused of mishandling the information regarding the JUPITER study and was terminated effective immediately (along with one hundred other sales representatives). (*Id.* at ¶¶ 50-55) De Souza alleges retaliation in count IV.[5] (*Id.* at ¶¶ 59-61)

IV. DISCUSSION

The FCA creates liability for any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" to the government.

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[5]AstraZeneca does not seek to dismiss the retaliation count in the present motion.

31 U.S.C. § 3729(a)(1)(A). The FCA seeks "to strike a balance between encouraging private persons to root out fraud and stifling parasitic lawsuits." *Graham Cnty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson*, 559 U.S. 280, 281 (2010). The FCA provides that "[w]hen a person brings an action under this subsection, no person other than the Government may . . . bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5). The Third Circuit has held that this

> phrase . . . clearly bars claims arising from events that are already the subject of existing suits. A later case need not rest on precisely the same facts as a previous claim to run afoul of this statutory bar. Rather, if a later allegation states all the essential facts of a previously-filed claim, the two are related and section 3730(b)(5) bars the later claim, even if that claim incorporates somewhat different details.

United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc., 149 F.3d 227, 232 (3d Cir. 1998) (citations omitted). "[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." *Id.* at 234.

De Souza acknowledges that *United States ex rel. Foote v. AstraZeneca LP*, Civ. No. 10-95-SLR (D. Del.) ("the Foote Complaint") was filed ten days before the original De Souza complaint; however, De Souza alleges that she is the first to file on the JUPITER scheme.[6] Applying the above interpretation of the statute, the court compares the De Souza complaint to the Foote complaint to determine whether any of the later filed claims survive the statutory bar. The Foote complaint generally asserts

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[6]As De Souza only challenges the motion to dismiss with regard to the JUPITER scheme, the court grants the motion to dismiss to the extent that the claims are based on the other facts (including the ASTEROID study) alleged in the De Souza complaint.

that AstraZeneca

> engaged in a scheme since at least 2007 to submit and cause to be submitted hundreds of thousands of false claims to federal and state healthcare programs by systematically and illegally promoting Crestor® for unapproved, off-label uses throughout the United States. These false claims cheated the federal and state Governments out of hundreds of millions of dollars that should not have been paid, thereby enriching [AstraZeneca], and [AstraZeneca] subjected patients to non-approved, ineffective and unsafe uses of Crestor®.

(Civ. No. 10-95, D.I. 2 at ¶ 2)

A. FCA Causes of Action

De Souza's count I alleges that "[a]s a result of AstraZeneca's off-label marketing scheme and kickbacks to physicians to induce them to prescribe high volumes of Crestor®," AstraZeneca knowingly caused to be presented false or fraudulent claims for payment or approval. (D.I. 4 at ¶¶ 92-95) The Foote complaint makes the following allegations. AstraZeneca initiated discussions with healthcare professionals about off-label uses of Crestor® and "planted" questions about off-label uses at AstraZeneca-sponsored presentations. (Civ. No. 10-95, D.I. 2 at ¶ 24) AstraZeneca announced that it was halting its ongoing JUPITER trial two years ahead of schedule because it showed that Crestor® prevents heart attacks and strokes. AstraZeneca instructed its sales representatives to promote JUPITER to physicians, healthcare professionals, and decision makers on formulary boards as being able to prevent heart attacks and strokes. (*Id.* at ¶¶ 148-51) A district sales manager, citing results of the JUPITER study, directed sales representatives to promote the superiority of Crestor® by using talking points emphasizing JUPITER's "supposed outcomes data." (*Id.* at ¶ 166) He also suggested sales dialogues including phrases such as: "Crestor® does

more inside the vessel to help prevent cardiovascular death, heart attacks and strokes" and "a generic . . . is not going to protect you from cardiovascular events like Crestor® will . . . ." Sales representatives told doctors that using Crestor® could "save [a patient's] life" and "argued that Crestor® had superior outcomes data for preventing cardiovascular events such as stroke, heart attack and sudden death." (*Id.* at ¶¶ 167-68, 173) AstraZeneca used "medical liaisons" (with or without accompanying sales representatives) to initiate discussions of off-label uses. (*Id.* at ¶¶ 152-55) AstraZeneca sought to promote Crestor® "irrespective of the condition for which the drug was prescribed." (*Id.* at ¶ 156)

The Foote complaint also alleged that AstraZeneca provided illegal kickbacks to healthcare professionals, such as paying for - but then not utilizing - full-day "tutorials" with healthcare professionals, and by entertaining healthcare professionals with lavish dinners. (Civ. No. 10-95, D.I. 2 at ¶ 26) AstraZeneca paid select physicians, "key opinion leaders," to make presentations to groups of doctors to encourage them to prescribe Crestor®. The presentations were held at expensive restaurants and included "planted" questions regarding off-label uses. (*Id.* at ¶¶ 129-130) AstraZeneca paid healthcare professionals for a variety of services and paid preferred speakers to promote off-label uses of Crestor® in lecture-style presentations to other doctors. (*Id.* at ¶¶ 182-83)

The Foote complaint describes AstraZeneca's illegal promotion of Crestor® and concludes that without such promotion, off-label and misbranded prescriptions for Crestor® would not have been written. The prescriptions resulted in submission of false claims for reimbursement and AstraZeneca benefitted. (Civ. No. 10-95, D.I. 2 at

¶¶ 108-109)

De Souza attempts to distinguish her allegations by contending that Foote does not plead the essential fact that the JUPITER study touted Crestor® as a drug that could "reduce mortality from any cause, not just prevent cardiovascular related events or strokes," i.e., "total mortality." Under the approach provided by the Third Circuit, the court compares the complaints to determine if the "material elements of [the De Souza] claim[s] are the same as those" in the Foote complaint. *LaCorte*, 149 F.3d at 235. If the De Souza complaint "merely echos" the broader allegations in the Foote complaint, or if the Foote complaint "fully subsumes all the material elements" of the De Souza complaint, then the first-to-file rule applies. *Id.* at 236, 238.

The Foote complaint sets out the JUPITER study and alleges that AstraZeneca improperly promoted Crestor®, including telling doctors that it could "save lives" and "had superior outcomes data for preventing cardiovascular events such as stroke, heart attack and sudden death." That AstraZeneca touted the decrease in total mortality, as pled by De Souza, is a different or additional detail, not a different type of wrongdoing. *See United States ex rel. Tillson v. Lockheed Martin Energy Sys., Inc.*, Civ. No. 5:00CV-39-M, 2004WL 2403114, at *10 (W.D. Ky. Sept. 30, 2004) (applying a standard similar to that of the Third Circuit and concluding that the counts of the later filed complaint which "'fail[] to allege a different type of wrongdoing, based on different material facts' . . . are barred by the first-to-file rule."). Similarly, De Souza's additional details describing the manner in which AstraZeneca promoted the JUNIPER study, i.e., the use of the purple and yellow envelopes, are part of the same fraudulent scheme described in the Foote complaint. De Souza also argues that she pled unlawful

kickbacks, but the Foote complaint describes kickbacks as discussed above. For these reasons, the court concludes that the allegations in the Foote complaint encompass the claims made in count I of the De Souza complaint, therefore, count I is barred by the first-to-file rule. *Cf. United States ex rel. Galmines v. Novartis Pharmaceuticals Corp.*, Civ. No. 06–3213, 2013 WL 2649704, at *10 (E.D. Pa. June 13, 2013) (finding that a later filed complaint which "pertain[ed] to a different off-label promotion scheme, . . . would [not] have informed the government of the need to investigate whether [defendant] was marketing" a drug for a different use, when the first-filed complaint "never alleged that such marketing occurred.").

Count II of the De Souza complaint alleges that AstraZeneca knowingly made or used false records or statements (the false or misleading marketing materials and other statements provided to physicians to induce them to prescribe high volumes of Crestor®) and knowingly caused physicians and pharmacists and third-party payers to make or use false records or statements (by falsely certifying and representing full compliance with all federal and state laws and regulations) to get false or fraudulent claims paid or approved by the government. (D.I. 4 at ¶¶ 96-100) Applying the same reasoning used for count I, the court concludes that the Foote complaint encompasses these allegations and De Souza's count II is barred by the first-to-file rule.

De Souza's count III alleges that AstraZeneca conspired with physicians to promote off-label uses of Crestor® in violation of the FCA and to pay kickbacks to physicians in violation of the Anti-Kickback Statute to induce physicians to prescribe high volumes of Crestor®, thereby causing benefit claims to be false or fraudulent. (D.I. 4 at ¶¶ 101-103) This count is based on the same fraudulent scheme described above,

and, therefore, is also barred by the first-to-file rule.[7]

De Souza argues that "only De Souza pleaded a reverse false claim under 31 U.S.C. § 3731(a)(7)" by describing AstraZeneca's coverup of the envelopes, termination of sales representatives and failure to report the misconduct as required under the Corporate Integrity Agreements. However, De Souza did not raise a reverse false claim in any of the counts. Moreover, the underlying facts of such a claim as argued by De Souza appear sufficiently in the Foote complaint, that is, "AstraZeneca attempted to conceal and cover up the off-label marketing and false and misleading promotion of Crestor® by making false statements to the FDA and directing employees to conceal evidence." (Civ. No. 10-95, D.I. 2 at ¶ 27) The Foote complaint also discusses the Zoladex CIA and the Seroquel settlement. (*Id.* at ¶ 192)

B. State Law Claims

The Foote complaint raises claims regarding AstraZeneca's alleged off-label scheme in California, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Indiana, Illinois, Louisiana, Commonwealth of Massachusetts, Michigan, Montana, New Hampshire, New Jersey, New Mexico, New York, Nevada, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Wisconsin. (Civ. No.

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[7]De Souza argues that the Foote complaint fails to comply with Federal Rule of Civil Procedure 9(b) and describes the reasons why the De Souza complaint meets the 9(b) requirements. Whether the first-filed complaint meets this requirement is not the question in need of analysis for the jurisdictional bar. *United States ex rel. Galmines v. Novartis Pharmaceuticals Corp.*, Civ. No. 06-3213, 2013 WL 2649704, at n.4 (E.D. Pa. June 13, 2013) ("[T]he Court finds that whether the [first-filed] complaint satisfied the pleading requirements of Rule 9(b) is inapposite, because the plain language of § 3730(b)(5) does not include an exception for situations in which a first-filed complaint is pled with insufficient particularity.").

10-95, D.I. 2 at ¶¶ 208-388) While De Souza alleges that the De Souza complaint pleads a corporate-wide and nationwide scheme (as opposed to the Foote complaint which "contains scant allegations reaching beyond the state of Indiana"), the allegations in the Foote complaint encompass the same fraudulent scheme as that described in the De Souza complaint, therefore, De Souza's state causes of action (counts V-XXIX) are dismissed.[8, 9]

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[8]As to the Louisiana cause of action (D.I. 4 at ¶¶172-181), De Souza argues that Louisiana's first-to-file statute in effect on the date of the filing of her complaint allows for duplicative complaints if such complaints were filed within thirty days. *See* La. Rev. Stat. Ann. § 46:439.2(A)(3)(b) (2010). The statute also requires filing "the complaint and information" with the secretary or attorney general within 30 days of the first-filed complaint. As De Souza has not pled the date when she filed this information, the state cause of action XI is dismissed without prejudice. De Souza has 30 days to provide such evidence to the court.

[9]De Souza's additional state law claims (Colorado, Iowa, Maryland and Minnesota) in the second amended complaint fail for the same reasons. Count XXX alleges recovery of a share of a common fund based on the same fraudulent scheme as the state law and FCA claims, therefore, it is also dismissed. (*Id.* at ¶¶ 362-363)