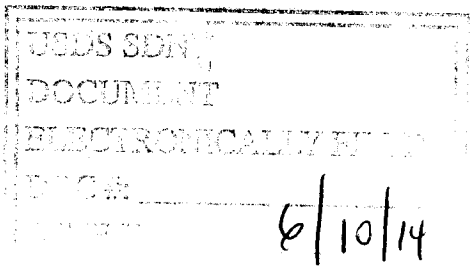
UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK



UNITED STATES OF AMERICA *ex rel.* DAVID M. KESTER, STATE OF CALIFORNIA *ex rel.* DAVID M. KESTER, STATE OF COLORADO *ex rel.* DAVID M. KESTER, STATE OF CONNECTICUT *ex rel.* DAVID M. KESTER, STATE OF DELAWARE *ex rel.* DAVID M. KESTER, DISTRICT OF COLUMBIA *ex rel.* DAVID M. KESTER, STATE OF FLORIDA *ex rel.* DAVID M. KESTER, STATE OF GEORGIA *ex rel.* DAVID M. KESTER, STATE OF HAWAII *ex rel.* DAVID M. KESTER, STATE OF ILLINOIS *ex rel.* DAVID M. KESTER, STATE OF INDIANA *ex rel.* DAVID M. KESTER, STATE OF LOUISIANA *ex rel.* DAVID M. KESTER, STATE OF MARYLAND *ex rel.* DAVID M. KESTER, STATE OF MASSACHUSETTS *ex rel.* DAVID M. KESTER, STATE OF MICHIGAN *ex rel.* DAVID M. KESTER, STATE OF MINNESOTA *ex rel.* DAVID M. KESTER, STATE OF MONTANA *ex rel.* DAVID M. KESTER, STATE OF NEVADA *ex rel.* DAVID M. KESTER, STATE OF NEW JERSEY *ex rel.* DAVID M. KESTER, STATE OF NEW MEXICO *ex rel.* DAVID M. KESTER, STATE OF NEW YORK *ex rel.* DAVID M. KESTER, STATE OF NORTH CAROLINA *ex rel.* DAVID M. KESTER, STATE OF OKLAHOMA *ex rel.* DAVID M. KESTER, STATE OF RHODE ISLAND *ex rel.* DAVID M. KESTER, STATE OF TENNESSEE *ex rel.* DAVID M. KESTER, STATE OF TEXAS *ex rel.* DAVID M. KESTER, STATE OF VIRGINIA *ex rel.* DAVID M. KESTER, and STATE OF WISCONSIN *ex rel.* DAVID M. KESTER,

Plaintiffs and Relator,

-against-

No. 11 Civ. 8196 (CM)

NOVARTIS PHARMACEUTICALS CORPORATION, ACCREDO HEALTH GROUP, INC., BIOSCRIP CORPORATION, CURASCRIPT, INC., CVS CAREMARK CORPORATION,

Defendants.

MEMORANDUM DECISION AND ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTIONS TO DISMISS

McMahon, J.:

Plaintiff-relator David M. Kester ("Relator") filed a sealed *qui tam* action asserting claims arising under the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.*, and related state laws. The Defendants named in the complaint include Novartis Pharmaceuticals Corporation ("Novartis") and certain specialty pharmacies, including CVS Caremark Corporation ("Caremark"), Accredo Health Group, Inc. ("Accredo"), and Curascript, Inc. ("Curascript"). The Relator alleges that Novartis and these pharmacies violated the FCA and the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), in connection with a kickback scheme.

Pending before the Court are the Defendants' motions to dismiss the Relator's Second Amended Complaint pursuant to Rule 9(b) of the Federal Rules of Civil Procedure for failure to plead fraud with particularity. For the reasons discussed below, those motions are granted in part and denied in part.[1]

BACKGROUND[2]

A. Procedural History

Pursuant to the False Claims Act ("FCA"), private persons known as "relators" may file *qui tam* actions and recover damages on behalf of the United States. *See* 31 U.S.C. § 3730(b). Plaintiff Kester ("Relator") originally filed this FCA action in November 2011 on behalf of the United States, 27 states, and the District of Columbia. The original named defendants in the Relator's complaint included Novartis and several pharmacy companies, including Caremark,

[1] I anticipate a large number of opinions in this case. This opinion is to be referred to in all future correspondence and papers as "*Novartis II*."

[2] The facts are taken from the Relator's Second Amended Complaint and the Government's Amended Complaint-in-Intervention (which the Relator incorporates by reference).

Accredo, Curascript (collectively, the "Pharmacy Defendants"), and BioScrip Corporation ("BioScrip"). The Relator alleged that Novartis and the pharmacies violated the FCA and the Anti-Kickback Statute by engaging in a kickback scheme and then submitting "false claims" for reimbursement to federal and state government programs.

The United States government ("the Government") began investigating the alleged kickback scheme. In April 2013, the Government elected to intervene as a plaintiff in this case, but only against Novartis and BioScrip. On January 8, 2014, the Government filed an Amended Complaint-in-Intervention ("the Government's Complaint").

In January 2014, Defendant BioScrip settled out of the case. *See* Docket No. 41. Eleven states have since intervened as co-plaintiffs against Novartis alone.

On January 30, 2014, the Relator filed a Second Amended Complaint ("the Relator's Complaint"). It brings claims against Novartis and the Pharmacy Defendants on behalf of the United States, 26 states, and the District of Columbia. The Relator asserts claims (Counts 1a, 1b, 1c, and 1d)[3] under four subsections of the FCA—31 U.S.C. §§ 3729(a)(1)(A), (a)(1)(B), (a)(1)(C), and (a)(1)(G). He also asserts claims (Counts 2-28) under 27 different state law analogues of the FCA, including the parallel false claim statutes in California, Colorado, Connecticut, Delaware, the District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, and Wisconsin.

Generally, the FCA outlaws the submission of a false or fraudulent "claim" for payment (*i.e.*, a request for reimbursement) to the government. *See* 31 U.S.C. § 3729(a)(1). Such claims

[3] The Relator asserts all four of his FCA claims as "Count 1." I will refer to these claims as Counts 1a, 1b, 1c, and 1d for clarity.

may be rendered "false" in a variety of ways. In this case, the Relator's FCA claims are predicated on underlying violations of the Anti-Kickback Statute ("AKS"). Under the AKS, it is illegal to offer a person "remuneration" (*i.e.*, kickbacks) in order to "induce" that person to "recommend" the purchase of a drug covered by a federal health care program. 42 U.S.C. § 1320a-7b(b)(2). It is likewise illegal to receive remuneration in exchange for "recommending" the purchase of such drugs. *See id.* at § 1320a-7b(b)(1).

The Relator alleges that Novartis conducted five illegal kickback schemes involving drugs covered by federal programs, and that the Pharmacy Defendants participated in those schemes.

B. The Alleged Kickback Schemes

The reader is presumed to be familiar with this Court's previous order denying Novartis's motion to dismiss the Government's Complaint pursuant to Rule 9(b). *See U.S. ex rel. Kester v. Novartis Pharmaceuticals Corp.*, No. 11 Civ. 8196 (CM), 2014 WL 2324465 (S.D.N.Y. May 29, 2014) (hereafter "*Novartis I*").

Defendant Novartis is a pharmaceutical company that develops, manufactures, and markets prescription drugs. It sells these drugs through various avenues, one of which is "specialty" pharmacies which sell drugs that are not available at normal retail pharmacies. *See* Compl.[4] at ¶ 1.

The Relator, David M. Kester, is a former sales employee of Novartis who discovered that Novartis was engaging in practices that allegedly violated the AKS and the FCA. *See id.* at ¶¶ 15-16. According to the Relator, Novartis realized that certain pharmacies had influence over doctors or patients. So beginning in January 2007 it decided to "leverage" these pharmacies'

[4] "Compl." refers to the Relator's Second Amended Complaint.

influence—it offered them kickbacks in the form of rebates, discounts, and patient referrals to induce them to "recommend" its drugs to doctors or patients. *Id.* at ¶ 2.

The Relator's Complaint contains a detailed description of the mechanics of the kickback schemes. It alleges that Novartis gave the pharmacies several types of remuneration: "first category rebates," which were volume-based rebates of about 1-3% of all sales of Novartis drugs; "second category rebates," which were performance-based payments depending on quantity sold or market share; and patient referrals, which Novartis controlled through its exclusive distribution networks. *See id.* at ¶¶ 63-65.

In return, the pharmacies (including Caremark, Accredo, and Curascript) allegedly agreed to promote Novartis drugs. Generally, the pharmacies would recommend to doctors and patients that patients switch to Novartis drugs, remain on Novartis drugs (as opposed to discontinuing treatment), or increase their dosages and refills. The pharmacies implemented "high touch nurse" programs in which nurses employed by the pharmacies would proactively "intervene"—they called patients or doctors under the guise of providing counseling services, but their true goal was to push Novartis drugs. *See id.* at ¶¶ 68, 89. Novartis also encouraged Caremark, Accredo, and Curascript to channel patients from their retail pharmacies to their specialty pharmacies, which had more patient contact and were, thus, better positioned to influence patients.

Novartis kept track of the pharmacies' success in promoting its drugs through "scorecarding"—comparing the specialty pharmacies in its networks (including Caremark, Accredo, and Curascript) to their peers. *Id.* at ¶¶ 89, 95-96. Higher performing pharmacies (*i.e.*, pharmacies which sold more Novartis drugs) were rewarded with more rebates and patient

referrals. The Relator claims that he attended a Novartis sales meeting in which these scorecards were reviewed.

The Relator alleges that Novartis orchestrated kickback schemes for five of its drugs—Myfortic, Exjade, Gleevac, Tasigna, and TOBI. Some of these drugs have serious side effects that can be harmful to patients. Caremark, Accredo, and Curascript allegedly participated in the Gleevac, Tasigna, and TOBI schemes. Accredo also participated in the Exjade scheme. *See id.* at ¶¶ 32, 37, 41, 77-127.

The Relator's Complaint also incorporates by reference the detailed allegations contained in the Government's Complaint relating to the involvement of Novartis, BioScrip, and five other pharmacies (which are not named as defendants in the Relator's Complaint) in the Myfortic and Exjade schemes. *See id.* at ¶¶ 79, 121. Those allegations are described in *Novartis I*. *See* 2014 WL 2324465, at *2-4.

C. The Relator's Causes of Action

The Relator alleges that these kickback schemes caused the Pharmacy Defendants (and the other pharmacies involved in the scheme) to submit "false claims" to several government programs: Medicare, Medicaid, the Federal Employee Health Benefits Plan, and the Department of Defense TRICARE and CHAMPUS programs. *See id.* at ¶ 19.

As in *Novartis I*, *see* 2014 WL 2324465, at *17-21, the plaintiff in this case contends that compliance with the AKS is a precondition to payment of claims submitted to government programs. *See* Compl. at ¶ 48. The pharmacies that participated in the kickback schemes (including the Pharmacy Defendants) allegedly made both "express" and "implied" certifications (*i.e.*, representations) of compliance with the AKS in connection with the claims for Novartis drugs that they submitted to government programs. *See id.* at ¶¶ 24, 49-51, 78. Because those

pharmacies were in fact receiving kickbacks in violation of the AKS, the Relator argues, the certifications were "false." Accordingly, every claim for Novartis drugs that was submitted while those certifications were in effect was "false" within the meaning of the FCA, since the pharmacies' AKS violations "tainted" those claims and rendered them ineligible for reimbursement.

Because the kickback schemes orchestrated by Novartis allegedly caused the Pharmacy Defendants to submit false claims to government programs, the Relator asserts several causes of action against Novartis and the Pharmacy Defendants under the False Claims Act.

The four FCA subsections at issue create civil liability where a defendant: (a) "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A); (b) "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," *id.* § 3729(a)(1)(B); (c) "conspires to commit a violation of" another subsection of the FCA, *id.* § 3729(a)(1)(C), or (d) "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government," *id.* § 3729(a)(1)(G).[5]

Each of the Defendants has moved to dismiss the Relator's Complaint pursuant to Rule 9(b) for failure to plead fraud with particularity.

[5] The Relator also mentions the versions of these FCA subsections that were in effect prior to the enactment of the Fraud Enforcement and Recovery Act of 2009, which amended the FCA. That statutory amendment is explained in *Novartis I*. *See* 2014 WL 2324465, at *6-7. The statutory changes do not affect the outcome of this motion.

DISCUSSION

I. Rule 9(b) and the False Claims Act

Where a cause of action sounds in fraud, the plaintiff must satisfy the heightened pleading standard of Rule 9(b). *See Rombach v. Chang*, 355 F.3d 164, 170-71 (2d Cir. 2004). Because the FCA is an "anti-fraud statute," claims brought under that statute "fall within the express scope of Rule 9(b)." *Gold v. Morrison-Knudsen Co.*, 68 F.3d 1475, 1476-77 (2d Cir. 1995); *see also Wood ex rel. U.S. v. Applied Research Assocs., Inc.*, 328 Fed. App'x 744, 747 (2d Cir. 2009). This rule provides that a party alleging fraud "must state with particularity the circumstances constituting fraud or mistake." FED. R. CIV. P. 9(b). Scienter, however, "may be alleged generally." *Id.*

To comply with Rule 9(b), a complaint must "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *Rombach*, 355 F.3d at 170. "In other words, Rule 9(b) requires that a plaintiff set forth the who, what, when, where and how of the alleged fraud." *U.S. ex rel. Polansky v. Pfizer, Inc.*, No. 04 Civ. 704, 2009 WL 1456582, at *4 (E.D.N.Y. May 22, 2009) (quoting *U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 903 (5th Cir. 1997)).

The particularity requirement of Rule 9(b) serves several purposes: "to provide a defendant with fair notice of a plaintiff's claim, to safeguard a defendant's reputation from improvident charges of wrongdoing, and to protect a defendant against the institution of a strike suit." *Rombach*, 355 F.3d at 171. It also "discourage[s] the filing of complaints as a pretext for discovery of unknown wrongs." *Madonna v. U.S.*, 878 F.2d 62, 66 (2d Cir. 1989) (citation omitted). A plaintiff must plead all the "circumstances constituting fraud or mistake" with

sufficient particularity to fulfill the purposes of Rule 9(b). *Id.* For the various subsections of the FCA, these "circumstances" depend upon the elements of the subsection at issue.

The four FCA subsections at issue in this case all require proof of a falsehood or fraudulent scheme that renders the claim or statement in question "false." In this case, the Relator alleges a kickback scheme. The Pharmacy Defendants argue that the Relator fails to plead the specifics of the alleged kickback scheme and the specifics of their involvement in the scheme with sufficient particularity.

The Court can easily dispose of this argument. The Relator offers detailed allegations about the mechanics of the five kickback schemes and the involvement of the Pharmacy Defendants. The Complaint describes the various types of "remuneration" that Novartis offered the Pharmacy Defendants between 2007 and 2014, *see* 42 U.S.C. § 1320a-7b(b)(1)—volume sales rebates, performance-based rebates, and patient referrals. It also provides details about the promotional services (the "recommendations") that the Pharmacy Defendants provided "in return for" these kickbacks, *see id.*; they implemented "high touch nurse" programs in which pharmacy employees called doctors and patients directly to encourage them to prescribe or order Novartis drugs. The pharmacies also channeled patients from their retail pharmacies to their specialty pharmacies so that they could increase patient contact. The Complaint specifies which Novartis drugs—Myfortic, Exjade, Gleevac, Tasigna, and/or TOBI—each pharmacy allegedly recommended in exchange for Novartis's largesse.

These allegations sufficiently describe the "who, what, when, where and how" of the alleged kickback scheme that rendered the claims "false." *Polansky*, 2009 WL 1456582, at *4.

The Pharmacy Defendants also challenge the particularity of the Relator's scienter allegations. But Rule 9(b) allows scienter to be alleged "generally." FED. R. CIV. P. 9(b); *In re*

Cardiac Devices Qui Tam Litig., 221 F.R.D. 318, 339 (2004). In order to be held liable under the FCA, the defendant must have acted "knowingly," which the statute defines as "ha[ving] actual knowledge of the information," "act[ing] in deliberate ignorance of the truth or falsity of the information," or "act[ing] in reckless disregard of the truth or falsity of the information;" the FCA "require[s] no proof of specific intent to defraud." 31 U.S.C. § 3729(b)(1).

The Relator's Complaint alleges that the Pharmacy Defendants "knowingly" violated the FCA. Compl. at ¶¶ 134-37. The Relator supports these allegations by describing the defendants' intentional involvement with the kickback scheme and their knowingly false certifications of compliance with the AKS. The scienter allegations suffice.

Finally, the Pharmacy Defendants and Novartis contend that the Relator fails to identify with particularity the precise false claims that were submitted to government programs. This argument applies differently to different FCA subsections.

A. Subsection (a)(1)(A) and (a)(1)(B) Claims

The Relator brings claims against Novartis and the Pharmacy Defendants under both subsection (a)(1)(A) (Count 1a) and subsection (a)(1)(B) (Count 1b).

Subsection (a)(1)(A) provides for liability where the defendant "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). To prove a claim under this subsection, a plaintiff must show that: (1) there was a false or fraudulent claim, (2) the defendant knew it was false or fraudulent, (3) the defendant presented the claim, or caused it to be presented, to the United States, and (4) it did so to seek payment from the federal treasury. *See Mikes v. Straus*, 274 F.3d 687, 695 (2d Cir. 2001); *U.S. ex rel. Pervez v. Beth Israel Med. Ctr.*, 736 F. Supp. 2d 804, 811 (S.D.N.Y. 2010).

Subsection (a)(1)(B) provides for liability where the defendant "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B). To prove a claim under this subsection, a plaintiff must show that: (1) the defendant made (or caused to be made) a false statement, (2) the defendant knew it to be false, and (3) the statement was material to a false claim. *See Pervez*, 736 F. Supp. 2d at 811. So proof of a false claim is an essential element of both subsection (a)(1)(A) and (a)(1)(B) claims.

As discussed in *Novartis I*, Rule 9(b) requires a plaintiff asserting FCA claims under these two subsections to plead the submission of false claims with a high enough degree of particularity that defendants can reasonably "identify particular false claims for payment that were submitted to the government." *U.S. ex rel. Karvelas v. Melrose-Wakefield Hospital*, 360 F.3d 220, 232 (1st Cir. 2004). The details included in the complaint must fulfill the purposes of Rule 9(b) by both (1) identifying which of the claims that the defendant submitted were "false," and (2) providing a factual basis (as opposed to mere speculation) to support the plaintiff's assertion that claims were actually submitted to a government program. *See Novartis I*, 2014 WL 2324465, at *9-14.

The Relator argues that he is entitled to a special relaxed pleading standard in this case because many of the relevant facts are within the defendants' exclusive control. *See* Docket No. 169 at 3, 7.

It is true that the Second Circuit has stated that Rule 9(b) may be "relaxed" where key facts are "are peculiarly within the opposing party's knowledge," and the plaintiff has no access to those facts. *See Boykin v. Keycorp*, 521 F.3d 202, 215 (2d Cir. 2008); *Wexner v. First Manhattan Co.*, 902 F.2d 169, 172 (2d Cir. 1990); *Luce v. Edelstein*, 802 F.2d 49, 54 n.1 (2d Cir. 1986). In those cases, however, "relaxation" of the pleading standard meant that the plaintiff

could plead on information and belief, which is usually prohibited under Rule 9(b). *See DiVittorio v. Equidyne Extractive Indus., Inc.*, 822 F.2d 1242, 1247 (2d Cir. 1987). Relaxation does not mean that a plaintiff can plead offering no detail at all. *See Karvelas*, 360 F.3d at 228; *U.S. ex rel. Smith v. Yale Univ.*, 415 F. Supp. 2d 58, 83 (D. Conn. 2006). The Second Circuit has stated: "This exception to the general rule must not be mistaken for license to base claims of fraud on speculation and conclusory allegations." *Wexner*, 902 F.2d at 172. Because the Relator did not plead details about allegedly false claims "on information and belief," the *Boykin* "relaxation" rule does not help him to satisfy Rule 9(b).

For the subsection (a)(1)(A) and (a)(1)(B) claims, the Relator must reasonably "identify particular false claims for payment that were submitted to the government." *Karvelas*, 360 F.3d at 232.

1. Novartis's Motion to Dismiss the Relator's Subsection (a)(1)(A) and (a)(1)(B) Claims is Granted in Part and Denied in Part.

Novartis I effectively disposes of Novartis's motion to dismiss the Relator's Complaint insofar as it concerns the alleged Myfortic and Exjade schemes. The Government's allegations (which are incorporated into the Relator's Complaint) state that Novartis caused BioScrip and other pharmacies (but not the Pharmacy Defendants) to submit false claims to Medicare and Medicaid. The Government's Complaint recites detailed data about the actual Myfortic and Exjade claims submitted by each pharmacy. For example, with respect to a pharmacy named Transcript, it states:

> Any Medicare or Medicaid claim submitted by Transcript for Myfortic dispensed in connection with its illegal arrangement with Novartis was false and ineligible for reimbursement because such a claim was tainted by kickbacks. In that regard, Medicare data shows that, between August 1, 2011, and February 28, 2013, Transcript submitted 614 Myfortic claims to Medicare Part B and

> obtained more than $354,000 in reimbursement based on such false claims.

Government Compl.[6] at ¶ 109. The Government's Complaint contains similarly detailed allegations regarding the Myfortic and Exjade claims submitted by BioScrip and four other pharmacies. *See id.* at ¶¶ 82, 91, 100, 121, 230.

I previously concluded that the sufficiency of the Government's pleadings under Rule 9(b) with respect to the "claim" submission element depends on the legal sufficiency of its "false certification" theory of claim falsity—that *all* claims for Myfortic and Exjade which a pharmacy submitted during the course of the kickback scheme were "false" claims because, even though the pharmacy had certified that it was not violating the AKS, the pharmacy received a kickback for every single drug sale, whether or not the pharmacy's recommendation yielded that particular sale. *See Novartis I*, 2014 WL 2324465, at *22.

Assuming the viability of the Government's false certification theory, the Government's Complaint satisfies Rule 9(b) because it contains enough information to allow Novartis to figure out which claims the Government contends were false (all the Myfortic/Exjade claims submitted by the six pharmacies during the scheme), and it provides enough detail about the Myfortic and Exjade claims submitted to government programs to demonstrate that the Government is not speculating that claims tainted by the scheme were actually submitted. *See id.*

The Relator adopts the same theory of claim falsity as the Government—that all claims for Novartis drugs submitted by pharmacies receiving kickbacks were "false." And the Relator's Complaint incorporates the Government's allegations with respect to the Myfortic and Exjade claims submitted by Transcript, BioScrip, and the four other pharmacies discussed in the Government's Complaint. This fact alone prevents me from fully granting Novartis's motion to

[6] "Government Compl." refers to the Government's Amended Complaint-in-Intervention.

dismiss the Relator's Complaint at this juncture, since the Government's allegations survive a Rule 9(b) challenge if its legal theory is viable. The sufficiency of the Relator's allegations against Novartis relating to the Myfortic and Exjade schemes also depends on the sufficiency of the plaintiffs' legal theory. For now, Novartis's motion to dismiss the Relator's Complaint for lack of particularity is denied as to Counts 1a and 1b, insofar as it concerns the Myfortic and Exjade schemes.

However, the Government's Complaint contains no allegations about the Gleevac, Tasigna, and TOBI schemes allegedly conducted by Novartis; only the Relator's Complaint deals with these three schemes. Even assuming the viability of the Relator's theory of claim falsity, the Relator's allegations relating to false claims for Gleevac, Tasigna, and TOBI are insufficiently particular.

The Relator's allegations regarding the false claims for these three drugs that Novartis allegedly caused the specialty pharmacies to submit are vague and unhelpful:

> The false claims that form the basis for the Defendants' liability based on the allegations herein include all claims for Exjade, Gleevec, Tasigna, TOBI and Myfortic that have been billed by a specialty pharmacy to Medicare, Medicaid or another government health care program during a period of time in which Novartis used entry into its exclusive specialty pharmacy distribution network, rebates or discounts, scorecarding and/or patient referrals to induce the billing pharmacy to recommend that patients start or continue on the Novartis drug.

Compl. ¶ 128. Unlike the Government's allegations relating to Myfortic and Exjade—which were based on actual Medicare and Medicaid claims data and broken down by pharmacy—these conclusory allegations do not provide any specifics (such as dollar amounts or the number of claims) about claims for Gleevac, Tasigna, or TOBI that were submitted to the government by any particular defendant.

As discussed above, a plaintiff asserting subsection (a)(1)(A) and (a)(1)(B) claims must fulfill the purposes of Rule 9(b) by not only identifying which of the claims that the defendant submitted were "false," but also providing a factual basis to support his assertion that claims were actually submitted to a government program. *See Novartis I*, 2014 WL 2324465, at *9-14. The plaintiff, whether Relator or government, may not allege, in conclusory fashion, that "claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government." *U.S. ex rel. Clausen v. Laboratory Corporation of America, Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002). Rule 9(b) forbids such speculation and conjecture, since its purposes include safeguarding defendants' reputations from improvident charges of wrongdoing, protecting defendants from strike suits, and discouraging the filing of suits as a pretext for the discovery of unknown wrongs. *See Rombach*, 355 F.3d at 171; *Madonna*, 878 F.2d at 66.

The Relator's allegations concerning the false claims for Gleevac, Tasigna, and TOBI are comparable to the "vague and generalized" allegations found insufficient in *United States ex rel. Blundell v. Dialysis Clinic, Inc.*, No. 09 Civ. 710 (NAM/DEP), 2011 WL 167246 (N.D.N.Y. Jan. 19, 2011), a case discussed at length in *Novartis I*. *See* 2014 WL 2324465, at *22-23. The Relator merely alleges that the "false" claims include: "all claims for . . . Gleevec, Tasigna, [and] TOBI . . . that have been billed by a specialty pharmacy to Medicare, Medicaid or another government health care program during a period of time in which Novartis used entry into its exclusive specialty pharmacy distribution network, rebates or discounts, scorecarding and/or patient referrals to induce the billing pharmacy to recommend that patients start or continue on the Novartis drug." Compl. ¶ 128. Though this allegation makes clear which false claims are at issue—all claims for Novartis drugs submitted by each pharmacy during the kickback scheme—

the Relator does not provide any factual basis to support his assertion that Novartis actually caused any pharmacy to submit claims for Gleevac, Tasigna, or TOBI to the government.

These conclusory allegations are insufficient under Rule 9(b). Accordingly, Novartis's motion to dismiss Counts 1a and 1b is granted without prejudice as to the Relator's allegations concerning the Gleevac, Tasigna, and TOBI schemes.

2. Caremark and Curascript's Motions to Dismiss the Relator's Subsection (a)(1)(A) and (a)(1)(B) Claims are Granted; Accredo's Motion to Dismiss These Claims is Granted in Part and Denied in Part.

The Government's Complaint likewise does not help the Relator identify particular false claims submitted by the Pharmacy Defendants—Caremark, Accredo, and Curascript. None of these pharmacies is mentioned in the Government's Complaint. So the Relator must rely on the allegations in his Complaint alone to sustain the subsection (a)(1)(A) and (a)(1)(B) claims against these defendants.

The Relator alleges that all three Pharmacy Defendants participated in the Gleevac, Tasigna, and TOBI schemes. He also alleges that Accredo participated in the Exjade scheme.

As discussed above, *see supra* at § I.A.1, the Relator's allegations about the false claims for Gleevac, Tasigna, and TOBI that Novartis allegedly caused pharmacies to submit to the government are too conclusory and speculative to satisfy Rule 9(b). As these drugs are the only ones for which Caremark and Curascript allegedly submitted false claims, the allegations against these two defendants fail to satisfy Rule 9(b). Accordingly, Counts 1a and 1b are dismissed without prejudice as against Caremark and Curascript.

The Relator's Complaint also fails to identify particular claims submitted by Accredo for Gleevac, Tasigna, or TOBI. The Relator merely speculates that Accredo submitted claims for these drugs. Such conclusory allegations are insufficient under Rule 9(b).

However, the Relator provides additional support for his allegation that Accredo submitted false claims for Exjade to government programs. The Relator's Complaint asserts that Novartis maintained tracking spreadsheets for prescriptions "that contained specific information for each prescription, including date of first and last shipment, dispensing pharmacy and payer." Compl. at ¶ 129. The only spreadsheet that the Relator identifies is one dated February 25, 2011 that tracks Exjade prescriptions; he does not identify any spreadsheets tracking prescriptions for Myfortic, Gleevac, Tasigna, or TOBI. The Relator's Complaint describes eleven rows of the Exjade spreadsheet. One such description states: "in row 63, a prescription issued by a physician with Novartis ID 2019238 for a patient with Sickle Cell Disease, dispensed by Accredo and paid for by Nevada Medicaid." *Id.* at ¶ 130. Six of the eleven rows described in the Complaint include Exjade prescriptions allegedly filled by Accredo and billed to government programs, including Nevada Medicaid, New York Medicaid, Georgia Medicaid, Texas Medicaid, and Medicare Part D. *See id.*

These allegations sufficiently "identify particular false claims for payment that were submitted to the government" by Accredo for Exjade prescriptions. *Karvelas*, 360 F.3d at 232. The Complaint provide six examples of false claims and includes details such as the particular pharmacy billing the drug (Accredo), the particular drug billed (Exjade), an identifying number for the physician who prescribed the drug, the diagnosis of the patient, and, critically, the particular government programs that reimbursed Accredo for the prescriptions.

Accordingly, Accredo's motion to dismiss Counts 1a and 1b for lack of particularity is denied insofar as it concerns the Relator's allegations about the Exjade scheme; the motion is granted without prejudice as to the Gleevac, Tasigna, and TOBI schemes.

B. Subsection (a)(1)(C) Claim

Novartis and the Pharmacy Defendants also move to dismiss the Relator's subsection (a)(1)(C) claim (Count 1c) pursuant to Rule 9(b).

Subsection (a)(1)(C) provides for liability where the defendant "conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G)"—meaning conspires to commit a substantive FCA violation. 31 U.S.C. § 3729(a)(1)(C). To prove a claim under this subsection, a plaintiff must show: (1) an unlawful agreement by the defendant to violate the FCA, and (2) at least one overt act performed in furtherance of that agreement. *See U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 193 (5th Cir. 2009); *U.S. ex rel. Sterling v. Health Ins. Plan of Greater New York, Inc.*, No. 06 Civ. 1141 (PAC), 2008 WL 4449448, at *4 (S.D.N.Y. Sept. 30, 2008). Because conspiracy is an inchoate crime, the plaintiff need not prove that the defendant actually achieved the object of the conspiracy and completed a substantive FCA violation (such as the presentment of a false claim).

Since no false claim need have been submitted for subsection (a)(1)(C) liability to attach, no claim need be identified with particularity. The Defendants do not otherwise challenge the particularity of the Relator's allegations regarding the subsection (a)(1)(C) claim. Accordingly, the motions to dismiss for failure to plead fraud with particularity are denied as to Count 1c.

C. Subsection (a)(1)(G) Claim

The Pharmacy Defendants move to dismiss the Relator's subsection (a)(1)(G) claim (Count 1d) pursuant to Rule 9(b). The Relator does not assert this claim against Novartis.

Subsection (a)(1)(G) provides for liability where the defendant "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or 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). To prove a claim under this subsection, a plaintiff must show: (1) "proof that the defendant made a false record or statement" (2) at a time that the defendant had a presently-existing "obligation" to the government—"a duty to pay money or property." *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 473 (6th Cir. 2011); *see also Wood*, 328 Fed. App'x at 748.

Subsection (a)(1)(G) is referred to as the "reverse false claims" provision because "it covers claims of money *owed to* the government, rather than payments *made by* the government." *U.S. ex rel. Capella v. Norden Sys., Inc.*, No. 94 Civ. 2063, 2000 WL 1336487, at *10 (D. Conn. Aug. 24, 2000) (emphasis added). A plaintiff asserting a claim under this subsection need not prove that the defendant submitted a false claim for repayment. *See Chesbrough*, 655 F.3d at 473. So as with the subsection (a)(1)(C) claim, the Pharmacy Defendants' argument that the Relator failed to sufficiently plead the submission of claims does not apply to the subsection (a)(1)(G) claim.

As the Pharmacy Defendants make no other arguments in support of their motions to dismiss the subsection (a)(1)(G) claim for failure to plead fraud with particularity, their motions are denied as to Count 1d.

II. State Law Claims

Finally, Novartis and the Pharmacy Defendants move to dismiss the Relator's claims arising under the 27 state FCA analogues (Counts 2-28) pursuant to Rule 9(b). The Relator's Complaint asserts a claim under each of the state false claim statutes generally without identifying a particular subsection.

The heightened pleading standard of Rule 9(b) applies to state law fraud claims brought in federal court, including claims brought under state analogues of the FCA. *See Polansky*, 2009 WL 1456582, at *4.

The only argument that the Defendants make in support of their motions to dismiss these claims for lack of particularity is that the Relator fails to identify the claims submitted to state Medicaid programs with the requisite particularity.

As discussed above, *see supra* at §§ I.B, I.C, that argument supports dismissal of state FCA claims that actually require proof that a false claim was submitted to a state Medicaid program. It does not, however, support dismissal of claims under state law analogues of subsection (a)(1)(C) or subsection (a)(1)(G).

This Court is aware that many (if not all) of the state false claim statutes at issue in this case contain a conspiracy provision. Since the Relator would not need to prove the actual submission of a false claim in order to prove a conspiracy claim, the Defendants' arguments regarding the particularity of the pleadings do not apply to these claims. The state false claim statutes may also contain "reverse false claim" provisions and other subsections that likewise require no proof that a claim was actually submitted.

This Court will not do the Defendants' work for them and undertake to learn on its own the details of the 27 state false claim statutes at issue in this case. As the state false claim statutes are modeled on the federal statute, it is fair to assume that each statute contains at least one subsection (such as conspiracy) that does not require proof that a false claim was submitted to a state Medicaid program. Accordingly, dismissal of these state law claims for lack of particularity is not required.

The Defendants also argue that the Court should decline to exercise supplemental jurisdiction over the state FCA claims. As federal claims remain, this argument falls away.

The Defendants' motions to dismiss for failure to plead fraud with particularity are denied as to Counts 2-28.

CONCLUSION

For the foregoing reasons, Novartis's motion to dismiss the Relator's Complaint pursuant to Rule 9(b) is granted as to Counts 1a and 1b insofar as it concerns the alleged Gleevac, Tasigna, and TOBI schemes; it is otherwise denied. Accredo's motion to dismiss the Relator's Complaint is granted as to Counts 1a and 1b insofar as it concerns the alleged Gleevac, Tasigna, and TOBI schemes; it is otherwise denied. Caremark and Curascript's motions to dismiss the Relator's Complaint are granted as to Counts 1a and 1b; they are otherwise denied. The Clerk of the Court is directed to close out the motion at Docket Nos. 161, 165, and 166 and to remove same from the Court's list of pending motions.

Dated: June 10, 2014

U.S.D.J.

BY ECF TO ALL COUNSEL