IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES EX REL. JANICE KEEN,	)	
Plaintiff and Relator,	)	**No. 15 C 2309**
v.	)	**Judge Jorge L. Alonso**
TEVA PHARMACEUTICALS USA INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., CEPHALON, INC., AND TEVA SALES AND MARKETING, INC.,	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Relator, Janice Keen, brings this case on behalf of the United States under the False Claims Act, 31 U.S.C. §§ 3729 *et seq.*, against her employer, defendant Teva Pharmaceuticals USA, Inc., and other associated business entities (collectively, "defendants" or "Teva"). Defendants move to dismiss. For the following reasons, the motion is granted.

BACKGROUND

In 2005, relator began working for defendant Cephalon, Inc. ("Cephalon") as a pharmaceutical sales representative. Teva subsequently acquired Cephalon as a wholly-owned subsidiary in 2011.

As a sales representative for Cephalon and then Teva, relator participated in promoting, marketing, and selling Amrix, a prescription medicine used to treat muscle spasms. Relator alleges in her complaint that after Teva acquired Cephalon, it began to train its sales force to market Amrix in a deliberately misleading way by emphasizing visual aids and a simple "core

message"—"Amrix is the only once-daily extended release cyclobenzaprine"—without devoting sufficient attention to details critical to ensuring safe and effective use of Amrix.

In particular, relator alleges that Teva marketed Amrix "off-label," or for use in a manner for which it had not received regulatory approval. Relator contends that Teva's marketing tactics were misleading in four ways.

First, she alleges that Teva misleadingly promoted Amrix as not merely an "adjunct" to rest and physical therapy but as a treatment that was sufficient by itself to stop muscle spasms. Teva's promotional materials contained pictures of people engaged in strenuous activities, as if Amrix alone had enabled them to participate in those activities, and Teva instructed its salespeople to emphasize these visual aids in promoting Amrix. Additionally, it instructed salespeople to give iPad presentations, which allowed them to breeze through safety information that was difficult to see on the small iPad screens.

Second, relator alleges that Teva promoted Amrix beyond its approved use to treat "acute" cases on a short-term basis, *i.e.*, for periods of two to three weeks, by distributing co-pay coupons that patients most often used to obtain thirty doses of Amrix, or a month's supply. Additionally, Teva promoted Amrix to physicians who worked in pain clinics and predominantly treated patients with chronic pain, without warning these physicians that Amrix was approved for short-term use in acute, not chronic, cases.

Third, relator alleges that Teva misleadingly overstated the efficacy of Amrix by promoting it as a treatment that will allow patients to get back to their everyday activities, when in fact Amrix had not been shown to significantly expand the range of activities patients could engage in.

Fourth, relator alleges that Teva omitted from its promotion of Amrix the "fourth arm" of the Amrix study, which dealt with daytime drowsiness. Teva trained its sales force to use as a selling point the fact that fewer patients treated with Amrix reported extreme drowsiness than patients treated with generic, immediate-release cyclobenzaprine. However, the difference is only a few percentage points; 17-19% of Amrix patients reported extreme drowsiness, whereas 24% of generic cyclobenzaprine patients did. Relator alleges that Teva's sales presentations should have used the actual figures of the fourth arm of the Amrix study, rather than misleadingly citing facts without providing the proper context for understanding them.

Relator's amended complaint consists of four counts. In Count I, relator claims that Teva violated the False Claims Act, 31 U.S.C. § 3729(a)(1)(A) and (B), by knowingly causing physicians to prescribe Amrix in situations for which it was not approved for use, with the effect that pharmacies submitted false claims to United States government health care programs, such as Medicare and Medicaid, seeking payment for filling Amrix prescriptions.

In Count II, relator alleges that Teva's off-label marketing violated the terms of a Corporate Integrity Agreement ("CIA") that Cephalon entered into with the Office of Inspector General ("OIG") of the Department of Health and Human Services. The CIA required Teva to report and correct any "probable violation[s] of criminal, civil, or administrative laws applicable to any federal health care program and/or applicable to any FDA requirements relating to the promotion of Cephalon products," and it set out stipulated penalties for any breach. (Am. Compl. at ¶ 24, ECF No. 22.) Relator claims that Teva is liable under 31 U.S.C. § 3729(a)(1)(G) for failing to pay the stipulated penalties it owes under the CIA.

In Counts III and IV, relator makes similar claims under the Illinois and Indiana versions of the False Claims Act.

ANALYSIS

"A motion under Rule 12(b)(6) tests whether the complaint states a claim on which relief may be granted." *Richards v. Mitcheff*, 696 F.3d 635, 637 (7th Cir. 2012). Under Rule 8(a)(2), a complaint must include "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). The short and plain statement under Rule 8(a)(2) must "give the defendant fair notice of what the claim is and the grounds upon which it rests." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (ellipsis omitted).

Under federal notice-pleading standards, a complaint's "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555. Stated differently, "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) (quoting *Twombly*, 550 U.S. at 570). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id*. (citing *Twombly*, 550 U.S. at 556). "In reviewing the sufficiency of a complaint under the plausibility standard, [courts must] accept the well-pleaded facts in the complaint as true, but [they] 'need[ ] not accept as true legal conclusions, or threadbare recitals of the elements of a cause of action, supported by mere conclusory statements.'" *Alam v. Miller Brewing Co.*, 709 F.3d 662, 665-66 (7th Cir. 2013) (quoting *Brooks v. Ross*, 578 F.3d 574, 581 (7th Cir. 2009)).

Additionally, any claims asserted under the False Claims Act must comply with Federal Rule of Civil Procedure 9(b), which requires the pleading party to "state with particularity the circumstances constituting fraud." *United States ex rel. Presser v. Acacia Mental Health Clinic, LLC*, 836 F.3d 770, 775 (7th Cir. 2016). Although fraudulent or deceptive intent "may be

alleged generally," Rule 9(b) requires a plaintiff (or in this case, relator) to describe the "circumstances" of the alleged fraud with "particularity" by including such information as the "the identity of the person who made the misrepresentation, the time, place and content of the misrepresentation, and the method by which the misrepresentation was communicated," *Windy City Metal Fabricators & Supply, Inc. v. CIT Tech. Fin. Servs., Inc.*, 536 F.3d 663, 668 (7th Cir. 2008), or, to put it differently, by providing the "who, what, where, when and how" of the alleged fraudulent conduct. *See Bank of Am., Nat'l Ass'n, v. Knight*, 725 F.3d 815, 818 (7th Cir. 2013).

I. COUNT I—FALSE CLAIMS ACT, 31 U.S.C. § 3729(a)(1)(A) & (B), FALSE PRESENTMENT AND FALSE STATEMENTS

Congress originally enacted the False Claims Act ("FCA") in 1863 to address the problem of "fraud and price-gouging in Civil War defense contracts." *Cause of Action v. Chi. Transit Auth.*, 815 F.3d 267, 272 (7th Cir. 2016). "Since then, Congress has repeatedly amended the Act, but its focus remains on those who present or directly induce the submission of false or fraudulent claims." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1996 (2016).[1]

The FCA provides in part that anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" by the United States government, or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," is liable to the United States government for civil penalties and treble damages. 31 U.S.C. § 3729(a)(1)(A) and (B).

[1] The Attorney General has primary authority for enforcing the FCA, but the FCA also includes a "so-called *qui tam* provision, which permits a private party, known as a 'relator,' to bring a civil action alleging fraud against the Government on its own behalf as well as on behalf of the United States," if the Attorney General declines to bring an enforcement action himself. *Cause of Action*, 815 F.3d at 272; 31 U.S.C. § 3730(b). If the relator prevails, she receives a percentage of the recovery. 31 U.S.C. § 3730(d).

Teva contends that the claim under § 3729(a)(1)(A) and (B) in Count I of relator's complaint suffers from a number of pleading defects. First, Teva argues, relator fails to state a plausible claim for relief under any of her off-label marketing theories because each theory is facially contradictory, *i.e.*, the very promotional materials that relator claims support those theories actually undermine them.[2] Further, Teva argues that relator fails to connect any of her off-label-marketing theories to the actual submission of any false claims by way of specific allegations meeting the Rule 9(b) standard for particularity.

Regardless of whether the promotional materials could plausibly mislead anyone to prescribe or seek Amrix for off-label use, the absence of allegations specifically linking the allegedly misleading promotional materials or sales presentations to the actual submission of false claims is fatal to relator's claim. "The False Claims Act is not 'an all-purpose antifraud statute' or a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Escobar*, 136 S. Ct. at 2003 (quoting *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 672 (2008)). "The submission of a false claim is . . . the *sine qua non* of a False Claims Act violation," and a relator must allege the submission of false claims specifically and with particularity under Rule 9(b). *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311-12 (11th Cir. 2002); *see United States ex rel. Crews v. NCS Healthcare of Ill., Inc.*, 460 F.3d 853, 857 (7th Cir. 2006), *United States ex rel. Booker v. Pfizer, Inc.*, 9 F. Supp. 3d

[2] Specifically, relator alleges that Teva marketed Amrix as a treatment sufficient by itself to get patients back to their everyday activities, but Teva argues that some of the very promotional materials relator submits contradict her allegations by warning that Amrix is to be used as an adjunct to rest and physical therapy, and the mere fact that Teva's visual aids depict people engaged in strenuous activity does not undo these express warnings. Similarly, relator alleges that Teva marketed Amrix for chronic use, rather than temporary acute use, particularly by providing coupons that patients could use to obtain more than the approved two-to-three-week supply, but again, Teva argues, the materials relator submits show that Teva did warn that Amrix should be used only on a short-term basis, and in any case, the coupons specifically state that they cannot be used with government healthcare programs. Finally, relator alleges that Teva hid the chance of suffering daytime drowsiness as a side effect, but according to Teva, the promotional materials are actually consistent in this respect with the prescribing information Teva provided, which indeed describes daytime drowsiness as a side effect.

34, 53-54, 57-58 (D. Mass. 2014), *Mason v. Medline Indus., Inc.*, No. 07 C 5615, 2009 WL 1438096, at *4-7 (N.D. Ill. May 22, 2009) (citing *United States ex rel. Gross v. AIDS Research Alliance-Chicago*, 415 F.3d 601, 604-05 (7th Cir. 2005) and *United States ex rel. Garst v. Lockheed-Martin Corp.*, 328 F.3d 374, 377-78 (7th Cir. 2003)).

Relator does not meet her pleading burden because, at best, she describes only the "general subject" of Teva's alleged off-label marketing by alleging that Teva instructed its sales force to promote Amrix for off-label uses, without identifying particular sales representatives who made misleading statements or distributed misleading promotional materials to particular physicians, or without alleging exactly when or how any particular Teva sales representatives made contact with any particular physicians or what they said to them on particular occasions. *See United States v. Ortho-McNeil Pharm., Inc.*, No. 03 C 8239, 2007 WL 2091185, at *4 (N.D. Ill. July 20, 2007) (citing *Uni*Quality, Inc. v. Infotronx, Inc.*, 974 F.2d 918, 923 (7th Cir. 1992)). Relator need not "plead every false statement made by [Teva] or every false claim made," but she does not so much as "set forth the circumstances of any particular false statement or cite a single example of a false claim or a provider that made a false claim." *See Ortho-McNeil*, 2007 WL 20911856, at *4; *see also United States ex rel. Grenadyor v. Ukrainian Vill. Pharmacy, Inc.*, 772 F.3d 1102, 1107 (7th Cir. 2014) (relator who failed to provide a single specific example of any patients who allegedly received a kickback from the defendant pharmacy failed to comply with Rule 9(b)); *Booker*, 9 F. Supp. 3d at 50, 58 (relators failed to meet the Rule 9(b) standard with respect to claims of "off-label uses as to which Relators could not even allege the simple fact that physicians were actually writing prescriptions for those uses").[3] If relator has "direct

[3] Relator does allege that, according to an email she submitted as Exhibit 11 to her original complaint, Teva was aware that at least a small percentage of the Amrix co-pay coupons it had distributed were being redeemed by patients without insurance coverage, and it was also aware that many of the coupons it had distributed were being redeemed to obtain supplies of Amrix in excess of the 21 daily doses for which Amrix had been approved. Even if

knowledge that sales representatives caused physicians to submit claims based on prescriptions of [Amrix] for non-FDA approved uses, [s]he must allege specifically the 'who, what, when, where, and how' of the false statements and false claims." *See Ortho-McNeil*, 2007 WL 20911856, at *5. Without at least "concrete examples of false statements and false claims," she fails to meet the standard set by Rule 9(b). *See id.*; *see also Mason v. Medline Indus.*, 731 F. Supp. 2d 730, 735 (N.D. Ill. 2010) ("A plaintiff who pleads a fraudulent scheme involving numerous transactions over a period of years need not plead specifics with respect to every instance of fraud, but he must at least provide representative examples.").

Relator's allegations focus on the training and instruction Teva gave to its sales force. At most, relator alleges that Teva encouraged its salespeople to promote its products off label,[4] but to state a claim under the FCA she must go farther and describe with particularity how, as a consequence of Teva's marketing effort, false claims were submitted to the government. By failing to allege that any allegedly off-label marketing actually caused any particular physician to prescribe Amrix for off-label use or that, as a result of some such prescriptions, a particular pharmacy actually dispensed Amrix to a patient and submitted a false claim for payment to a government payor, she fails to state a plausible, non-speculative claim with particularity.

Relator argues that she cannot meet the Rule 9(b) standard for particularity in this case because, as in *United States ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 854-55 (7th Cir. 2009), in which the relator was a non-financial employee who lacked access to the invoices the

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this is a fair reading of the email, which is unclear on its face because it consists of tables of figures without the context or explanation necessary to interpret them, it does not amount to a plausible allegation that Teva's off-label marketing (as opposed to some other cause) actually caused physicians to prescribe Amrix for longer periods than 21 days, and more importantly, that those prescriptions resulted in false claims for payment to the government. At best, these are allegations that it is at least possible that false claims were submitted to the government, without rising above the speculative level, or meeting the Rule 9(b) standard for particularity. *Crews*, 460 F.3d at 857.

[4] Even that is a generous interpretation of her allegations. Teva persuasively argues that relator does not plausibly allege that Teva's marketing was off-label at all, as described above in note 2. Nevertheless, for purposes of the present motion, the Court assumes that Teva encouraged its salespeople to promote off-label use of Amrix.

defendant had submitted to the government, she lacks access to the necessary payment information, which is in the possession of Teva and various third-party physicians and pharmacies. But in *United States ex rel. McGinnis v. OSF Healthcare Sys.*, No. 11-CV-1392, 2014 WL 2960344, at *8 (C.D. Ill. July 1, 2014), the court rejected a similar argument under similar circumstances, distinguishing *Lusby* because "[t]he complaint in *Lusby* did not leave the court to speculate on whether claims were ever submitted." In *Lusby*, "the relator did not possess an actual bill or invoice, but he alleged specific [goods], dates, and details of payment in his complaint. In short, the relator provided specific factual allegations concerning how the defendant submitted false claims to the government." *McGinnis*, 2014 WL 2960344, at *8 (citing *Lusby*, 570 F.3d at 853-54). In *McGinnis*, by contrast, the relator provided no such details about any specific false claims submitted to the government. This case is similar in that respect, and the Court is persuaded by *McGinnis*'s reasoning. *See also United States ex rel. Walner v. NorthShore Univ. Healthsystem*, 660 F. Supp. 2d 891, 898 (N.D. Ill. 2009).

Relator attempts to save her claims by citing the "implied certification" doctrine, which the United States Supreme Court recently held "can be a basis for liability, at least where two conditions are satisfied: first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *Escobar*, 136 S. Ct. at 2001. But changing the theory of falsity does not change the fact that relator has not alleged with the requisite particularity that Teva caused the submission of false claims or made false statements or records material to false claims submitted to the government. Count I must be dismissed.

II. COUNT II—FALSE CLAIMS ACT, 31 U.S.C. § 3729(a)(1)(G), REVERSE FALSE CLAIMS

Under the FCA, anyone who "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," is liable to the United States government for civil penalties and treble damages. 31 U.S.C. § 3729(a)(1)(G). In Count II, relator claims that Teva made "reverse false claims" by failing to report to the government its unlawful promotion of its products, in breach of its CIA with the OIG, and failing to pay to the government the stipulated penalties its breaches triggered under the CIA, *i.e.* "avoid[ing its] obligation to pay or transmit money . . . to the Government" in violation of § 3729(a)(1)(G).

Teva argues that relator fails to plausibly allege any underlying violations of the CIA that would trigger its reporting obligation, so she cannot prevail on her claim that Teva defrauded the government by failing to pay stipulated penalties for committing those violations. Further, Teva argues that even if relator did sufficiently allege underlying violations of the CIA, she fails to allege that Teva actually owes stipulated penalties because OIG never exercised its discretion to seek them.

Even assuming that relator has adequately alleged that Teva engaged in any improper marketing that might have been reportable under the CIA as "a probable violation of criminal, civil, or administrative laws," the Court agrees with Teva that it did not have an "obligation," within the meaning of § 3729(a)(1)(G) of the FCA, to pay stipulated penalties for any such marketing unless and until OIG exercised its discretion to seek them. In support of its position, Teva cites *Booker*, in which the court concluded that a CIA with similar language did not impose on the defendant an "obligation" to pay the government because it provided only that "failure to

comply '*may* lead to the imposition' of the Stipulated Penalties *if the OIG* '*determin[ed] that Stipulated Penalties are appropriate*.'" 9 F. Supp. 3d at 49 (emphasis added). The CIA imposed a reporting obligation, but it did not impose a payment obligation arising "merely upon occurrence of reportable events." *Id.* at 50. The payment obligation arose only "upon OIG's decision to assess the stipulated penalties." *Id.* The defendant's obligation to pay stipulated penalties "depend[ed] on intervening discretionary government acts," and until the government performed those discretionary acts, there was no "obligation" to "avoid" within the meaning of § 3729(a)(1)(G). *Id.* at 49-50.

Relator concedes that *Booker* is directly on point and "squarely against Relator's position," but it is not binding on this Court, and relator argues that this Court should decline to follow it. Instead, relator argues, the Court should follow *United States ex rel. Boise v. Cephalon, Inc.*, No. CIV.A. 08-287, 2015 WL 4461793, at *5-7 (E.D. Pa. July 21, 2015), which, incidentally, involves the same CIA between Cephalon and the OIG that relator invokes in this case. In *Boise*, the court rejected *Booker*'s analysis, reasoning that the mere fact that the government had not yet demanded payment of stipulated penalties did not mean the stipulated penalties were not an "obligation" the defendant had tried to avoid; to so hold would be essentially to hold that a party to a contract had no obligation to perform until the other party sued for breach. *Id.*

The *Boise* reasoning is insufficiently attentive to the language of the CIA, which appears to be intentionally structured to give Teva an obligation first to report potentially unlawful conduct in order to give OIG an opportunity to "determine" whether it is "appropriate," under the circumstances, to seek stipulated penalties. Presumably, if the parties to the CIA intended to impose on Teva an immediate obligation to pay stipulated penalties for any unlawful marketing,

the CIA would not have included the language about "determining" whether the stipulated penalties are "appropriate." As *Booker* recognized, some reverse false claims cases do involve contracts that impose "clear obligations to pay money or transmit government" immediately upon the occurrence of certain conditions. 9 F. Supp. 3d at 50 (citing *United States ex rel. Matheny v. Medco Health Sols., Inc.*, 671 F.3d 1217 (11th Cir. 2012) (pharmaceutical company was contractually obligated to return government overpayments) and *United States v. Penco Aeroplex, Inc.*, 195 F.3d 1234, 1237 (11th Cir. 1999) (government contractor was contractually obligated to dispose of excess government property in its possession by returning or purchasing it)). There was no such clear obligation in this case. Even if Teva had reported its marketing practices as potentially unlawful, it is unclear whether it would ever have had to pay anything to OIG.

Boise relied heavily on *United States ex rel. Landis v. Tailwind Sports Corp.*, 51 F. Supp. 3d 9, 55-60 (D.D.C. 2014), but importantly, the *Landis* court has since reversed itself, recognizing that its earlier decision suffered from a "basic oversight": "its failure to distinguish between legal instruments that actually create an obligation and those that condition indebtedness on the exercise of governmental discretion." *See United States ex rel. Landis v. Tailwind Sports Corp.*, 160 F. Supp. 3d 253, 271 (D.D.C. 2016). The same flaw runs through the decisions that have relied on it, including *Boise*.

Teva had no "obligation" to pay stipulated penalties under the CIA because OIG did not exercise its discretion to impose them, regardless of whether Teva engaged in unlawful promotion. Relator does not meet her pleading burden in Count II, which is dismissed.

III. COUNTS III AND IV—STATE LAW CLAIMS

Because relator's federal claims are dismissed, the Court declines to exercise jurisdiction over her state law claims. Counts III and IV are dismissed.

CONCLUSION

For the reasons set forth above, the Court grants Teva's motion to dismiss [27]. The complaint is dismissed without prejudice. Status hearing remains set for January 10, 2017, at 9:30 a.m.

SO ORDERED.

ENTERED: January 4, 2017

HON. JORGE L. ALONSO
United States District Judge