

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

UNITED STATES OF AMERICA ex rel. : CIVIL ACTION
BRUCE BOISE, et al. : NO. 08-287
: :
v. : :
: :
CEPHALON, INC., et al. : :
: :
O'NEILL, J. : October 9, 2014

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, 31 U.S.C. §§ 3729, et. seq. (FCA) and analogous state laws. This matter comes before me on Cephalon's motion to dismiss plaintiffs' Fentora claims in their second amended complaint for lack of subject matter jurisdiction pursuant to Fed. R. Civ. P. 12(b)(1) (Dkt. No. 77) and plaintiffs' response (Dkt. No. 88). Defendant contends that 31 U.S.C. § 3730(e)(4)(A) bars plaintiffs' assertion of the Fentora claims because the allegations those claims are based upon were publicly disclosed in a related complaint filed in Cestra v. Cephalon, Inc., No. 14-01842 (E.D. Pa.). The Cestra action was originally filed in the Southern District of New York on August 30, 2010. See Cestra v. Cephalon, Inc., No. 14-091842, Dkt. No. 1-2. On March 27, 2014, Judge Stein transferred the Cestra action to me. See id., Dkt. No. 1. For the reasons that follow, I will grant Cephalon's motion.

BACKGROUND

In this action, plaintiffs allege that defendants violated the FCA by, inter alia, engaging in the off-label, meaning unapproved by the FDA, promotion of various medications. At issue here

are plaintiffs' claims with regard to defendants' alleged off-label promotion of the medication Fentora. Fentora is a potent pain reliever. See Dkt. No. 69 at ¶ 266. In 2006, the FDA approved Fentora for the treatment of breakthrough cancer pain, meaning spikes in pain that cannot be controlled with normal pain medication, in adult patients who are opioid tolerant. See id. at ¶ 263. Plaintiffs allege that counter to the FDA's approval, defendants promoted Fentora for uses other than breakthrough cancer pain. See id. at ¶ 312. Plaintiffs allege that defendants' off-label promotion of Fentora caused the submission of false claims for reimbursement from various government programs because those programs only reimburse for FDA approved uses of medications. See id. at ¶ 419-26. Plaintiffs' detailed claims and allegations and a discussion of the complaints at issue in Cephalon's motion to dismiss pursuant to § 3730(e)(4) follow.

A. The Boise First Amended Complaint

On January 3, 2008, Boise filed his original complaint in this action. See Dkt. No. 1. On January 14, 2010, Boise filed his first amended complaint.¹ See Dkt. No. 14. I discuss the Boise first amended complaint here in order to provide context for the later discussion of public disclosures that were incorporated into plaintiffs' second amended complaint following the filing of the Cestra second amended complaint. Cephalon employed Boise in sales representative and management positions from 1996 until June 2003. See Dkt. No. 69 at ¶ 20. Boise was terminated in 2003 allegedly for refusing to incorporate off-label marketing strategies into his sales approach and for sharing information regarding Cephalon's conduct with the FDA. Id.

¹ Thus, the Fentora claims in the Boise original and first amended complaints were filed before the Cestra action commenced. For that reason, Cephalon has also filed a motion to dismiss the Fentora claims in the Cestra action on first-to-file grounds. Even if Cestra's Fentora claims are dismissed on first-to-file grounds, however, for the purposes of the public disclosure bar plaintiffs' second amended complaint could still have been based upon the public disclosure of allegations contained in Cestra's second amended complaint.

Count I of Boise's first amended complaint claimed defendants' marketing of Fentora and other medications violated 31 U.S.C. §§ 3729(a)(1)(A), (B), and (C). See Dkt. No. 14 at ¶¶ 100-08.

Boise's first amended complaint contained the following allegations regarding Fentora, which I will group into two categories. First, the complaint mentioned that the FDA approved Fentora for treatment of breakthrough cancer pain, but provided no other history regarding the FDA and Fentora. See id. at ¶ 77. The complaint also mentioned that Cephalon's medication Actiq was going to lose patent protection, which was an impetus to develop and market Fentora off-label. See id. at ¶¶ 76, 78-79.

Second, the complaint alleged that Cephalon conducted a widespread off-label promotion effort for Fentora that caused prescribing physicians and pharmacists to submit false claims for reimbursement from the government. See id. at ¶ 83. The complaint made various specific allegations regarding how defendant had promoted Fentora off-label. Boise alleged that Robert Roche, Cephalon's Senior V.P. of Marketing informed sales representatives that "Cephalon was losing too much money by abandoning off-label marketing efforts on its drugs and thus that it would be worth" it to use off-label promotion even if it meant being fined by the government. See id. at ¶ 82. Boise alleged that defendants marketed Fentora off-label to non-oncologists and dedicated its sales staff primarily to marketing to pain specialists who would prescribe Fentora off-label. See id. at ¶¶ 83-84. Boise did not provide any specific information regarding that marketing effort. The complaint alleged Cephalon focused its Fentora marketing efforts on off-label promotion through speaker programs. See id. at ¶ 84. Plaintiff did not provide any specific information regarding those speaker programs. The complaint alleged that defendants used kickbacks and preceptorships to promote Cephalon's drugs off-label, but alleged no specific facts of this activity with regard to Fentora. See id. at ¶ 3. Lastly, Boise also alleged that

Fentora's form of delivery, potential accidental use by children and dosing advice that defendants gave to physicians all raised the risk of accidental overdose. See id. at ¶¶ 83, 85.

B. The Cestra Second Amended Complaint

On June 24, 2013, in a separate action against Cephalon, relator Cestra filed his second amended complaint in the Southern District of New York. See Cestra v. Cephalon, Inc., No. 14-091842, Dkt. No. 1-30 (Second Amended Complaint). Counts I-IV of Cestra's second amended complaint assert four claims that defendants violated the FCA. Count I claims that defendants violated 31 U.S.C. § 3729(a)(1)(A) by knowingly presenting or causing to be presented to the government false or fraudulent claims for payment for Fentora. See No. 14-091842, Dkt. No. 1-30 at ¶¶ 427-29. Count II claims that defendants violated 31 U.S.C. § 3729(a)(1)(B) when they knowingly made, used, or caused to be made or used, false or fraudulent records or statements material to the payment of a false or fraudulent claim and that the claims were actually paid or approved in violation of 31 U.S.C. § 3729(a)(2). See id. at ¶¶ 430-33. Count III claims that defendants knowingly conspired with health professionals to commit the violations alleged in Counts I and II. See id. at ¶¶ 434-36. Count IV claims that defendants violated 31 U.S.C. § 3729(a)(1)(G) when they knowingly made or used false records or statements material to an obligation to pay or transmit money or property to the Government and concealed, avoided, or decreased that obligation. See id. at ¶¶ 437-39.

The Cestra second amended complaint relies upon the following allegations to support its claims, which I will group into three categories. First, the Cestra complaint provides a detailed history of FDA monitoring of Fentora including four specific times that the FDA issued warnings related to the off-label use of Fentora. See id. at ¶¶ 268-90. The Cestra complaint also provides a brief background regarding the drug Actiq and discusses Cephalon's loss of patent

protection for Actiq as an impetus for converting off-label prescriptions of Actiq to off-label prescriptions of Fentora. See id. at ¶¶ 255-63.

Second, the Cestra complaint alleges defendants conducted a widespread off-label promotion effort for Fentora that caused prescribing physicians and pharmacists to submit false claims for reimbursement from the government. The Cestra complaint includes specific allegations of how defendant promoted Fentora off-label. The Cestra complaint alleges defendant used speaker programs to promote Fentora off-label and provided specific names of doctors involved, their specialties and the nature of payments defendants made to them. See id. at ¶¶ 299-304. The Cestra complaint alleges that defendants used journal supplements to promote Fentora off-label and discussed specific examples of articles and authors. See id. at ¶¶ 305-10. Cestra alleges that defendants' own market studies confirmed they were promoting Fentora off-label. See id. at ¶¶ 311-17. The Cestra complaint alleges that defendants' own 2011 Brand Plan for Fentora specifically targeted non-oncology pain specialists for off-label promotion and listed oncology physicians for secondary targeting. See id. at ¶¶ 318-29. The Cestra complaint alleges that defendant used the Fentora Reimbursement Program to assist doctors in obtaining fraudulent reimbursements for off-label Fentora prescriptions from the government. Cestra alleges that this assistance constituted illegal kickbacks because it subsidized the high labor costs associated with obtaining reimbursement for off-label prescriptions and therefore increased physicians' willingness to prescribe Fentora off-label. See id. at ¶¶ 341-77. Through this program, Cestra alleges that defendants made false statements material to the submission of false claims to the government. See id. at ¶¶ 330-40.

Third, Cestra alleges that defendants' conduct violated Cephalon's Corporate Integrity Agreement and that defendants concealed these violations from the government. This alleged

concealment also led defendants to allegedly make false statements to the government that furthered their Fentora off-label promotion scheme. See id. at ¶¶ 374-75. Finally, the Cestra complaint articulates how defendants' off-label promotion scheme and kickbacks led to the submission of false claims to Medicaid, Medicare Part B and Part D. See id. at ¶¶ 379-42.

C. Plaintiffs' Second Amended Complaint

On February 27, 2014, plaintiffs filed a second amended complaint in this action adding claims by relators Dufour and Augustine and supplementing their claims and allegations from the Boise first amended complaint. See Dkt. No. 69. Plaintiffs' FCA claims are contained in Counts I-IV and are identical to the counts in the Cestra second amended complaint, except that in Count III plaintiffs allege that defendants conspired with Takeda Pharmaceuticals to commit the violations alleged in Counts I and II. See id. at ¶¶ 453-65. In contrast, Cestra alleges that the conspiracy was with healthcare professionals rather than Takeda.

Plaintiffs' second amended complaint makes the following allegations related to Fentora, which I will group into three categories. First, the second amended complaint provides a detailed history of FDA monitoring of Fentora, follows same structure and includes the same content as the description of the FDA monitoring history in the Cestra second amended complaint. See id. at ¶¶ 273-93. The second amended complaint also copies word-for-word the discussion from the Cestra second amended complaint regarding the history of the Fentora predecessor Actiq and defendants' loss of patent protection for Actiq as an impetus for converting off-label prescriptions of Actiq to off-label prescriptions of Fentora. See id. at ¶¶ 257-62.

Second, the second amended complaint alleges that defendants conducted a widespread off-label promotion effort for Fentora that caused prescribing physicians and pharmacists to

submit false claims for reimbursement from the government. Plaintiffs make the following specific allegations regarding that promotion effort. Plaintiffs allege for the first time that defendants funded “front organizations” and the Federation of State Medical Boards to assist in the off-label promotion of Fentora. See id. at ¶¶ 294-306. Plaintiffs allege for the first time that defendants’ own 2006 and 2007 marketing plans focused sales efforts on the off-label promotion of Fentora. See id. at ¶¶ 322-36. Plaintiffs allege that defendants’ own marketing audit addressed marketing irregularities. See id. at ¶¶ 337-43. Plaintiffs allege defendants targeted non-oncology physicians and for the first time provide specific examples in a similar manner as in the Cestra second amended complaint. See id. at ¶¶ 344-51. Plaintiffs allege that defendants promoted Fentora through speaker programs and for the first time identify specific names and specialties of doctors and the nature of their payments. See id. at ¶¶ 352-59. The specific physicians discussed are not identical to those discussed in the Cestra second amended complaint. For the first time plaintiffs allege that defendants used journal supplements to promote Fentora off-label. See id. at ¶¶ 352-59. This is the same allegation included in the Cestra second amended complaint and contains similar details. Plaintiffs allege that defendants used preceptorships to promote Fentora off-label. See id. at ¶¶ 366-68. Plaintiffs allege that defendants sponsored clinical studies, though these allegations are tied to the allegation of off-label promotion through journal articles. For example, the Boise complaint copies Cestra’s allegations of off-label promotion of Fentora through journal supplements by a Cephalon employee named Dr. Narayana, but the Boise complaint also alleges Narayana’s involvement in the clinical study context. See id. at ¶¶ 369-75. Plaintiffs allege for the first time, using identical language and substance as included in the Cestra second amended complaint, that defendants

offered kickbacks in the form of the Fentora Reimbursement Program to induce the off-label prescription of Fentora. See id. at ¶¶ 376-84.

Third, also for the first time and using language and substance identical to the Cestra second amended complaint, plaintiffs allege that Cephalon violated its Corporate Integrity Agreement with the government by engaging in the alleged off-label promotion and kickback schemes. See id. at ¶¶ 385-402. Plaintiffs make the same allegation as in the Cestra second amended complaint that these violations constituted false statements to the government that specifically furthered their Fentora off-label promotion scheme. See id. at ¶¶ 398-99. Plaintiffs additionally copy an entire section from the Cestra second amended complaint detailing how defendants' off-label promotion led to false claims from Medicaid and Medicare Parts B and Part D. See id. at ¶¶ 403-441. Finally, plaintiffs apparently concede and certainly do not dispute that specific details of fraud included in their second amended complaint were publicly disclosed in the Cestra second amended complaint. See Dkt. No. 88 at 3.

STANDARD OF REVIEW

Federal Rule of Civil Procedure 12(b)(1) authorizes dismissal of a complaint for lack of subject matter jurisdiction. A motion under Rule 12(b)(1) may be treated as either a facial attack on the complaint or a factual challenge to the Court's subject matter jurisdiction. Gould Elecs., Inc. v. United States, 220 F.3d 169, 176 (3d Cir. 2000). A court reviewing a facial attack may consider only the allegations of the complaint and any documents referenced therein or attached thereto in the light most favorable to the plaintiff. Id. In reviewing a factual attack, a court may consider evidence outside the pleadings. Id.

A plaintiff bears the burden of persuasion when subject matter jurisdiction is challenged, but the legal standard for surviving a Rule 12(b)(1) motion is a low one. Kehr Packages v.

Fidelcor, Inc., 926 F.2d 1406, 1409 (3d Cir. 1991). “A claim may be dismissed under Rule 12(b)(1) only if it ‘clearly appears to be immaterial and made solely for the purpose of obtaining jurisdiction’ or is ‘wholly insubstantial and frivolous.’” Gould, 220 F.3d at 178. Nevertheless, “dismissal for lack of jurisdiction is not appropriate merely because the legal theory alleged is probably false, but only because the right claimed is ‘so insubstantial, implausible, foreclosed by prior decisions of this Court, or otherwise completely devoid of merit as not to involve a federal controversy.’” Kulick v. Pocono Downs Racing Ass’n, 816 F.2d 895, 899 (3d Cir. 1987), quoting Oneida Indian Nation v. Cnty. of Oneida, 414 U.S. 661, 666 (1974).

DISCUSSION

I. Retroactivity of 2010 FCA Amendments

As a threshold matter, the parties dispute which version of the FCA I should apply in this case. The FCA was amended in 2010 to include various changes, such as the elimination of jurisdictional language from the public disclosure bar and changes to the language of the original source rule. Plaintiffs contend that the amended version should apply to my analysis because their second amended complaint was filed after the effective date of the amendments. See Dkt. No. 88 at 7-8. Plaintiffs also assert that I should apply the 2010 amendments retroactively because they are procedural rather than substantive changes to the statute. Plaintiffs further contend that various consequences for this case flow from the application of the 2010 amended provisions rather than the earlier version of the statute. For example, plaintiffs argue that the post-2010 public disclosure bar is non-jurisdictional and should be raised as an affirmative defense rather than as a motion to dismiss pursuant to Rule 12(b)(1). See Dkt. No. 88 at 8-12. In response, Cephalon asserts that the time the action was brought, rather than the time of filing of

plaintiffs' latest complaint, determines which version of the FCA applies. See Dkt. No. 77 at 3 n.3, Dkt. No. 90 at 5-6.

Cephalon is correct. Courts that have considered the issue have held that the timing of the filing of the action rather than the time of the amendment of the complaint determines whether the 2010 amendments to the public disclosure bar apply. See U.S. ex rel. Solis v. Millennium Pharm., Inc., No. 09-03010, 2014 WL 1270581, at *6 (reasoning that an amended complaint typically relates back to the time of filing) (E.D. Cal. Mar. 26, 2014); U.S. ex rel. Doe v. Staples, Inc., 932 F. Supp. 2d 34, 39 n.1 (D.D.C. 2013) (holding timing of filing determines application of the 2010 amendments).

Further, the Supreme Court has twice held that courts cannot apply the 2010 amendments to the public disclosure bar retroactively. See Graham Cnty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson, 559 U.S. 280, 283 n.1 (2010); Schindler Elevator Corp. v. U.S. ex rel. Kirk, 131 S. Ct. 1885, 1889 n.1 (2011) (stating “the amendments [to the public disclosure bar] are not applicable to pending cases”). The United States Court of Appeals for the Third Circuit has agreed. See U.S. ex rel. Zizic v. Q2Administrators, LLC, 728 F.3d 228, 232 n.3 (3d Cir. 2013). Thus, I will apply the pre-2010 version of the public disclosure bar in this case.

II. Public Disclosure Analysis

The pre-2010 FCA public disclosure bar provides that “[n]o court shall have jurisdiction over an action under this section based upon the public disclosure of allegations . . . unless . . . the person bringing the action is an original source of the information.” 31 U.S.C. § 3730(e)(4)(A). The statute defines an original source as “an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is

based on the information.” 31 U.S.C. § 3730(e)(4)(B). Therefore, when applying the public disclosure bar I consider if (1) there are any “public disclosures” at work in plaintiffs’ claim, (2) if so, whether they disclose “allegations” of fraud or fraudulent “transactions,” (3) if so, whether plaintiffs’ claim is “based upon” those “allegations or transactions” and (4) if so, whether plaintiffs are an “original source” of those “allegations or transactions.” See U.S. ex rel. Waris v. Staff Builders, Inc., No. 96-1969, 1999 WL 788766, at *4 (E.D. Pa. Oct. 4, 1999). Here, the parties only dispute steps three and four, whether plaintiffs’ second amended complaint is “based upon” allegations in the Cestra second amended complaint and, if so, whether plaintiffs are “original sources” of those allegations.²

Before conducting that analysis, I must consider which claims and allegations contained in the Cestra second amended complaint and plaintiffs’ second amended complaint should be compared. The Court of Appeals has held that in a multi-count complaint there must be a claim-by-claim analysis of the application of the public disclosure bar. U.S. ex rel. Merena v. SmithKline Beecham Corp., 205 F.3d 97, 102 (3d Cir. 2000), as amended (Apr. 21, 2000) (“[I]n applying section (e)(4), it seems that each claim in a multi-claim complaint must be treated as if it stood alone.”). If only some claims in the second amended complaint were based upon publicly disclosed information this “should not result in the dismissal of claims that would have otherwise survived.” Id. As an initial matter then, I will consider what are the claims and underlying allegations contained in plaintiffs’ second amended complaint. Then I will if plaintiffs were original sources of the information underlying their allegations and if plaintiffs’

² Cephalon correctly contends that I must consider plaintiffs’ second amended complaint when applying the public disclosure bar. See Dkt. Nos. 77 at 4, 90 at 1-2. Plaintiffs do not appear to disagree. Rather, plaintiffs only contend that Boise’s “original Fentora allegations” cannot be considered “based upon” the Cestra second amended complaint. See Dkt. No. 88 at 3.

claims are based on publicly disclosed allegations. See U.S. ex rel. Atkinson v. Pa. Shipbuilding Co., 255 F. Supp. 2d 351, 369 (E.D. Pa. 2002), aff'd on other grounds, 473 F.3d 506 (3d Cir. 2007).

In some cases, courts have conducted a claim-by-claim analysis by looking at each count of the complaint. See id. Of course, I am not bound by the formal structuring of the counts of a complaint. For example, a plaintiff might lump multiple claims together into one count. See U.S. ex rel. Davis v. Prince, 753 F. Supp. 2d 569, 578 (E.D. Va. 2011), citing U.S. ex rel. Boothe v. Sun Healthcare Grp., Inc., 496 F.3d 1169, 1177 (10th Cir. 2007) (separating claims from a single count that included a laundry list of claims where each claim alleged a separate fraudulent scheme). Alternatively, despite a complaint's division of separate statutory causes of action into separate counts, only a single "claim" or "theory" of wrongdoing may actually exist. See U.S. ex rel. Kennedy v. Aventis Pharm., Inc., No. 03-2750, 2007 WL 3145010, at *1 (N.D. Ill. Oct. 23, 2007) (finding that although an off-label promotion complaint included separate counts for causing the submission of false claims, the making of false statements causing the submission of false claims and conspiracy to submit false claims, the complaint simply alleged "three separate iterations" of the same claim).

In other qui tam cases in this district kickback allegations have been considered to make separate claims from off-label marketing allegations. U.S. ex rel. Galmines v. Novartis Pharm. Corp., No. 06-3213, 2013 WL 2649704, at *10 (E.D. Pa. June 13, 2013) (holding in the first-to-file context that "the claim-by-claim analysis adopted by LaCorte indicates . . . [the plaintiff's] off-label marketing claim should proceed even if the first-to-file rule bars his kickback allegations from moving forward"). Additionally, conspiracy allegations have been considered to create separate claims from an underlying allegation of the submission of false claims. See

Atkinson, 255 F. Supp. 2d at 369; see also Gross ex rel. U.S. v. AIDS Research Alliance-Chicago, No. 01-8182, 2004 WL 905952, at *9 (N.D. Ill. Apr. 27, 2004), aff'd on other grounds sub nom. U.S. ex rel. Gross v. AIDS Research Alliance-Chicago, 415 F.3d 601 (7th Cir. 2005) (same). In this case, I find that it is appropriate to compare each theory of recovery arising under the FCA pled in plaintiffs' complaint, which are separately alleged as Counts I-IV, with the allegations disclosed in the Cestra second amended complaint.

A. Original Source

First, I will consider whether plaintiffs are original sources of the information underlying their claims because the public disclosure bar does not apply to original sources. Cephalon contends that neither relator Boise nor relators Augustine and Dufour are original sources of any of the Fentora allegations contained in their second amended complaint. First, Cephalon contends that Boise is not an original source of plaintiffs' Fentora claims because Boise was not employed at Cephalon during the relevant time period when Fentora was introduced and marketed. Second, Cephalon contends that plaintiffs' second amended complaint alleges that Augustine and Dufour have knowledge regarding the promotion of Provigil and Nuvigil and thus they cannot be original sources with regard to plaintiffs' Fentora allegations. Plaintiffs do not argue that Augustine and Dufour are original sources with regard to their Fentora claims. Instead, plaintiffs claim that Boise is an original source of their Fentora allegations and that his knowledge is based upon his own "investigation" in which he learned information from company "insiders" and former Cephalon employees. See Dkt. No. 88 at 6-7.

The first requirement under § 3730(e)(4)(B) is that an original source must have "direct" knowledge of the alleged fraudulent conduct. See U.S. ex rel. Paranich v. Sorgnard, 396 F.3d 326, 335 (3d Cir. 2005). An original source need not have knowledge of every element

underlying his claims, but at least the “most critical element of [his] claims.” U.S. ex rel Mistick PBT v. Hous. Auth. of City of Pittsburgh, 186 F.3d 376, 388 (3d Cir. 1999). While it is possible for a non-insider to have direct knowledge of an organization’s fraud, I am “mindful of suits based only on secondhand information, speculation, background information or collateral research.” Atkinson, 473 F.3d at 523 (citation omitted).

The Court of Appeals has strictly construed the direct knowledge requirement. Direct knowledge is “marked by the absence of an intervening agency, instrumentality, or influence: immediate.” U.S. ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v. Prudential Ins. Co., 944 F.2d 1149, 1160 (3d Cir. 1991) (holding that the plaintiff could not have “direct” knowledge because plaintiff’s information came through intermediaries). Direct knowledge is based only on “first-hand” information. See Zizic, 728 F.3d at 239 (citations omitted). Furthermore, it is not “derivative of the information of others.” U.S. ex rel. Feldstein v. Organon, Inc., 364 F. App’x 738, 743 (3d Cir. 2010) (citation omitted).

A relator who claims direct knowledge of events that occurred after he left his workplace and merely relies upon contact with former colleagues does not have direct knowledge of his allegations. See U.S. ex rel. Repko v. Guthrie Clinic, P.C., No. 04-1556, 2011 WL 3875987, at *16 (M.D. Pa. Sept. 1, 2011), aff’d, 490 F. App’x 502 (3d Cir. 2012) (finding that a relator “cannot allege that he had direct and independent knowledge of the information contained in the complaint produced after he left” his workplace despite relator’s “claims to have kept in close contact with his former colleagues”); see also Rockwell International Corp. v. United States, 549 U.S. 457, 475 (2007) (finding that relator was not original source “[b]ecause [the relator] was no longer employed by [the defendant] at the time” and thus he could not have direct and independent knowledge of the factual allegations underlying his claim).

Cephalon employed Boise in sales representative and management positions from 1996 until he was terminated in June 2003. See Dkt. No. 69 at ¶ 20. The FDA approved Fentora for the treatment of breakthrough cancer pain in 2006. Id. at ¶ 4. Plaintiffs’ claim that defendants’ marketed Fentora off-label could arise only after the FDA approved the marketing of Fentora at all. Thus, the claims plaintiffs assert with respect to Fentora cannot be a product of Boise’s first-hand information but can only be derived from intervening sources within Cephalon. Further, plaintiffs do not cite a single case from this Circuit to support their argument that Boise qualifies as an original source of their allegations solely based on his investigation. Thus, Boise can hardly be considered an original source of the essential elements of plaintiffs’ Fentora claims.

Furthermore, plaintiffs’ second amended complaint seems not even to allege as much. While previous versions of the complaint alleged that Boise derived information from “personal knowledge, discussions with former Cephalon employees, and relevant documents,” see Dkt. No. 1 at ¶ 2, Dkt. No.14 at ¶ 2, in their second amended complaint plaintiffs do not allege any basis for Boise’s knowledge. Rather, they simply state in a conclusory fashion that “Relator Boise has direct and independent knowledge of the allegations and transactions herein.” See Dkt. No. 69 at ¶ 21. Similarly, plaintiffs allege no basis for any knowledge that Augustine and Dufour might have regarding Fentora. See id. at ¶¶ 22-25. Thus, I find that plaintiffs are not original sources of the information that forms the basis of their Fentora claims.

B. “Based Upon”

1. Threshold Issues

Now I address whether the claims in plaintiffs’ second amended complaint are “based upon” the public disclosures in the Cestra second amended complaint. “To be ‘based upon’ the publicly revealed allegations or transactions the complaint need only be ‘supported by’ or

‘substantially similar to’ the disclosed allegations and transactions.” Atkinson, 473 F.3d at 519. Furthermore, the public disclosure bar covers actions “even partly based upon such allegations or transactions.” Zizic, 728 F.3d at 238 (citations omitted). This interpretation comports with the understanding that “the threshold ‘based upon’ analysis is intended to be a quick trigger for the more exacting original source analysis.” U.S. ex rel. Precision Co. v. Koch Indus., Inc., 971 F.2d 548, 552 (10th Cir. 1992).

The parties do not apparently dispute that plaintiffs’ second amended complaint contains identical language and details borrowed directly from the Cestra complaint. See Dkt. No. 77 at 7-9. Indeed, a comparison of the identical language contained in both complaints runs 33 pages in length. See Dkt. No. 77, Ex. C. Thus, plaintiffs do not attempt to demonstrate that each of their claims do not include publicly disclosed allegations from the Cestra second amended complaint. Instead, plaintiffs advance two related arguments. First, plaintiffs argue that Cephalon “cannot argue that Relator Boise based his original Fentora allegations on anything alleged by Cestra” because Boise’s original complaint preceded the Cestra second amended complaint. See Dkt. No. 88 at 3. Second, plaintiffs contend that the public disclosure bar is inapplicable “to an amended complaint that merely added details to a core allegation of fraud that the relator first pled before any alleged public disclosure.” Id. Instead, they contend the public disclosure bar is only applicable to “distinct claims that relators gleaned from publicly available sources and then newly asserted in an amended complaint.” Id.

As to plaintiffs’ first argument, if “‘based upon’ meant ‘actually derived’ from, then this argument would [be] persuasive.” U.S. ex rel. Waris v. Staff Builders, Inc., No. 96-1969, 1999 WL 788766, at *7 (E.D. Pa. Oct. 4, 1999). The Court of Appeals, however, “specifically rejected the ‘actually derived’ test in favor of a stricter standard.” Id. Instead, “[t]o be ‘based

upon' the publicly revealed allegations or transactions the complaint need only be 'supported by' or 'substantially similar to' the disclosed allegations and transactions." Atkinson, 473 F.3d at 519.

The public disclosure bar "applies to amended pleadings that rely on publicly disclosed information coming after the complaint but before the amended pleading that is based upon them." Bannon v. Edgewater Med. Ctr., 406 F. Supp. 2d 907, 924 (N.D. Ill. 2005) (emphasis omitted) ("There is no principled difference between a complaint based upon information contained in public disclosures (of which [the relator] was not a source) and an amended complaint that is based upon and can only be sustained by resort to that information. The goal of prohibiting parasitic suits requires application of the public disclosure bar in the latter case no less than in the former."). Indeed, in U.S. ex rel. Montgomery v. St. Edward Mercy Medical Center, "[r]elators argue[d] that the alleged public disclosure occurred after the filing of the original complaint and therefore d[id] not trigger the public disclosure inquiry." No. 05-00899, 2007 WL 2904111, at *7 (E.D. Ark. Sept. 28, 2007). The Court rejected that argument, reasoning that it "appears to be the consensus view of every court to consider the issue" that the public disclosure bar applies to an amended complaint filed after a public disclosure even if the public disclosure occurred after the filing of the original complaint. Id. at *8.

Similarly, in Atkinson, the plaintiff argued that "pre-public disclosure allegations . . . cannot be 'based upon' subsequent public disclosures no matter how similar they may be . . . [because] the repetition of those same allegations in subsequent pleadings can not render them . . . any more 'based upon' the intervening disclosures than they were at the earlier time of their first assertion." 255 F. Supp. 2d at 371. Addressing the plaintiff's argument, the Court concluded that "wholly beside the point . . . is a relator's own previous assertion of the relevant

allegation or transaction in a prior action or his previous discovery of such via non-public means.” Id. at 373.

Indeed, in Rockwell, 549 U.S. at 473, the Supreme Court “held that an amended complaint had to satisfy the jurisdictional requirement that a *qui tam* claim not be based on publicly disclosed material unless the relator is an original source, regardless of whether the original complaint had cleared the public disclosure bar.” U.S. ex rel. Palmieri v. Alpharma, Inc., 928 F. Supp. 2d 840, 851 (D. Md. 2013) . Thus, “plaintiff[s]’ argument based on the timing of [the] first complaint [in this action] must . . . be rejected.” Waris, 1999 WL 788766, at *7.

I also reject plaintiffs’ second argument that the public disclosure bar does not apply to amended complaints that incorporate publicly disclosed factual allegations, as opposed to entirely new legal claims. Plaintiffs cite no case law in support of their position. Defendants primarily rely upon Waris, in which I dismissed an amended complaint that incorporated allegations arising from a public disclosure that occurred after the filing of the plaintiff’s original complaint. See Waris, 1999 WL 788766. There, Waris brought a *qui tam* action under the FCA alleging that the defendant had submitted false claims for reimbursement from Medicare for consulting services Waris had performed. See id. at *2. Waris based his claim on a single false invoice the defendant had given him. See id. I dismissed the plaintiff’s original complaint under Rule 9(b) for failure to plead fraud with sufficient particularity, but granted leave for Waris to amend his complaint. See id. Waris filed an amended complaint, but included information from a government audit report disclosed after Waris brought his action but before he filed his amended complaint. See id. at *3. That audit report concluded that the defendant had improperly claimed over six million dollars in Medicare reimbursements. See id. I found that Waris’s amended complaint was “based upon” the audit report for the purposes of the public

disclosure bar because they both “contain[ed] essentially the same allegation of fraud; namely, that defendant Staff Builders improperly claimed consulting expenses that were not Medicare reimbursable.” See id. at *7. Like plaintiffs here, Waris attempted to argue that his allegations could not be “based upon” the audit report because his original claims were not totally congruent with those in the audit report, thus implicitly saving his original claims from the public disclosure bar. I found that the lack of complete congruence did not save Waris’s claims and that a contrary finding would undermine the policy purposes underlying the public disclosure bar. Id.

Other courts agree that the public disclosure bar applies to the addition of publicly disclosed allegations in an amended complaint to support claims first asserted in an original complaint. See Montgomery, 2007 WL 2904111, at *9 (E.D. Ark. Sept. 28, 2007) (rejecting proposition that relators can amend a complaint and “use records later obtained from the Government over a broad period of time to mine for facts to support a False Claims Act case . . . This is the very danger for which § 3730(e)(4) was enacted to prevent”); Gross, 2004 WL 905952, at *7-8 (applying the public disclosure bar to the plaintiff’s second amended complaint that added publicly disclosed factual allegations to substantiate claims after the plaintiff’s original complaint was dismissed under Rule 9(b)); Bannon, 406 F. Supp. 2d at 924, 926 (applying public disclosure bar where the third amended complaint told “much the same story as those that came before it” but incorporated publicly disclosed materials after the Court found the plaintiff’s second amended complaint had failed to plead fraud with sufficient particularity and noting that the “third amended complaint makes it plain (and the relator’s responsive brief concedes) that the allegations added to overcome the previous dismissal are based upon publicly disclosed information”).

Of course, as in Waris, the issue of an amended complaint adding publicly disclosed allegations typically arises in the procedural posture where a court has already dismissed the plaintiff's original complaint with leave to amend, after which the plaintiff re-pleads his or her claims by amended complaint with the addition of factual details that have been publicly disclosed after the dismissal of the original claims. Here, Boise initially pled claims with bare factual allegations to support them and then amended the complaint to incorporate factual allegations based upon public disclosures in anticipation of, rather than response to, a motion to dismiss under Rules 12(b)(6) and 9(b). I see no reason, however, and have been provided none by plaintiffs, why an amended complaint in this posture should be excepted from the public disclosure bar. Further, applying the public disclosure bar here supports the "dual goals of encouraging whistle-blowers while discouraging parasitic suits because the putative relator is not sounding the alarm, but echoing it, and he does nothing to further the government's efforts to ferret out fraud." Waris, 1999 WL 788766, at *7 (citations omitted). Indeed, such a situation "seems to [me] a classic example of the 'opportunistic' litigation that the public disclosure bar is designed to discourage." Schindler, 131 S. Ct. at 1888.

2. Comparison of Complaints

I will now consider whether the claims plaintiffs advance in their second amended complaint are based upon allegations publicly disclosed in the Cestra second amended complaint. Initially, I note that generally "[p]laintiffs' [second amended c]omplaint reveals its dependence on the [Cestra] litigation on its face, quoting extensively from the case." U.S. ex rel Ward v. Commercial Metals Co., No. 05-56, 2007 WL 1390612, at *7 (S.D. Tex. May 9, 2007).

Count I of plaintiffs' second amended complaint alleges that defendants violated 31 U.S.C. § 3729(a)(1)(A) by knowingly presenting or causing to be presented to the government

false or fraudulent claims for payment. This claim is clearly “supported by” and at least “partly based” upon the allegations regarding defendants’ off-label promotion of Fentora disclosed in the Cestra second amended complaint. First, both complaints claim that defendants engaged in a widespread off-label promotion effort for Fentora and the specific allegations underlying that claim are substantially similar. Additionally, allegations that were not present at all in the Boise first amended complaint but appear in plaintiffs’ second amended complaint are clearly copied from the Cestra second amended complaint. For example, plaintiffs’ second amended complaint incorporates the Cestra complaint’s allegation that Cephalon used journal supplements to promote Fentora off-label. Plaintiffs’ complaint also copies substantial details from the Cestra complaint regarding the FDA’s monitoring history with the off-label promotion of Fentora.

Finally, plaintiffs also plead a violation of the FCA in Count I through defendants alleged use of kickbacks. See Dkt. No. 69 at ¶¶ 405-415. Plaintiffs’ kickback allegations based upon the Fentora Reimbursement Program, however, did not exist in Boise’s first amended complaint and are instead copied from Cestra’s second amended complaint. Although not exhaustive, this comparison demonstrates that Count I of plaintiffs’ second amended complaint is based upon publicly disclosed allegations in the Cestra second amended complaint. Accordingly, Count I is precluded by the public disclosure bar with regard to the medication Fentora.

Count II of plaintiffs’ second amended complaint alleges that defendants violated 31 U.S.C. § 3729(a)(1)(B) when they knowingly made, used or caused to be made or used, false or fraudulent records or statements that were material to the payment of a false or fraudulent claim and that the claims were actually paid or approved in violation of 31 U.S.C. § 3729(a)(2). This count primarily appears to be based upon plaintiffs’ kickback allegations and their allegation that defendants made false statements in required reporting pursuant to Cephalon’s Corporate

Integrity Agreement. See Dkt. No. 69 at ¶¶ 405-15, 398-99. As discussed above, plaintiffs' kickback allegations are primarily copied from the Cestra second amended complaint.

Additionally, the Corporate Integrity Agreement allegations were not a part of Boise's first amended complaint and were disclosed in the Cestra second amended complaint. Thus, Count II of plaintiffs' second amended complaint is based upon publicly disclosed allegations in the Cestra second amended complaint and is precluded by the public disclosure bar with regard to the medication Fentora.

Count III of plaintiffs' second amended complaint alleges that defendants knowingly conspired with Takeda Pharmaceuticals to commit the violations alleged in Counts I and II. However, this count relies exclusively upon allegations contained in plaintiffs' second amended complaint regarding defendants' promotion of Provigil, not Fentora. See Dkt. No. 69 at ¶¶ 449-52. Thus, I need not consider whether the public disclosure of Fentora allegations in the Cestra second amended complaint bars Count III because, by its terms, plaintiffs' second amended complaint does not make any factual allegations that Cephalon conspired with Takeda to promote Fentora off-label. Thus, the public disclosure bar does not preclude Count III of plaintiffs' second amended complaint in so far as it does not relate to the medication Fentora.

Count IV of plaintiffs' second amended complaint alleges that defendants violated 31 U.S.C. § 3729(a)(1)(G) when they knowingly made or used false records or statements material to an obligation to pay or transmit money or property to the Government and concealed, avoided, or decreased that obligation. It is unclear which allegations contained in plaintiffs' second amended complaint are intended to support this claim. However, this entire claim was not contained in the Boise first amended complaint and only first appeared in the Cestra second amended complaint. Plaintiffs appear to have simply copied this theory of relief from the Cestra

complaint. Indeed, this is the exact kind of impermissible claim-copying plaintiffs attempt to distinguish in their response. See Dkt. No. 88 at 3. Thus, I find that Count IV of plaintiffs' second amended complaint is based upon the publicly disclosed claims of the Cestra second amended complaint to the extent that plaintiffs' claims in Count IV relate to Fentora.

Thus, I conclude that plaintiffs' Fentora claims in their second amended complaint are based upon allegations contained in the Cestra second amended complaint.

CONCLUSION

For the reasons set forth above, I will grant Cephalon's motion to dismiss plaintiffs' Fentora claims.

An appropriate Order follows.

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

UNITED STATES OF AMERICA ex rel.	:	CIVIL ACTION
BRUCE BOISE, et al.	:	NO. 08-287
	:	
v.	:	
	:	
CEPHALON, INC., et al.	:	

ORDER

AND NOW, this 9th day of October, 2014, upon consideration of the motion to dismiss by defendant Cephalon, Inc. (Dkt. No. 77) and plaintiffs' response (Dkt. No. 88), and consistent with the accompanying memorandum of law, it is ordered that Cephalon's motion is GRANTED and plaintiffs' Fentora claims are DISMISSED.

s/Thomas N. O'Neill, Jr.

THOMAS N. O'NEILL, JR., J.