IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA ex rel. BRUCE BOISE, et al.	:	CIVIL ACTION NO. 08-287
v.	:	
CEPHALON, INC., et al.	:	
O'NEILL, J.	:	April 15, 2015

MEMORANDUM

Plaintiffs Bruce Boise, Keith Dufour and Andrew Augustine bring this action against defendants Cephalon, Inc. and John Does #1-100 to recover damages and civil penalties on behalf of the United States as qui tam relators pursuant to the False Claims Act (FCA), 31 U.S.C. §§ 3729, et seq. and analogous state laws. Now before me are Cephalon's motion to dismiss relators' second amended complaint pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b) (Dkt. No. 105), relators' response (Dkt. No. 108) and Cephalon's reply (Dkt. No. 109). For the reasons set forth below, I will grant Cephalon's motion in part and deny it in part.

BACKGROUND

Relators are former employees of Cephalon, which is a pharmaceutical company. See Dkt. No. 69 at ¶¶ 26, 20-25. Relator Boise filed the original complaint in this action on January 3, 2008 and an amended complaint on January 10, 2010. See Dkt. Nos. 1, 14. On February 28, 2014, Boise filed a second amended complaint adding relators Dufour and Augustine. See Dkt. No. 69.

Relators allege that Cephalon submitted or caused the submission of false claims for reimbursement from federal health programs for prescriptions of the drugs Provigil and Nuvigil

in violation of various provisions of the FCA and analogous state laws. Id. at ¶ 1. I will briefly summarize relators' allegations.

I. Off-Label Promotion Allegations

Provigil is a medication approved by the FDA to improve wakefulness in adult patients with excessive sleepiness associated with obstructive sleep apnea/hypopnea syndrome, narcolepsy and shift work sleep disorder. Id. at ¶ 3. Nuvigil is a successor drug to Provigil that the FDA approved for the same uses in June 2007. Relators allege that after December 31, 2006 Cephalon began promoting Provigil off-label, meaning for non-FDA approved uses. Id. at ¶ 5. Relators claim that Cephalon has promoted Nuvigil off-label since its launch in June 2009. Id. at ¶ 6.

Relators allege that Cephalon promoted Provigil and Nuvigil off-label by (1) targeting physicians who did not prescribe the medications for on-label uses, id. at ¶¶ 103-119, (2) promoting the medications to treat specific conditions off-label such as ADHD, Multiple Sclerosis, Schizophrenia, Parkinson's Disease, Jet Lag and Depression, id. at ¶¶ 120-90, (3) setting quota and bonus programs that necessitated off-label marketing by Cephalon's sales force, id. at ¶¶ 240-246, (4) utilizing speaker programs and round-table discussions to promote the medications off-label, id. at ¶¶ 191-205, and (5) minimizing safety risks associated with off-label use of the medications. Id. at ¶¶ 206-223.

First, Cephalon allegedly targeted specific physicians, such as Dr. Siraj Siddiqui, who only prescribed Provigil and Nuvigil for off-label uses and refused to remove those physicians from marketing lists. Id. at ¶ 115. For example, relators allege that "Cephalon insisted Dr. [Bharat C.] Shah remain a targeted physician" on relator Augustine's marketing call lists despite

a Cephalon District Manager's knowledge that Dr. Shah did not use Provigil for any on-label use. Id. at ¶ 118.

Second, relators allege that Cephalon targeted specific conditions for off-label promotion of Provigil and Nuvigil. For example, despite Provigil and Nuvigil allegedly never being approved for pediatric use in any circumstance, id. at ¶ 121, relators allege that "beginning from at least 2007, sales representatives were compensated based on the number of Provigil prescriptions that were written in their territories by pediatricians and child psychiatrists to treat ADHD." Id. at ¶ 130. Relators identify specific child psychiatrists targeted for promotion of Provigil and Nuvigil for off-label use in children suffering from ADHD and the percentage of their patients who utilized government health benefits. Id. at ¶ 132.

Third, relators allege that Cephalon structured its sales compensation and quota programs to compel its sales force to promote Provigil and Nuvigil off-label. Id. at ¶ 240. For example, "prescribers Cephalon included in its quota and bonus programs were doctors who would not normally treat patients with both Provigil and Nuvigil's limited approved indications." Id. at ¶ 242. Cephalon also allegedly increased quotas and decreased effective sales staff to a point that "required the promotion of the drug for off-label sales in order to meet [ ] sales objectives." Id. at ¶ 246.

Fourth, relators allege that Cephalon sponsored speaker programs and roundtable discussions to promote Provigil and Nuvigil off-label. While relators acknowledge that at these events speakers "may answer questions about unapproved drug uses so long as the questions posed by the audience are unsolicited" they also contend that "Cephalon instructed its sales representatives to prompt off-label discussions upon completion of the original speaker presentation." Id. at ¶¶ 192, 196. For example, relators assert that at a Cephalon sponsored

speaker event, relator Dufour "followed the training he had received from Cephalon and encouraged Dr. Duffourc [the attendee] to ask Dr. Brown [the speaker] about his experiences prescribing Provigil off-label." Id. at ¶ 196.

Relators also identify speakers Cephalon paid to promote Provigil and Nuvigil off-label by name, in some cases allege the amounts paid to them, id. at ¶ 199, and even assert that Cephalon "measure[d] the effectiveness of its off-label promotional speaker programs through LaunchTrack" which is a computer program that monitored "a promotional speaker's 'effectiveness' as observed through increases in the prescribing habits of the physicians who attended such programs." Id. at ¶ 200. Relators' allegations of off-label promotion at round-table discussions are specific, for example describing the year, location, doctors in attendance and off-label uses that were discussed. Id. at ¶ 204. Relators allege that attendees at these roundtable events were selected based on their potential to prescribe large amounts of Cephalon medications off-label. Id. at ¶ 203.

Fifth, relators allege that Cephalon promoted Provigil and Nuvigil off-label by intentionally minimizing safety risks associated with off-label use of the medications and that Cephalon ignored adverse events. In particular, relators allege that Cephalon misrepresented the underlying scientific data which supported switching patients from Provigil to Nuvigil despite alleged indications that there were safety risks associated with that switch. Id. ¶ 214-218. Indeed, relators state that relator "Augustine was aware of at least three instances in which patients were treated in hospital emergency rooms as the result of being switched from Provigil to Nuvigil" and that when "Cephalon did not change its marketing campaign for Nuvigil, which continued to focus on conversion, Augustine left his employment with the company." Id. at ¶ 221.

II. Kickback Allegations

Relators allege that Cephalon employed two kickback schemes in order to induce prescriptions of Provigil and Nuvigil. First, relators assert that Cephalon paid "key physicians by keeping more than 100 of them on its speakers' payroll" even when the majority of them were not sent out as promotional speakers. Id. at ¶ 248. Relators contend that these payments "caused the speakers to prescribe and recommend that other physicians prescribe its products for use in off-label treatments . . . ." Id. at ¶ 249.

In a slight variation on this scheme, relators allege that Cephalon rewarded physicians who prescribed large amounts of Provigil or Nuvigil off-label by appointing and paying them substantial fees as promotional speakers. For example, relators assert that "Dr. Anil Parikh, a psychiatrist from Akron, Ohio, was paid $1,500 per program to be a promotional speaker based solely on the fact that he prescribed large quantities of Provigil and Nuvigil . . . written for off-label uses, including for fatigue associated with depression." Id. at ¶ 197. Relators identify Dr. Tim Brown and Dr. Earl Bowie as speakers who were specifically "paid to participate in numerous speaker programs as a reward for prescribing Provigil and, later, Nuvigil." Id. at ¶ 199. Relators also allege that roundtable discussions functioned as kickbacks since Cephalon provided doctors honoraria and expensive meals. Id. at ¶ 202.

Second, relators contend that Cephalon provided physicians with front office "personnel in the form of Cephalon sales representatives who were instructed to provide free services to ensure that the physicians obtained reimbursement from Medicare and Medicaid without having to pay their own staff to perform the work." Id. at ¶ 251. In this way, relators allege that Cephalon relieved some of the burden that providers encountered in obtaining reimbursement

from government programs for off-label prescription of Provigil and Nuvigil. Id. Relators claim these free reimbursement services constituted illegal kickbacks. Id. at ¶¶ 254-55.

Relators allege that Cephalon has violated the FCA by providing free prior authorization services to physicians. Prior authorization

> refers to the process of obtaining prior approval from a private or public third-party prescription insurer about the correctness, suitability, and coverage of a service or medication that allows a physician, as well as the patient, to thus know in advance about whether a procedure, treatment, or service will be covered under his or her health plan.

Id. at ¶ 224. Relators contend that Cephalon was faced with payer "resistance to reimbursing for many of its drugs for off-label uses" and so it "paid doctors to facilitate falsified prior authorization requests in order to obtain reimbursement." Id. at ¶ 225. Those payments were allegedly made in the form of free reimbursement services provided by Cephalon, where "at the instruction of their managers, sales representatives [ ] (1) induced physicians and staff to complete prior authorization requests; (2) coached physicians and staff on language, often false, to include in prior authorization requests; and (3) themselves completed and submitted prior authorization requests, including by reviewing patient files." Id. at ¶ 235. Thus, relators assert that Cephalon helped submit false claims to the government because it "employed its nonmedically trained employees to complete the reasons on the requests why patients require its particular drugs." Id. at ¶ 225. Specifically, relators allege that relator Dufour was expected to assist an otolaryngologist named Dr. Bowie with prior authorizations and that Dufour worked with Bowie's office manager to ensure prior authorizations submitted for Provigil and Nuvigil were successful. Id. at ¶ 238.

IV. Corporate Integrity Agreement Allegations

In 2008 Cephalon entered into a Corporate Integrity Agreement (CIA) with the Office of the Inspector General (OIG) of the Department of Health and Human Services. Relators allege that by failing to report its alleged off-label promotion and payment of illegal kickbacks, Cephalon "engaged in a deliberate plan to knowingly submit false reports to the OIG—as required per the terms of the CIA—that either materially misrepresented the facts concerning its illegal conduct or concealed such conduct altogether" and thus "improperly avoided or decreased an obligation to pay or transmit money or property to the Government." Id. at ¶ 386.

V. Conspiracy Allegations

Cephalon and Takeda Pharmaceuticals entered into a co-promotion agreement lasting from June 12, 2006 until November 1, 2008. Id. at ¶ 450. Relators claim that Cephalon conspired with Takeda to promote Provigil off-label. Cephalon allegedly trained Takeda sales representatives to market Provigil off-label, shared Provigil speakers that promoted off-label with Takeda and directed which physicians Takeda sales representatives should target. Id.

STANDARD OF REVIEW

I. Rule 12(b)(6)

Federal Rule of Civil Procedure 12(b)(6) permits a court to dismiss all or part of an action for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). Typically, "a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations," though plaintiff's obligation to state the grounds of entitlement to relief "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007). "Factual allegations must be enough to raise a right to relief above the speculative level . . . on the

assumption that all of the allegations in the complaint are true (even if doubtful in fact)." Id. (citations omitted). This "simply calls for enough fact[s] to raise a reasonable expectation that discovery will reveal evidence of" the necessary element. Id. at 556. The Court of Appeals has made clear that after Ashcroft v. Iqbal, 556 U.S. 662 (2009), "conclusory or 'bare-bones' allegations will no longer survive a motion to dismiss: 'threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.' To prevent dismissal, all civil complaints must now set out 'sufficient factual matter' to show that the claim is facially plausible." Fowler v. UPMC Shadyside, 578 F.3d 203, 210 (3d Cir. 2009), quoting Iqbal, 556 U.S. at 678. The Court also set forth a two part-analysis for reviewing motions to dismiss in light of Twombly and Iqbal:

> First, the factual and legal elements of a claim should be separated. The District Court must accept all of the complaint's well-pleaded facts as true, but may disregard any legal conclusions. Second, a District Court must then determine whether the facts alleged in the complaint are sufficient to show that the plaintiff has a "plausible claim for relief."

Id. at 210-11, quoting Iqbal, 556 U.S. at 679. The Court explained, "a complaint must do more than allege the plaintiff's entitlement to relief. A complaint has to 'show' such an entitlement with its facts." Id., citing Phillips v. Cnty. of Allegheny, 515 F.3d 224, 234-35 (3d Cir. 2008). "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged–but it has not 'show[n]'–'that the pleader is entitled to relief.'" Iqbal, 556 U.S. at 679, quoting Fed. R. Civ. P. 8(a)(2).

II. Rule 9(b)

Rule 9(b) of the Federal Rules of Civil Procedure provides that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.

Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). "FCA claims must be pleaded with particularity in accordance with [Rule] 9(b)." U.S. ex rel. Schmidt v. Zimmer, Inc., 386 F.3d 235, 242 n.9 (3d Cir. 2004). The Court of Appeals has elaborated that "Rule 9(b) requires plaintiffs to plead with particularity the 'circumstances' of the alleged fraud in order to place the defendants on notice of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges of immoral and fraudulent behavior." Seville Indus. Mach. Corp. v. Southmost Mach. Corp., 742 F.2d 786, 791 (3d Cir. 1984). Thus, "the purpose of Rule 9(b) is to provide defendants with fair notice of the plaintiffs' claims . . . ." Foglia v. Renal Ventures Mgmt., LLC, 754 F.3d 153, 156 (3d Cir. 2014) (internal citations omitted) (adopting a more lenient pleading requirement for false claims actions under 9(b) because the touchstone consideration is fair notice).

DISCUSSION

Plaintiffs have filed this action as qui tam relators under 31 U.S.C. § 3730(b), which provides that a private person may bring an action on behalf of the government to enforce the FCA. "On May 20, 2009, Congress enacted the Fraud Enforcement and Recovery Act of 2009" (FERA), which amended the FCA. Foglia v. Renal Ventures Mgmt., LLC, 830 F. Supp. 2d 8, 15 (D.N.J. 2011). Relators allege violations of § 3729(a)(1)(A)[1] for presenting or causing the submission of false claims, § 3729(a)(1)(B)[2] for making or using a false record or statement to

[1] Relators state they allege violations of 31 U.S.C. § 3729(a)(1) to the extent wrongdoing occurred prior to May 20, 2009. See Dkt. No. 69 at ECF 145 n.1. "Neither party addresses" the separate versions of the statute or how they might affect my analysis here. Foglia v. Renal Ventures Mgmt., LLC, 830 F. Supp. 2d 8, 15 (D.N.J. 2011).

[2] Relators state that they allege violations of 31 U.S.C. § 3729(a)(2) to the extent wrongdoing occurred prior to May 20, 2009. See Dkt. No. 69 at ECF 146 n.2. "Neither party addresses" the separate versions of the statute or how they might affect my analysis here. Foglia, 830 F. Supp. 2d at 15.

cause the submission of false claims, § 3729(a)(1)(C)[3] for conspiracy and § 3729(a)(1)(G)[4] for avoiding or decreasing an obligation to pay the government and bring claims under analogous state laws. Cephalon moves to dismiss relators' claims for failure to plead fraud with particularity under Rule 9(b) and for failure to state a claim under Rule 12(b)(6).

I. Off-Label Promotion Claims under § 3729(a)(1)(A) and § 3729(a)(1)(B)

First, Cephalon argues that relators have not sufficiently pled that Cephalon ever promoted Provigil or Nuvigil off-label. Second, Cephalon argues that under Foglia relators fail to adequately plead that false claims involving Provigil or Nuvigil were actually submitted to the government.

Section 3729(a)(1)(A) gives rise to liability where one "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" by the government. 31 U.S.C. § 3729(a)(1)(A). Thus, the elements of a prima facie claim under § 3729(a)(1)(A) are: "(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent." U.S. ex rel. Schmidt v. Zimmer, Inc., 386 F.3d 235, 242 (3d Cir. 2004) (citations omitted) (discussing pre-FERA provision). Section 3729(a)(1)(B) gives rise to liability where one "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim" from the government. 31 U.S.C. § 3729(a)(1)(B). Thus, under § 3729(a)(1)(B) a plaintiff must allege that the "defendant made or used (or caused someone else to make or use) a false record in order to cause the false claim to be actually paid or approved." Schmidt, 386 F.3d at 242 (discussing pre-FERA provision).

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[3] Relators state that they allege violations of 31 U.S.C. § 3729(a)(3) to the extent wrongdoing occurred prior to May 20, 2009. See Dkt. No. 69 at ECF 146 n.3.

[4] Relators state that they allege violations of 31 U.S.C. § 3729(a)(7) to the extent wrongdoing occurred prior to May 20, 2009. See Dkt. No. 69 at ECF 147 n.4.

The Court of Appeals has held that in order to satisfy the particularity standard under Rule 9(b), a plaintiff bringing an FCA claim does not have to allege that actual submission of a false claim occurred but must only "provide particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." Foglia, 754 F.3d at 157-58 (citations omitted). Thus, the standard is two-fold: to satisfy Rule 9(b) first relators must allege particular details of a scheme to submit false claims and second must provide reliable indicia that lead to a strong inference the scheme caused claims to be actually submitted for reimbursement by government health programs. Additionally, because I find that relators "provided sufficient facts to meet the requirements under Rule 9(b)" with regard to their off-label and kickback claims, they have "therefore also met the requirements to state a claim under 12(b)(6)." Foglia, 754 F.3d at 158.

A. Sufficiency of Allegations of Off-Label Promotion

1. Relators' Off-Label Promotion Scheme Allegations

First, Cephalon contends that relators' second amended complaint is carefully worded to avoid alleging that relators themselves actually promoted either Provigil or Nuvigil to doctors for an off-label as opposed to an on-label use. For example, when discussing the use of Provigil and Nuvigil for the off-label treatment of schizophrenia, the second amended complaint alleges that:

> Despite the force of contrary evidence, Cephalon's sales representatives were instructed to use misleading clinical evidence to promote Nuvigil as effective for patients suffering from various conditions associated with schizophrenia. Following December 31, 2006, the sales force was instructed to target numerous physicians who the company knew would not use the drugs on-label. Those physicians to whom Relators Dufour and Augustine (as they had been trained to do by the company) promoted Provigil after December 31, 2006 and later Nuvigil include: [list of doctors by name, location, specialty and percentage of Medicare/Medicaid beneficiary patients]."

Dkt. No. 69 at ¶ 163. The Court acknowledges that the sentence addressing Dufour and Augustine's promotion activities stating they promoted Provigil and Nuvigil "as they had been trained to do" creates some ambiguity as to whether Dufour and Augustine actually promoted the drugs off-label or simply visited those doctors and conveyed information regarding on-label use. At the pleading stage, even with that somewhat ambiguous wording, given the specificity of the context of the alleged off-label promotion including the doctors' names, relators' allegations are sufficient to put Cephalon on notice of the claims against it. Foglia, 754 F.3d at 156. Additionally, the paragraph excerpted above clearly states that Cephalon instructed its representatives to use "misleading clinical evidence" to promote Nuvigil for an off-label use and thus relators' allegation they promoted Nuvigil "as they had been trained to do" logically refers to those instructions. Dkt. No. 69 at ¶ 163.

At least once, however, the second amended complaint does not employ that somewhat ambiguous wording—when it alleges that Augustine and Dufour visited specific doctors to promote Provigil and Nuvigil "for the treatment of Parkinson's-associated fatigue" which is allegedly an off-label use. Id. at ¶ 171. Additionally, relators employ the more ambiguous wording in the context of other allegations that are clearly well-pled examples of off-label use. For example, regarding off-label promotion of Provigil and Nuvigil for treatment of ADHD among adolescents, relators specify that they themselves promoted Provigil and Nuvigil to child psychiatrists. Id. at ¶ 132. Promotion of Provigil and Nuvigil for adolescent ADHD was allegedly "doubly off-label—lacking approval for both the conditions themselves as well as the pediatric patient population in which Cephalon promoted them." Id. at ¶ 121. Although relators only state they promoted Provigil and Nuvigil for ADHD "as they had been trained to do," by

specifying they promoted to doctors who are child psychiatrists they have clearly alleged promotion activities related to an off-label patient population. Id. at ¶ 132.

Second, Cephalon contends that it is legal for a speaker to respond to questions from the audience about the off-label use of a medication because that does not constitute off-label promotion. Thus, Cephalon argues that absent more detailed allegations that off-label discussions were not initiated by Cephalon sponsored speakers themselves, relators have not adequately alleged off-label promotion occurred at speaker events.

Relators allege specifically that "Cephalon instructed its sales representatives to prompt off-label discussions upon completion of the original speaker presentation." Id. at ¶ 196. Even more specifically, relators allege that when relator Dufour was approached by Dr. Duffourc about potential off-label uses of Provigil, Dufour "followed the training he had received from Cephalon and encouraged Dr. Duffourc to ask [the presenter] about his experiences prescribing Provigil off-label." Id. While this may be a more nuanced allegation of Cephalon's initiation of off-label promotion by its speakers, given the particularity of the allegation I find there is fair notice under Rule 9(b) of relators' claim that such interactions constituted the initiation of off-label promotion by Cephalon.

Relators also make other allegations regarding off-label discussions that state the specific presenters, attendees and locations of roundtable discussions in which off-label promotion allegedly occurred. For example, relators allege that "Dr. Stephen Ellen . . . gave dozens of Provigil and Nuvigil speaker programs, including for a wide variety of off-label uses." Id. at ¶ 199. In particular, "in 2009, Dr. Ellen led a physician round table funded by a Cephalon grant at La Provence, an upscale French restaurant in Lacombe, Louisiana. The other doctors in attendance were Dr. Geraldine Payne (a psychiatrist from Mandeville, Louisiana), Dr. Tim

Brown (a child psychiatrist from Covington, Louisiana) and Dr. Rene Duffourc (psychiatrist from New Orleans, Louisiana). The presentation discussed the off-label uses of Provigil, including for the treatment of depression." Id. at ¶ 204. Relators have alleged the particular speakers, attendees, locations, and off-label subject matter as part of their off-label promotion allegations. These allegations are sufficiently particular under Rule 9(b) to put Cephalon on notice of the circumstances of its allegedly fraudulent conduct.

2. Sufficiency of Allegations of Actual Submission

Cephalon contends that relators have not provided "reliable indicia that lead to a strong inference that claims were actually submitted" as a result of Cephalon's alleged off-label promotion scheme. Foglia, 754 F.3d at 156. The second amended complaint contains specific allegations, however, about how Cephalon "was able to measure the effectiveness of its off-label promotional speaker programs through LaunchTrack—a spreadsheet that contained weekly prescribing data for each physician appearing on a sales representative's call list" in order to track "increases in the prescribing habits of the physicians who attended" its speaker programs. Dkt. No. 69 at ¶ 200. Relators specifically allege that Dr. Chevies Newman moved from prescribing almost no Provigil to "writing 50 to 60 Provigil prescriptions a month primarily for the treatment of depression, an approximate 20-fold increase" after attending a Cephalon sponsored presentation by Dr. Ellen in which off-label uses of Provigil were discussed. Id. at ¶ 201. Relators also contend that the "majority of these Provigil prescriptions were written for Medicare and Medicaid patients." Id.

In other areas of the second amended complaint, relators not only allege off-label promotion to specific doctors, but also the percentage of patients those doctors see using government funded health programs. See, e.g., id. at ¶¶ 132, 189. Relators also allege causation

regarding specific doctors with particularity, for example in the case of ADHD relators state that "each of these physicians began prescribing Provigil (and later Nuvigil) to treat their Medicare and Medicaid patients suffering from ADHD" as a result of sales visits by relators themselves. Id. at ¶ 133. Relators allege specific activities, such as prior authorization assistance and the use of LaunchTrack, that are reliable indicia Cephalon took steps to ensure claims for off-label uses of Provigil and Nuvigil were successfully submitted. Id. at ¶¶ 200, 225, 238. Taken together, these allegations are reliable indicia that lead to a strong inference claims were actually submitted for reimbursement as a result of Cephalon's alleged off-label promotion scheme. See Foglia, 754 F.3d at 157-58.

Thus, I will deny Cephalon's motion to dismiss relators' FCA claims premised on allegations of Cephalon's off-label promotion of Provigil and Nuvigil.

B. Sufficiency of Kickback Allegations

Relators allege that Cephalon provided kickbacks in the form of (1) speaker fees and (2) free reimbursement services in order to induce off-label prescriptions of Provigil and Nuvigil, which were "false [claims] because they were tainted by the underlying kickback, which rendered the claims ineligible for reimbursement." Dkt. No. 69 at ¶ 249. The Anti-Kickback Act (AKA) provides in relevant part:

> (2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320(a)-7(b)(2). "'[F]alsely certifying compliance with the . . . Anti–Kickback Act[ ] in connection with a claim submitted to a federally funded insurance program is actionable under the FCA,' and can stand upon a theory of implied false certification." U.S. ex rel. Bergman v. Abbot Labs., 995 F. Supp. 2d 357, 373 (E.D. Pa. 2014), citing U.S. ex rel. Wilkins v. United Health Grp., Inc., 659 F.3d 295, 313 (3d Cir. 2011). Under Rule 9(b), kickback allegations must provide the "essential factual background regarding th[e] claim" such as "facts regarding specific patients, doctors, or offices." Hericks v. Lincare Inc., No. 07-387, 2014 WL 1225660, at *12 (E.D. Pa. Mar. 25, 2014) (dismissing kickback claims under Rule 9(b) that were "based on speculation and conjecture").

First, Cephalon argues that relators have not adequately alleged how speaker fees constituted kickbacks because they have not alleged the amount of fees, how they were excessive, who received them or identified a specific physician who was induced to prescribe off-label due to the fees. See Dkt. No. 105-1 at ECF 23. Similarly, in U.S. ex rel. Booker v. Pfizer, Inc., No. 10-11166, 2014 WL 1271766, at *13 (D. Mass. Mar. 26, 2014), the defendant in an FCA action argued that the relators "needed to allege that its payments to any physician speakers exceeded their fair market value in order to establish that those payments constituted an illegal kickback, which Relators undoubtedly did not do." The Court reasoned that since the AKA itself does not require "an exchange at non-market value to constitute an illegal kickback," it would be anomalous to impose such a requirement on FCA claims premised upon kickback allegations. Id. Thus, the Court concluded that while "payment for services at more-than-market value might be helpful evidence of a kickback scheme, [it was] not convinced it is necessary to establishing a kickback in all cases." Id. I am also convinced that relators need not allege that

speaker fees were provided at higher than market rates for similar speaking engagements in order to constitute kickbacks underlying a theory of FCA liability.

Cephalon further contends that relators' kickback allegations are analogous to those dismissed by the Court in U.S. ex rel. Joseph Piacentile v. Sanofi Synthelabo, Inc., No. 05-2927, 2010 WL 5466043 (D.N.J. Dec. 30, 2010). In Piacentile, the relator alleged that the "[defendants] promoted their drugs off-label and paid kickbacks to doctors in the form of free drug samples, overfilled prescriptions, educational grants, and speaker's fees." Id. at *8. In considering the relator's kickback allegations, however, the Court reasoned that while the relator "identifies doctors whom he claims received speaker's fees . . . the only allegation that any of these doctors actually prescribed" the drug Taxotere was "that purchases of Taxotere [increased] from 170 vials a month to as many as 400 vials a month, mostly for off-label use." Id. The Court found that these allegations were insufficient under Rule 9(b) because there was "no mention of how Piacentile knows these vials were used off-label, but baldly states that they were" and that "[o]ther allegations that certain doctors increased their use [the defendants'] drugs are similarly conclusory." Id.

Relators contend that their kickback allegations are more akin to those in U.S. ex rel. Underwood v. Genentech, Inc., 720 F. Supp. 2d 671 (E.D. Pa. 2010), in which the "[r]elator alleged that the Genentech sales department disguised [ ] bribes as consultantships although they were unrelated to any scientific or educational activity, cash payments, travel benefits, entertainment, and other benefits" in order to induce the prescription and reimbursement of drugs off-label. Id. at 675 (citations omitted). Thus, the Court concluded that "[t]here is no mystery or ambiguity to [relator's] allegations. Either Genentech lavishly bribed doctors to prescribe Rituxan for off-label use or it did not. Relator's allegations are sufficiently specific both to

inform Genentech of the 'precise misconduct' charged, and to make it unlikely that Relator has commenced this action in bad faith." Id. at 680. Further, in U.S. ex rel. Bergman v. Abbot Labs., 995 F. Supp. 2d 357 (E.D. Pa. 2014), the Court denied a motion to dismiss kickback based FCA claims under Rule 9(b) where the "[r]elator alleges in the Complaint that Abbott provided illegal financial incentives to physicians to prescribe TriCor for off-label and medically unnecessary uses . . . [and] also details how Abbott allegedly provided its representatives with funds for honoraria and meals as rewards for physicians who prescribed or encouraged other physicians to prescribe TriCor." Id. at 375.

First, relators have identified the specific physicians, events and, in some instances, amounts of compensation provided to speakers to allegedly promote Provigil and Nuvigil off-label or as a reward for prescribing the drugs off-label. See e.g., Dkt. No. 69 at ¶¶ 197, 199; Hericks, 2014 WL 1225660, at *12. These allegations are at least as detailed as the allegations found to be well-pled in Genentech and Bergman. For example, relators' roundtable allegations are pled with particularity, see supra § I(A)(1), and "also served as kickbacks to the attendees, who not only received honoraria but were provided with expensive meals." Id. at ¶¶ 202, 204 (discussing roundtable hosted by Dr. Ellen). As discussed above, see supra § I(A)(2), relators plead reliable indicia giving rise to a strong inference that Cephalon's speaker program resulted in increases in submissions for reimbursement of off-label prescriptions. Id. at ¶¶ 200-01.

Second, relators allege that Cephalon supplies "physicians with 'front office' personnel in the form of Cephalon sales representatives who were instructed to provide free services to ensure that the physicians obtained reimbursement from Medicare and Medicaid without having to pay their own staff to perform the work" and that this

> use of free reimbursement services for off-label prescriptions violates the Federal Anti-Kickback Act in that its actions have

> been, and are continuing to be, taken as part of a scheme to induce physicians to prescribe and utilize Provigil and Nuvigil for off-label uses without concern for the time, resources or lost profits associated with addressing reimbursement issues raised by payors, such as Medicare or Medicaid, themselves.

Id. at ¶¶ 251-54. It is unclear from the second amended complaint whether these "free reimbursement services" are the same services or are additional to the alleged prior-authorization services that Cephalon provided to physicians and which are pled with greater factual specificity. Cf. id. at ¶¶ 224-39 with ¶¶ 250-56. However, it is easy to infer from the second amended complaint that relators are incorporating prior authorization allegations into their kickback section by reference to "free reimbursement services" generally.

Cephalon argues that relators have not pled how reimbursement services actually induced the off-label prescription of Provigil or Nuvigil and that there are therefore no reliable indicia that lead to a strong inference that false claims were actually submitted due to Cephalon's reimbursement services. See Dkt. No. 105-1 at ECF 23. Yet, this alleged kickback is unique in that the form of the kickback, free reimbursement services, is oriented towards ensuring the actual submission of claims tainted by that kickback. Thus, the form of the alleged kickback itself provides a strong inference that claims were actually submitted as a result of the kickback being provided to physicians. Relators also plead with particularity the nature of the prior authorization scheme that Cephalon allegedly utilized to overcome denials of coverage and include the name of at least one physician that relator Dufour personally provided with free reimbursement services. Id. at ¶ 238. In conjunction with the properly pled kickback allegations of speaker fees and allegations of Cephalon's detailed tracking mechanisms to monitor the effectiveness of its schemes, id. at ¶¶ 197, 199-201, relators' allegations regarding the provision

of free reimbursement services merely provide one more detail in what is a properly-alleged over-arching scheme of kickback violations and off-label promotion.

As in Underwood, there is no mystery here as to the factual basis of relators' kickback allegations. See Underwood, 720 F. Supp. 2d at 680. Relators' kickback allegations are specific enough to indicate this action was not commenced in bad-faith. See id. There is little question that Cephalon has fair notice of the particular allegations of kickbacks made against it. See Foglia, 754 F.3d at 156. Considering Cephalon's alleged prescription tracking mechanisms, Dkt. No. 69 at ¶ 200, the nature of its kickbacks related to free reimbursement services, id. at ¶ 251, the alleged use of speaker fees as a reward for off-label prescribing behavior with regard to particular doctors, id. at ¶ 197, and allegations of increases in off-label prescribing behavior of individual doctors tied to allegedly kickback tainted events or speakers, id. at ¶ 201, there are reliable indicia that give rise to a strong inference that false claims were actually submitted as a result of Cephalon's alleged kickback scheme. Thus, I will deny Cephalon's motion to dismiss relators' FCA claims premised on allegations of Cephalon's payment of illegal kickbacks.

II. Reverse False Claims Allegations

Relators allege that Cephalon made "reverse" false claims in violation of 31 U.S.C. § 3729(a)(1)(G) by failing to comply with the Corporate Integrity Agreement (CIA) it entered into with the Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services. Relators allege that Cephalon's CIA prohibited it from engaging in off-label promotion of Provigil and Nuvigil and that Cephalon violated its duty to report any violations of the CIA to the OIG. See ¶¶ 387-396 (discussing monitoring and reporting requirements and failure to report off-label promotion); ¶¶ 400-02 (discussing alleged failure to report kickbacks).

In their opposition to Cephalon's motion to dismiss, relators argue that Cephalon would incur stipulated penalties as a contractual remedy for failure to report violations. See Dkt. No. 108 at ECF 22. Thus, relators argue that by failing to report its violations of the CIA when it promoted Provigil and Nuvigil off-label or paid kickbacks and by this failing to pay contractual penalties, Cephalon avoided an obligation to pay money to the government in violation of § 3729(a)(1)(G). Section 3729(a)(1)(G) makes liable any person 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.

31 U.S.C. § 3729(a)(1)(G).

Cephalon argues that relators' § 3729(a)(1)(G) claims should be dismissed because relators have not adequately alleged a violation of an obligation to pay the government under the CIA, but rather only alleged a violation of Cephalon's obligation to report.[5] Relators allege once in the second amended complaint that Cephalon "improperly avoided or decreased an obligation to pay or transmit money or property to the Government." Dkt. No. 69 at ¶ 386. However, relators "did not plead any reference to the stipulated-penalties provisions of the CIA[ ] in the SAC" and thus provided no factual allegations giving rise to a claim under § 3729(a)(1)(G). U.S. ex rel. Ibanez v. Bristol-Myers Squibb Co., No. 1:11-029, 2015 WL 1439054, at *10 (S.D. Ohio Mar. 27, 2015) (finding similar vague references to obligations to pay under a corporate integrity agreement insufficient under Rule 12(b)(6)). Rather, relators only mention stipulated penalties in their opposition to the motion to dismiss. See Dkt. No. 108 at 22. Since I "test the sufficiency of the allegations in the SAC, not the sufficiency of Relators' arguments in

[5] Because I find Cephalon's argument persuasive, I will not reach its other arguments in support of its motion to dismiss relators' § 3729(a)(1)(G) claims.

opposition" I will grant Cephalon's motion to dismiss relators § 3729(a)(1)(G) with leave to amend. Ibanez, 2015 WL 1439054, at *10.

III. Conspiracy Claims

Relators allege that Cephalon conspired with Takeda Pharmaceuticals North America, Inc. to further its fraudulent marketing of Provigil. Cephalon argues that relators have failed to plead a conspiratorial agreement between Cephalon and Takeda in violation of 31 U.S.C. § 3729(a)(1)(C). As a threshold matter, relators allege that Cephalon conspired with Takeda between June 12, 2006 and November 1, 2008 when the Provigil co-promotion agreement was in effect. See Dkt. No. 69 at ¶ 450. Section 3729(a)(1)(C) does not apply retroactively. See U.S. ex rel. Mooney v. Americare, Inc., No. 06-1806, 2013 WL 1346022, at *1 (E.D.N.Y. Apr. 3, 2013); U.S. ex rel. Westrick v. Second Chance Body Armor, Inc., 685 F. Supp. 2d 129, 140 n.11 (D.D.C. 2010). Thus, the pre-FERA version of the FCA's conspiracy provision, 31 U.S.C. § 3729(a)(3), applies to relators' conspiracy allegations.

Another threshold matter is the proper standard of review of FCA conspiracy claims. Cephalon contends that relators' conspiracy claim should be analyzed under Rule 9(b). In Rose v. Bartle, 871 F.2d 331 (3d Cir. 1989), the Court of Appeals concluded that a RICO claim of civil conspiracy was subject to the more liberal pleading requirements of Rule 8(a) while the underlying elements of fraud were subject to Rule 9(b). Id. at 366. Thus, allegations of conspiracy must only be sufficient to "describe the general composition of the conspiracy, some or all of its broad objectives, and the defendant's general role in that conspiracy." Id. At the same time, "[a] conspiracy claim must also contain supportive factual allegations." Id. Similarly, a conspiracy claim under the FCA is "required to allege the underlying fraud with particularity, but the allegations of the conspiracy need only satisfy the notice pleading standards

of Rule 8." U.S. ex rel. Atkinson v. Pa. Shipbuilding Co., No. 94-7316, 2000 WL 1207162, at *10 (E.D. Pa. Aug. 24, 2000) aff'd on other grounds U.S. ex rel. Atkinson v. Pa. Shipbuilding Co., 473 F.3d 506 (3d Cir. 2007); see also U.S. ex rel. Bartlett v. Tyrone Hosp., Inc., 234 F.R.D. 113, 123 (W.D. Pa. 2006) (agreeing with Atkinson and analyzing § 3729(a)(3) conspiracy claim under Rule 8(a)). Thus, I will consider whether relators have stated a claim for conspiracy pursuant to Rule 8(a).

Cephalon contends that relators have failed to state a claim for conspiracy under Rule 8(a) because there are no allegations that Takeda agreed to promote off-label or knew that Cephalon was directing Takeda's sales staff to physicians who prescribed Provigil off-label. See Dkt. No. 105-1 at ECF 26. To plead a claim for conspiracy under § 3729(a)(3), a plaintiff must allege (1) a conspiracy to get a false or fraudulent claim allowed or paid; and (2) an act in furtherance of the conspiracy. U.S. ex rel. Lampkin v. Johnson & Johnson, Inc., No. 08-05362, 2013 WL 2404238, at *6 (D.N.J. May 31, 2013). "The essence of a conspiracy under the Act is an agreement between two or more persons to commit a fraud." Piacentile, 2010 WL 5466043, at *9.

Relators allege that "Cephalon and Takeda conspired to ensure that . . . Takeda would continue the off-label promotion" while Cephalon was under federal investigation for its off-label promotion activities. Dkt. No. 69 at ¶ 451. Pursuant to that agreement and in order to further the conspiracy, relators allege that Cephalon "conspired to have Takeda representatives call on the very physicians whom Cephalon knew were writing exclusively off-label." Id. at ¶ 450. Additionally, relators allege that Cephalon "trained Takeda sales representatives to sell Provigil, including off-label in the same manner [Cephalon] had been doing" and shared its

Provigil promotional speakers with Takeda. Id. These actions were allegedly taken in order "to get a false or fraudulent claim allowed or paid by the United States." Id. at ¶ 452.

Relators' allegations give rise to a plausible claim for conspiracy. All of these actions in furtherance of the alleged conspiracy were allegedly undertaken pursuant to a formal co-promotion agreement between Cephalon and Takeda. See id. at ¶ 450. There is therefore little ambiguity in the second amended complaint's allegations that Takeda agreed to enter into a conspiracy with Cephalon and allegedly took actions in furtherance of that conspiracy. At least, these allegations provide "sufficient circumstantial evidence" from which "I can easily infer the existence of an agreement." U.S. ex rel. Gohil v. Sanofi-Aventis U.S. Inc., No. 02-2964, 2015 WL 1456664, at *13 (E.D. Pa. Mar. 30, 2015) (inferring agreement sufficient to support an FCA conspiracy claim from general allegations that the defendant pharmaceutical company paid doctors kickbacks in order to increase their use of a prescription medication and thus caused the submission of false (kickback tainted) claims for federal reimbursement). See also Palladino ex rel. U.S. v. VNA of S. N.J., Inc., 68 F. Supp. 2d 455, 463 (D.N.J. 1999) (inferring "missing" conspiracy allegations from the well-pled factual allegations of the complaint). Thus, I will deny Cephalon's motion to dismiss relators' FCA conspiracy claims.

IV. State Law Claims

I will now consider Cephalon's motion to dismiss certain claims brought by relators under various state false claims provisions.

A. Delaware Claims

The prior version of the Delaware False Claims and Reporting Act required the Delaware Attorney General to issue a written determination that there is substantial evidence of a violation of the Act before a relator could pursue a non-intervened qui tam action. See Del. Code. Ann.

tit. 6, § 1203(b)(4)(b) (2009). That requirement was removed by a July 16, 2009 amendment. See Del. Code. Ann. tit. 6, § 1203(b)(1) (2010). That amendment is not retroactive, however. Here, relators have not alleged that they obtained a written determination that there was substantial evidence before pursuing their claims. Thus, only allegations based upon conduct after July 16, 2009 are properly pled by relators and I will grant Cephalon's motion to dismiss with regard to prior conduct. See U.S. ex rel. Streck v. Allergan, Inc., 894 F. Supp. 2d 584, 603 (E.D. Pa. 2012) (dismissing claims based upon conduct prior to Delaware's 2009 amendment where the relator had not complied with the written determination requirement but permitting claims based upon conduct following the amendment).

B. New York Claims

Cephalon moves to dismiss relators' claims under the New York False Claims Act (NYFCA) that are premised on conduct prior to the enactment of the NYFCA on April 1, 2007. See N.Y. State Fin. Law § 187 et seq. (McKinney 2007). The NYFCA, however, is retroactively applicable on the face of the statute and has been found retroactively applicable by multiple courts. See United States ex rel. Bilotta v. Novartis Pharms. Corp., No. 11-0071, 2014 WL 4922291, at *36 (S.D.N.Y. Sept. 30, 2014) (collecting cases). Thus, I will deny Cephalon's motion to dismiss relators NYFCA claims based on conduct occurring before April 1, 2007.

C. Georgia Claims

Relators bring claims pursuant to the Georgia False Claims Act. Georgia's False Claims Act became effective on May 24, 2007. The Georgia FCA does not contain a retroactivity provision and relators have failed to substantively oppose Cephalon's motion to dismiss their Georgia claims. See Ga. Code Ann. § 49-4-168 et seq. (2007). Under Georgia law, legislation affecting substantive rights may only operate prospectively. See Fowler Props., Inc. v. Dowland, 646 S.E.2d 197, 200 (Ga. 2007). Thus, I will grant Cephalon's motion to dismiss relators'

claims under Georgia law to the extent that they arise from conduct occurring before May 24, 2007.

D. New Jersey Claims

The New Jersey False Claim Act became effective beginning on March 13, 2008. See N.J. Stat. Ann. § 2A:32C-1 (2008). The New Jersey False Claims Act is not retroactively applicable. See State ex rel. Hayling v. Correctional Med. Servs., Inc., 28 A.3d 1246, 1250-51 (N.J. Super. Ct. 2011). Thus, I will grant Cephalon's motion to dismiss with regard to relators' claims under New Jersey law to the extent that they arise from alleged conduct prior to March 13, 2008.

E. Oklahoma Claims

Under Oklahoma law, "[a]bsent a plain legislative intent to the contrary, statutes are generally presumed to operate prospectively only." Cole v. Silverado Foods, Inc., 78 P.3d 542, 546 (Okla. 2003). The Oklahoma FCA became effective on effective November 1, 2007. See Okla. Stat. Ann. tit. 63, § 5053.1 et seq. (2007). The Oklahoma statute does not apply retroactively because there is no plain legislative intent contrary to the presumption of prospective application. See U.S. ex rel. King v. Solvay S.A., 823 F. Supp. 2d 472, 529-30 (S.D. Tex. 2011) order vacated in part on reconsid., No. 06-2662, 2012 WL 1067228 (S.D. Tex. Mar. 28, 2012). Thus, I will grant Cephalon's motion with regard to relators' claims under Oklahoma law to the extent that they arise from alleged conduct prior to November 1, 2007.

F. Rhode Island Claims

Under Rhode Island law, courts ordinarily presume that statutes operate prospectively "unless there is clear, strong language or a necessary implication that the General Assembly intended to give the statute retroactive effect." Direct Action for Rights & Equality v. Gannon,

819 A.2d 651, 658 (R.I. 2003). Cephalon states that Rhode Island's False Claims Act became effective February 15, 2008. See Dkt. No. 105-1 at ECF 29 n.12. However, it appears that the Rhode Island FCA became effective on July 1, 2007. See R.I. Gen. Laws Ann. § 9-1.1-1 et seq. (2007). Relators have not provided any justification for finding contrary to Rhode Island's ordinary assumption that its False Claims Act would only apply prospectively. Absent any argument supporting an effective date of February 15, 2008, I will grant Cephalon's motion with regard to relators' claims under Rhode Island law to the extent that they arise from alleged conduct prior to July 1, 2007.

CONCLUSION

For the reasons set forth above, I will grant Cephalon's motion to dismiss with regard to relators' claims under 31 U.S.C. § 3729(a)(1)(G) with leave to amend. I will also grant Cephalon's motion and will dismiss relators' claims under Delaware, Georgia, New Jersey, Oklahoma and Rhode Island law to the extent that the claims relate to alleged conduct prior to the relevant effective dates of those states' FCA legislation. I will deny Cephalon's motion to dismiss in all other respects.

An appropriate Order follows.