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

PATRICK LUPINETTI, Plaintiff, v. EXELTIS USA, INC.; AVION PHARMACEUTICALS, LLC; MISSION PHARMACAL COMPANY; VERTICAL PHARMACEUTICALS, LLC; and WOMEN'S CHOICE PHARMACEUTICALS LLC, Defendants.	No. 19 C 825 Judge Thomas M. Durkin

MEMORANDUM OPINION AND ORDER

Defendants manufacture prenatal vitamins. Patrick Lupinetti alleges that Defendants "mislabel[] and mispresent[] their [prenatal vitamins] as 'Rx' or prescription only" to ensure coverage under Medicaid, and that these alleged misrepresentations violate the False Claims Act. Defendants have moved to dismiss for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6). R. 46. That motion is granted.

Legal Standard

A Rule 12(b)(6) motion challenges the "sufficiency of the complaint." *Berger v. Nat. Collegiate Athletic Assoc.*, 843 F.3d 285, 289 (7th Cir. 2016). A complaint must provide "a short and plain statement of the claim showing that the pleader is entitled to relief," Fed. R. Civ. P. 8(a)(2), sufficient to provide defendant with "fair notice" of the claim and the basis for it. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

This standard "demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). While "detailed factual allegations" are not required, "labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555. The complaint must "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570). "'A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Boucher v. Fin. Sys. of Green Bay, Inc.*, 880 F.3d 362, 366 (7th Cir. 2018) (quoting *Iqbal*, 556 U.S. at 678). In applying this standard, the Court accepts all well-pleaded facts as true and draws all reasonable inferences in favor of the non-moving party. *Tobey v. Chibucos*, 890 F.3d 634, 646 (7th Cir. 2018).

Background

The Center for Medicare & Medicaid Services ("CMS") administers Medicaid. For Medicaid to cover a certain drug, the drug manufacturer must enter into a rebate agreement with CMS. Drugs covered by Medicaid are known as "covered outpatient drugs," or "CODs."

States participating in Medicaid are permitted to exclude or restrict coverage of certain CODs. *See* 42 U.S.C. § 1396r-8(d). However, states are prohibited from excluding "prescription . . . prenatal vitamins" from coverage. *Id.* § 1396r-8(d)(2)(E).

Lupinetti alleges that Defendants falsely label and identify their prenatal vitamins as requiring prescriptions so that state Medicaid programs cannot exclude

them from coverage. He alleges Defendants make these false statements by including the mark "Rx" or phrase "prescription only" on their products and by reporting them as such to CMS, causing the government to pay for their coverage under Medicaid.

Lupinetti also alleges that Defendants falsely state their prenatal vitamins are approved by the U.S. Food and Drug Administration. He alleges Defendants make these false statements by: (1) identifying their products with "National Drug Codes," which are allegedly only available for FDA-approved products; (2) identifying their products to CMS with the "Drug Type Indicator" of "1 = Rx," again to claim prescription status; and (3) reporting an FDA "approval date" for their prenatal vitamins. Lupinetti alleges that the FDA prohibits the use of these identifiers on any product that is not an FDA-approved drug.

Lupinetti does not explain how Defendants would benefit by misrepresenting that their prenatal vitamins are FDA-approved. Indeed, he argues in his brief that this "case is not about 'FDA-approval' status." R. 52 at 16.

Lastly, Lupinetti alleges that Defendants also make these misrepresentations about prescriptions and FDA approvals to private companies that compile "compendia" of information about drugs. According to Lupinetti, "Medicaid and other government healthcare programs rely on drug compendia companies for obtaining drug information, electronically processing claims, and automatically calculating reimbursement amounts." R. 20 ¶ 66.

Lupinetti worked for a compendia company called First Databank. Prior to working for First Databank, Lupinetti was an Assistant Attorney General in the New

York Medicaid Fraud Control Unit for more than 20 years. Lupinetti alleges that he was able to discover Defendants' alleged misrepresentations regarding prenatal vitamins by applying his experience as a Medicaid fraud investigator to the information Defendants submitted to First Databank.

Analysis

The False Claims Act permits private citizens to file a civil action on behalf of the government to recover money that the government paid based on false or fraudulent claims. 31 U.S.C. § 3730(b)(1). "To establish civil liability under the [FCA], [a plaintiff] generally must prove (1) that the defendant made a statement in order to receive money from the government; (2) that the statement was false; and (3) that the defendant knew the statement was false." *U.S. ex rel. Yannacopoulos v. Gen. Dynamics*, 652 F.3d 818, 822 (7th Cir. 2011).[1]

I. Public Disclosure Bar

An FCA complaint must be dismissed if:

> substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed . . . in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation [or] from the news media, unless . . . the person bringing the action is an original source of the information. . . .
>
> "[O]riginal source" means an individual who . . . has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who

[1] Specifically, these statutes prohibit "knowingly present[ing], or caus[ing] to be presented, a false or fraudulent claim for payment," and "knowingly mak[ing] or us[ing] . . . a false record or statement material to a false or fraudulent claim" paid by the government. *See* 31 U.S.C. §§ 3729(a)(1)(A), (B); 740 ILCS 175/3(a)(1)(A), (B).

> has voluntarily provided the information to the Government before filing an action under this section.

31 U.S.C. § 3730(e)(4). The Seventh Circuit has explained that applying this "public disclosure bar" requires the following three-step analysis:

> [F]irst examine whether the allegations in the complaint have been "publicly disclosed" through one of the enumerated channels. If so, ... determine whether the . . . lawsuit is "based upon," i.e., "substantially similar to," those publicly disclosed allegations. If it is, the public-disclosure bar precludes the action unless "[the plaintiff] is an 'original source' of the information upon which [the] lawsuit is based."

Cause of Action v. Chi. Trans. Auth., 815 F.3d 267, 274 (7th Cir. 2016). "The [plaintiff] bears the burden of proof at each step of the analysis." *Id.* The public disclosure bar "is a jurisdictional requirement that must be addressed before a court can reach the merits of the FCA claims." *Bellevue v. Universal Health Servs. of Hartgrove, Inc.*, 867 F.3d 712, 716-17 (7th Cir. 2017).

A. Publicly Disclosed

The "allegations in a complaint are publicly disclosed when the critical elements exposing the transaction as fraudulent are placed in the public domain." *Cause of Action*, 815 F.3d at 274. "[M]aterial is in the public domain when the information is open or manifest to the public at large," or "where the facts disclosing the fraud itself are in the government's possession." *Id.* The Seventh Circuit has explained that "the public-disclosure bar removes jurisdiction only where one can infer, as a direct and logical consequence of the disclosed information, that the

defendant knowingly—as opposed to negligently—submitted a false set of facts to the Government." *Id.* at 279.

Defendants argue that the statements Lupinetti alleges are false were all made expressly in reports to the government or in public product labels and advertising. Defendants cite CMS and FDA websites they contend published Defendants' statements about prescription requirements and that their vitamins were not FDA approved. *See* R. 47 at 10. The Court cannot decipher the information in these websites. But that is of no moment because Lupinetti does not dispute that Defendants' labels and descriptions of their products are in the public domain. *See* R. 52 at 21-28 (Lupinetti's arguments against application of the public disclosure bar do not include an argument that Defendants government reports, advertising, and product labels were not in the public domain.)

Lupinetti argues, however, that these reports, advertisements, and labels do not disclose Defendants' fraud because "[n]one of Defendants' purported 'disclosures' actually disclose that Defendants' products should not have been labeled 'Rx' or 'Rx Only." R. 52 at 24. In other words, Lupinetti concedes that Defendants' statements about their products were made publicly but argues that knowledge of the statements' falsity requires information not contained in the statements themselves.

The problem with this argument is that the only information not contained in Defendants' statements necessary to reveal their alleged falsity is readily available in the relevant statutes and regulations. Under the Federal Food, Drug, and Cosmetic Act, Defendants' prenatal vitamins are categorized as "dietary supplements," as

opposed to "drugs." *See* 21 U.S.C. §§ 321(g), (ff) (separate definitions for "drugs" and "dietary supplements"); *see also* R. 20 ¶ 39 (Lupinetti expressly alleges that Defendants' vitamins are "dietary supplements," not "drugs."). Lupinetti argues that the relevant law permits only "drugs" to be labeled as "prescription only" or "FDA-approved," and prohibits application of such terms to "dietary supplements" like Defendants' prenatal vitamins. But Lupinetti offers no reason why CMS, an agency tasked with administering reimbursement for drugs as well as dietary supplements, would not be aware of relevant statutes and regulations. *See Cause of Action*, 815 F.3d at 279 (finding public disclosure because "the regulatory scheme here does not involve any qualitative judgments"). CMS is just as capable as Lupinetti, if not more so, of understanding that prenatal vitamins are not FDA-approved drugs. *See Bellevue*, 867 F.3d at 719 ("There is no reason that the government could not have made the same inference[.]"). The potential falsity of Defendants' statements can be gleaned simply by viewing the information Defendants included on their product labels and submitted to the government in light of the relevant statutes and regulations. Lupinetti's knowledge adds nothing. Thus, his allegations were publicly disclosed.

B. Original Source

Lupinetti argues that even if the allegations were publicly disclosed, he is an "original source" of the allegations because his analysis was necessary to reveal the falsity of Defendants' statements that was "hidden in plain sight." R. 52 at 27 (citing *U.S. ex rel. Osheroff v. Tenet Healthcare Corp.*, 2012 WL 2871264, at *3 (S.D. Fla.

July 12, 2012), and *U.S. ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1017 (7th Cir. 1999)). Unlike the plaintiffs in *Osheroff* and *Lamers*, however, Lupinetti does not allege that he uncovered any hidden information.

In *Osheroff*, the plaintiff alleged that a healthcare company was providing doctors with below market-rate office space and other financial benefits in exchange for referrals that the healthcare company then billed to federal healthcare programs. The plaintiff analyzed "otherwise innocuous, garden-variety real estate/financial information" to uncover the alleged kickbacks. 2012 WL 2871264, at *3.

In *Lamers*, the plaintiff alleged that a municipality was using its transit system to provide school bus service in violation of federal law. The plaintiff walked the bus routes and observed the buses following routes that revealed the violations. 168 F.3d at 1017.

In both cases, the underlying facts were in the public domain: i.e., the financial transactions in *Osheroff*, and the bus routes in *Lamers*. But work was necessary to show that those facts constituted violations of federal law: the *Osheroff* plaintiff had to examine the financial relationships between the doctors and the hospitals and determine that the rental agreements were below-market, among other analysis; the *Lamers* plaintiff literally had to walk the streets.

Lupinetti has not taken any comparable actions. The plaintiffs in both *Osheroff* and *Lamers* added new information to the facts that were already disclosed. Lupinetti has not added any new information to the already disclosed facts. He merely opines that the already disclosed facts constitute a violation of federal law. He argues that

his ability to recognize the violations is the work he has done to reveal the fraud. But the Seventh Circuit has explained that a plaintiff who merely "references . . . the statutes and regulations that support its legal theory of fraud" has made allegations that "are substantially similar to the publicly disclosed allegations," and thus such a plaintiff cannot be an original source. *See Cause of Action*, 815 F.3d at 282-83; *see also Bellevue*, 867 F.3d at 721 (7th Cir. 2017) ("In [*Cause of Action*], we found that because the plaintiff's allegations were 'substantially similar to' the publicly disclosed allegations, the plaintiff did not 'materially add' to the public disclosure and could not be an original source."). Lupinetti's opinion that Defendants' product labels and descriptions violate federal law does not make him an original source.

Therefore, the public disclosure bar requires dismissal of Lupinetti's complaint.

II. Scienter

Even if the public disclosure bar does not require dismissal here, Lupinetti has failed to plausibly allege scienter. "A party who submits a false claim to the government is on the hook for FCA liability only if it acted knowingly." *United States v. Supervalu Inc.*, 9 F.4th 455, 463 (7th Cir. 2021) (citing 31 U.S.C. § 3729(a)(1)(A)). The FCA defines knowingly to "mean that a person, with respect to information (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth

or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A).

In *Supervalu*, the Seventh Circuit applied this standard to allegations that pharmacies had improperly reported the "usual and customary" price of certain drugs to Medicaid as required by regulation. The court held that in the context of an FCA claim alleging violation of a regulatory regime, a defendant can show it lacked the requisite scienter if: "(a) it has an objectively reasonable reading of the statute or regulation and (b) there was no authoritative guidance warning against its erroneous view." 9 F.4th at 468; *see also id.* at 470 ("The FCA establishes liability only for knowingly false claims—it is not enough that a defendant suspect or believe that its claim was false.").

Lupinetti cites no statute or regulation preventing Defendants from labeling their prenatal vitamins as "prescription only." Indeed, CMS guidance expressly anticipates that some prenatal vitamins will be prescription only. In 2011, CMS issued guidance explaining that "non-prescription [over-the-counter] prenatal vitamins do not appear to meet the definition of a covered outpatient drug as set forth in section [1396r-8]," but "prescription prenatal vitamins continue to meet the definition of a covered outpatient drug and are rebate-eligible." CMS, Release No. 159 (Dec. 28, 2011), at 2.[2] Further, in 2014, CMS issued a "covered outpatient drug" code, Code 7, for prescription prenatal vitamins. *See* R. 55 at 3. CMS has instructed

[2] Available at https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-159.pdf.

manufacturers to use Code 7 in their rebate agreements when seeking Medicaid coverage for prescription prenatal vitamins. *See National Drug Rebate Agreement Reference Guide* (Dec. 22, 2020).[3] It is objectively reasonable for Defendants to interpret this guidance to permit them to label prenatal vitamins as "prescription only."

Lupinetti argues regardless of the CMS guidance, the FDA restricts the use of "prescription only," citing the Federal Food, Drug, and Cosmetic Act. That requires "drugs" to be "dispensed" only with a doctor's prescription if:

> (A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, [it] is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or
> (B) it is limited by an approved application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug[.]

21 U.S.C. § 353(b)(1). The Act also provides that the "act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale." *Id.* Lupinetti contends that Defendants' prenatal vitamins do not meet the statutory requirements to be prescription only, and so marking them as such constitutes "misbranding."

The problem with this argument is that, as discussed, the Act expressly distinguishes "drugs," which must be approved by the FDA, from "dietary supplements" like Defendants' prenatal vitamins. *See* 21 U.S.C. §§ 321(g), (ff). The

[3] Available at https://www.medicaid.gov/medicaid/prescription-drugs/downloads/ndra-ref-guide.pdf.

foregoing provision restricts what "drugs" can be labeled as prescription only. But it says nothing about "dietary supplements" like Defendants' prenatal vitamins.

Lupinetti cites several other provisions of the Federal, Food, Drug, and Cosmetic Act and its regulations restricting use of "National Drug Codes," the "Drug Type Indicator" of "1 = Rx," and FDA "approval dates." To the extent these provisions can be interpreted as limiting the use of these identifiers to "drugs," and prohibiting their use on non-drug products, CMS has instructed manufacturers to use them anyway. *See* CMS, Release No. 159 (Dec. 28, 2011), at 2 (referring to NDCs); CMS, *Drug Product Data: Web File Structure and Definitions* (Aug. 2018), at 2 (referring to "Drug Type Indicators").[4] Indeed, Lupinetti *alleges* that CMS "*requires* manufacturers to report an 'Approval Date' for their products, which is defined as 'The NDC or monograph approval date,'" and that "CMS *instructed* prenatal vitamin manufacturers to use a proxy date of September 30, 1990 for the FDA approval date." R. 20 ¶ 61 and n.5 (emphases added). And Lupinetti concedes that CMS has "for years" been reimbursing payments for prescription prenatal vitamins identified with this information. *See id.* ¶ 96.

All of these facts taken together show that Defendants had an objectively reasonable belief that they were legally permitted to describe their prenatal vitamins as "prescription only" and using FDA identifiers, and that there was no "authoritative guidance" to the contrary. These allegations, regulations, and reports show that

[4] Available at https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/recordspecficationanddefinitions.pdf.

Lupinetti has failed to plausibly allege that Defendants submitted claims for payment to the government knowing they were based on false statements. Indeed, there is an objectively reasonable argument that Defendants' statements were truthful or at least that they were made in accordance with express instructions from CMS.

Conclusion

Therefore, Defendants' motion to dismiss, R. 46, is granted. The case is dismissed without prejudice. However, Lupinetti may not immediately file an amended complaint. If Lupinetti believes he can cure the deficiencies described by the order, he should file a brief of no more than five pages explaining how he would amend his complaint, attaching his proposed amended complaint as an exhibit. Based on this submission, the Court will determine whether to permit Lupinetti to file an amended complaint. Lupinetti's counsel should contact the Courtroom Deputy by November 23, 2021 to state whether and when they plan to make this submission, or instead that the case should be dismissed. Defendants should not respond unless ordered by the Court.

ENTERED:

Thomas M Durkin

Honorable Thomas M. Durkin
United States District Judge

Dated: November 19, 2021