UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
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UNITED STATES OF AMERICA; THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA; THE STATES OF CALIFORNIA, DELAWARE, CONNECTICUT, MARYLAND, COLORADO, FLORIDA, GEORGIA, ILLINOIS, INDIANA, HAWAII, LOUISIANA, MICHIGAN, MONTANA, NEW HAMPSHIRE, NEW MEXICO, NEW YORK, NEVADA, TENNESSEE, NEW JERSEY, RHODE ISLAND, OKLAHOMA, WISCONSIN, NORTH CAROLINA, MINNESOTA AND WASHINGTON, THE CITY OF CHICAGO AND THE DISTRICT OF COLUMBIA ex rel. ALLISON ZAYAS,

Plaintiff-Relator,

-against-

ASTRAZENECA BIOPHARMACEUTICALS, INC., ASTRAZENECA PLC, ASTRAZENECA, LP, and ASTRAZENECA PHARMACEUTICALS, LP,

Defendants.
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MEMORANDUM AND ORDER
14-1718 (FB)

Appearances:

For the Plaintiff-Relator
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For the Defendants
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BLOCK, Senior District Judge:

Plaintiff-relator Allison Zayas ("plaintiff") brought a *qui tam* suit under the False Claims Act ("FCA") and multiple related state-law causes of action against defendants Astrazeneca Biopharmaceuticals, Inc.; Astrazeneca PLC; Astrazeneca, LP; and Astrazeneca Pharmaceuticals, LP (together, "defendants"). In her Amended Complaint, plaintiff alleges that defendants (1) marketed Seroquel IR and Seroquel XR (together, "Seroquel") as safe to be prescribed with QT/QTc prolonging medications when they knew of the risks of such concomitant prescriptions, and (2) engaged in off-label promotion of Seroquel, and that both of these actions led to the submission of false claims for payments to state and federal governments. Defendants now move to dismiss plaintiff's off-label promotion claims pursuant to Federal Rule of Civil Procedure 12(b)(1), and all of plaintiff's claims under Rule 12(b)(6). For the following reasons, the Rule 12(b)(1) motion is GRANTED and the Rule 12(b)(6) is DENIED as to the QT/QTc federal claim in Count One and GRANTED as to Count Two.[1]

A. Rule 12(b)(1) Motion.

The first-to-file rule under the FCA bars any new claim if it is "related" to an FCA

[1] As discussed at the March 31, 2017 oral argument plaintiff agreed to withdraw her state law claims without prejudice to re-instate with a letter application. On April 6, 2017, the New York Attorney General's office filed a letter claiming that plaintiff did not have the authority to withdraw those claims and requesting three weeks "to confer with all of the Plaintiff States and decide whether to seek reinstatement of the State law claims." April 6 Letter at 2. Plaintiff subsequently filed a letter "withdrawing consent to the dismissal of those claims." April 12 Letter at 1. The Court will revisit this issue should the states implicated in this matter timely seek reinstatement.

claim in an already-pending action. *See* 31 U.S.C. § 3730(b)(5) ("[N]o person other than the Government may intervene or bring a related action based on the facts underlying the pending action . . . ."). When considering a challenge under that rule, a court must therefore determine if a new FCA claim is related to an already-pending FCA claim. To do so, the Court will apply the test used by the majority of Circuits—the essential claim test—which looks not to whether the more recently-filed FCA claim is *identical* to an FCA claim in an already-pending action, but to "whether the complaints allege the same material facts, *i.e*. whether they involve the same core conduct, and would give rise to separate recovery." *Id.* at 76.

Defendants argue that plaintiff's off-label promotion claim is barred by the first-to-file rule—and this Court therefore does not have subject matter jurisdiction over such claim—because it is based on the same facts as an earlier-filed case in Delaware, which also alleges off-label promotion. In rebuttal, plaintiff argues that her claim is distinct because (1) she alleges off-label promotion to treat different diseases than those alleged to have been promoted off-label in the Delaware action, (2) she alleges off-label promotion of Seroquel IR, whereas the Delaware action concerns off-label promotion of Seroquel XR, a different drug, and (3) the Delaware action is no longer pending.

Plaintiff's first argument is unavailing. The False Claims act bars any person from bringing a *related* action based on the facts underlying an already-filed action. To find that

plaintiff could avoid the first-to-file bar by enumerating different diseases for which defendants promoted the same prescription drug off-label would mean transforming the statute's language from "*related* action" to "*identical* action." *See* 31 U.S.C. § 3730(b)(5). It would also mean disregarding the First Circuit's well-reasoned application of the essential element test, which concluded that "promotion of off-label uses of the two same drugs, but tied to [different] diseases and symptoms . . . [is] not enough to reasonably conclude the earlier . . . Complaint was not a related claim to the government based on the facts." *See U.S. ex rel. Wilson v. Bristol-Myers Squibb, Inc*., 750 F.3d 111, 119 (1st Cir. 2014).

Plaintiff's second argument is factually incorrect. The Third Amended Complaint in the Delaware action expressly alleges that "AstraZeneca's off-label promotion of Seroquel IR and Seroquel XR caused physicians to prescribe both drugs for non-medically accepted uses . . . ." *U.S. ex rel. Tracey Miksell-Branch v. AstraZeneca, et al.*, No. 10-cv-154 (D. Del.), Third Amended Complaint at ¶¶ 112-135.

Plaintiff's final argument is that the Delaware case is no longer pending because the parties agreed to stay the case. After such agreement, the district court stayed and administratively terminated the case "in a way that preserves the status quo of [the a]ction as of the date of the stay." *U.S. ex rel. Tracey Miksell-Branch v. AstraZeneca, et al.*, No. 10-cv-154 (D. Del.), Joint Stipulation Requesting Stay of Action at 4. However, the Delaware case was never *dismissed*. And as the Supreme Court recently instructed, "a *qui*

tam suit under the FCA ceases to be 'pending' once it is *dismissed*." *Kellogg Brown & Root Servs., Inc. v. U.S., ex rel. Carter*, 135 S. Ct. 1970, 1979 (2015) (emphasis added).

As the pending Delaware action alleges off-label promotion of Seroquel IR and Seroquel XR, plaintiff's off-label promotion allegations are barred by the first-to-file rule. Therefore, pursuant to Rule 12(b)(1), the Court dismisses those claims.

B. Rule 12(b)(6) Motion.

1. Count One.

Count One in the Ninth Amended Complaint alleges a violation of the False Claims Act. An entity is liable under the False Claims Act when it "'knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval' to the U.S. government; or . . . 'knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.'" *U.S. ex rel. Polansky v. Pfizer, Inc.*, 822 F.3d 613, 618 (2d Cir. 2016) (quoting 31 U.S.C. § 3729(a)-(b)).

The Court, taking the allegations as true and viewing the complaint in the light most favorable to plaintiff, finds she has met this burden with regards to the QT/QTc interval prolongation claims. Plaintiff alleges that federal Medicare paid for Seroquel prescriptions that were prescribed concomitantly with QT/QTc prolonging medications from 1997 to 2009. NAC at ¶¶ 259, 815. She alleges those claims were factually false because defendants misrepresented the risk of drug interaction between Seroquel and QT/QTc prolonging medications in the requisite drug utilization review so that the Seroquel

prescriptions would be filled and the government would pay those claims. *Id*. at, e.g. ¶ 106; *see also Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001) (abrogated on other grounds by *Universal Health Servs., Inc. v. United States*, 136 S. Ct. 1989, 195 L. Ed. 2d 348 (2016)) ("[A] factually false' certification, . . . involves an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided.").

Plaintiff also alleges the claims were legally false. Defendants were party to two Corporate Integrity Agreements with the federal government that required compliance with all relevant laws to participate in federal health programs. However, they allegedly disregarded these agreements when they failed to disclose the risk of prescribing Seroquel with QT/QTc prolonging medications—as required by federal regulations—so that they could continue to participate in federal health programs. *See Mikes*, 274 F.3d at 697 (A legally false certification is "a false representation of compliance with a federal statute or regulation or a prescribed contractual term.").

The Court is satisfied that plaintiff has met the pleading standard for False Claims Act cases under Rule 9(b). She alleges facts throughout her complaint that establish a fraudulent scheme in each instance where Seroquel was prescribed with QT/QTc medications without warning from defendants, who allegedly knew of the risk in concomitantly prescribing such medications. In this way, plaintiff appropriately alleges a "complex fraudulent scheme . . . occurring over a lengthy period of time and involving thousands of billing documents," which relaxes the Rule 9(b) pleading standard. *U.S. ex*

rel. Mooney v. Americare, Inc., 2013 WL 1346022, at *3 (E.D.N.Y. Apr. 3, 2013).

2. Count Two.

Count Two in the Ninth Amended Complaint alleges that defendants violated the Corporate Integrity Agreements. In oral argument, plaintiff acknowledged that Count Two was not intended to be a breach of contract claim—for which she would lack standing—but rather an inartfully pleaded reverse false claim. A reverse false claim would be extant when an individual "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(1)(G).

Plaintiff reasons that defendants' failure to disclose the risks of concomitantly prescribing Seroquel with QT/QTc prolonging medications enabled them to avoid paying stipulated damages to the federal government for this breach of the Corporate Integrity Agreements. This argument is unpersuasive for the same reason the Massachusetts district court dismissed a plaintiff's reverse false claim in *U.S. ex rel. Booker v. Pfizer, Inc.*, 9 F. Supp. 3d 34, 50 (D. Mass. 2014): the stipulated penalties themselves are not an *obligation* owed to the federal government. They are not automatically imposed; rather, the government must choose to impose stipulated penalties and defendants may appeal such imposition with an administrative law judge. As the district court in *Booker* convincingly reasoned:

> The mere fact that [defendant's] failure to report "*might* result in a fine or penalty is insufficient" to establish an "obligation" to pay the government

> under § 3729(a)(1)(G). *U.S. ex rel. Bahrani v. Conagra, Inc*., 465 F.3d 1189, 1195 (10th Cir.2006). When "potential fines depend on intervening discretionary governmental acts, they are not sufficient to create 'obligations to pay.'" *U.S. ex rel. Marcy v. Rowan Companies, Inc*., 520 F.3d 384, 391 (5th Cir.2008). Without an obligation, [defendant] had nothing to avoid, and relators' claim under § 3729(a)(1)(G) must fail.

Id. at 49-50.

CONCLUSION

For the aforementioned reasons, defendants' Rule 12(b)(1) motion is GRANTED and the Rule 12(b)(6) motion is DENIED as to the QT/QTc federal claim in Count One and GRANTED as to Count Two.

SO ORDERED

/S/ Frederic Block_____
FREDERIC BLOCK
Senior United States District Judge

Brooklyn, New York
April 17, 2017