UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THE UNITED STATES of AMERICA, et al., *ex rel.* JULIE LONG,	)	
Plaintiffs,	)	**Civil Action No. 16-12182-FDS**
v.	)	
JANSSEN BIOTECH, INC.,	)	
Defendant.	)	

MEMORANDUM AND ORDER ON DEFENDANT'S MOTION FOR JUDGMENT ON THE PLEADINGS

SAYLOR, C.J.

This is a *qui tam* action alleging that a pharmaceutical company unlawfully provided free services to physicians who prescribed its medications. Relator Julie Long has sued defendant Janssen Biotech, Inc., a company that manufactures and sells Remicade and Simponi ARIA, two infusible medications used to treat various conditions. She contends that the services constituted alleged kickbacks in violation of 42 U.S.C. § 1320a-7b(b), which in turn resulted in the payment of false claims in violation of 31 U.S.C. § 3729(a).

Defendant has moved for a judgment on the pleadings under Fed. R. Civ. P. 12(c), contending that the complaint's allegations were disclosed during prior legal proceedings, and thus are barred. Relator responds that the public-disclosure bar does not apply here. For the following reasons, the motion will be denied.

I. Background

Janssen Biotech, Inc. is a wholly-owned subsidiary of Johnson & Johnson.[1] It manufactures and sells pharmaceutical products, including the biopharmaceuticals Remicade and Simponi ARIA. Relator Julie Long was an employee of Janssen from 2003 to February 2016, where she worked as an Area Business Specialist.

The second amended complaint alleges that Janssen provided free business advisory services to rheumatology and gastroenterology practices that prescribed and infused Remicade and Simponi ARIA. Janssen allegedly employed teams of practice advisers, including the relator, and hired outside consultants to provide those services, including presentations, advice, and customized analysis on how to run a profitable in-office infusion ("IOI") business.

According to the complaint, IOI practices derived significant value from those business support services, ranging from the management of a practice's full schedule to advisory consulting that allowed them to increase their profits on many other prescribed medications, apart from Remicade or Simponi ARIA. The complaint alleges that by providing those services, Janssen violated the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and caused physicians to submit false claims for reimbursement to Medicare and Medicaid in violation of the False Claims Act ("FCA"), 31 U.S.C. § 3729(a).

The relator first filed this suit on October 28, 2016, brought on behalf of the United States and 28 states. On August 9, 2019, the United States and the various states declined to intervene. On December 13, 2019, the court ordered the unsealing of the matter.

[1] The facts and procedural background are set forth in more detail in the court's Memorandum and Order on Defendant's Motion to Dismiss filed October 21, 2020. (ECF No. 75).

Defendant has now moved for judgment on the pleadings based on the public-disclosure bar of the FCA.

II. Legal Standard

A motion for judgment on the pleadings under Rule 12(c) differs from a motion to dismiss under Rule 12(b)(6) primarily because it is filed after the close of pleadings and "implicates the pleadings as a whole." *Aponte-Torres v. University of P.R.*, 445 F.3d 50, 54-55 (1st Cir. 2006). It is, however, treated similarly. *See id.* at 54. To survive a motion for judgment on the pleadings, a complaint must state a claim that is plausible on its face. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). For a claim to be plausible, the "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Id.* at 555 (internal citations omitted). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 556).

In determining whether a complaint satisfies that standard, a court must assume the truth of all well-pleaded facts and give the plaintiff the benefit of all reasonable inferences. *See R.G. Fin. Corp. v. Vergara-Nuñez*, 446 F.3d 178, 182 (1st Cir. 2006). In addition to well-pleaded facts, a court may consider documents incorporated by reference into the complaint, matters of public record, and facts susceptible to judicial notice. *Grajales v. Puerto Rico Auth.*, 682 F.3d 40, 44 (1st Cir. 2012). A court may also consider documents whose authenticity is not disputed by the parties and documents central to the plaintiff's claim, even when those documents are incorporated into the movant's pleadings. *Curran*, 509 F.3d at 44.

A court may only enter a judgment on the pleadings "only if the uncontested and properly considered facts conclusively establish the movant's entitlement to a favorable judgment." *Aponte-Torres*, 445 F.3d at 54.

III. Analysis

Defendant contends that the remaining claims in the complaint are barred by the public-disclosure bar of the statute, 31 U.S.C. § 3730(e)(4)(A).

The *qui tam* provisions of the FCA permit relators under some circumstances to reap substantial financial gains from violations of federal law, despite not having suffered any injury. "Although this financial incentive encourages would-be relators to expose fraud, it also attracts parasitic relators who bring FCA damages claims based on information within the public domain or that the relator did not otherwise discover." *U.S. ex rel. Duxbury v. Ortho Biotech Prods.*, 719 F.3d 31, 33 (1st Cir. 2013) ("*Duxbury II*") (quotations and citations omitted).

To strike a balance between encouraging whistleblowing and discouraging opportunistic behavior, the FCA contains a "public-disclosure bar." *Id.* The public-disclosure bar seeks to "prevent parasitic *qui tam* actions in which relators, rather than bringing to light independently discovered information of fraud, simply feed off of previous disclosures of public fraud." *U.S. ex rel. Duxbury v. Ortho Biotech Prods.*, 579 F.3d 13, 26 (1st Cir. 2009) ("*Duxbury I*").

The public-disclosure bar provides that courts "shall" dismiss claims arising under the FCA "if substantially the same allegations or transactions" were previously publicly disclosed:

> i. in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;
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> ii. in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or
>
> iii. from the news media,
>
> unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

31 U.S.C. § 3730(e)(4)(A).

The public-disclosure bar applies when "(1) 'there has been a prior, public disclosure of

fraud,' (2) 'that prior disclosure of fraud emanated from a source specified in the statute's public disclosure provision,' and (3) 'the relator's *qui tam* action is 'based upon' that prior disclosure of fraud.'" *U.S. ex rel. Banigan v. PharMerica, Inc.*, 950 F.3d 134, 142-43 (1st Cir. 2020) (quoting *U.S. ex rel. Poteet v. Bahler Med., Inc.*, 619 F.3d 104, 109 (1st Cir. 2010)).

A. Prior Actions

Defendant contends that the marketing techniques it employed to promote Remicade were disclosed during proceedings before this court in *In re Pharmaceutical Indus. Average Wholesale Price Litig.*, No. 01-12257 (D. Mass. 2001) ("*AWP*"). It also asserts that many of the same IOI practices were disclosed in two other proceedings: *U.S. ex rel. Heineman v. Johnson & Johnson*, No. 05-2633 (D.N.J. 2005) ("*Heineman*"), and *U.S. ex rel. Greer v. Johnson & Johnson d/b/a Centocor*, No. 07-1660 (D. Minn. 2007) ("*Greer*").[2]

AWP was a multidistrict litigation proceeding that focused on allegations that various pharmaceutical companies falsely reported the "average wholesale price" for several drugs to inflate the reimbursement paid by government and private payors for those drugs. In particular, Centocor (the prior name of Janssen Biotech) was alleged to have marketed Remicade infusions by promoting the "spread" between what physicians would pay to buy the product and the reimbursement they would receive based on the inflated wholesale price. (*AWP* Master Consolidated Compl., Def. Ex. A at 75-76).

During the *AWP* litigation, which included a bench trial, Centocor disclosed several of its marketing practices concerning Remicade. Among other things, it produced its "Remicade Practice Management Assistant" (Def. Ex. H) and the "Office Based Infusion Guide" (Def.

[2] The Court takes judicial notice of the proffered pleadings and transcripts as undisputed documents provided by the parties in connection with a Rule 12(c) motion. *U.S. ex rel. Winkelman v. CVS Caremark Corp.*, 827 F.3d 201, 208 (1st Cir. 2016).

Ex. I), both of which seemed to be intended to help physicians start and run an infusion practice. It appears that there were other disclosures of Centocor's programs to assist physicians. Defendant acknowledges, however, that none of those practices were specifically alleged in that proceeding to be fraudulent. (Def. Reply at 2).

Heineman was a *qui tam* action in the District of New Jersey filed in 2002. The government did not intervene. That complaint alleged, among other things, that the same marketing of a "spread" between the cost and reimbursement of Remicade was unlawful. (*Heineman* Compl., Def. Ex. N at 3-5). It also alleged various other improper marketing techniques, including the use of preceptorships, "reimbursement specialists," "business reviews," and "practice consultants." (*See id.* at 2-9). Some of those practices were generally alleged to have been "kickbacks." (*Id.* at 11). It did not allege how any of those services were provided to physicians. *Heineman* was dismissed in 2012 for the relator's failure to prosecute before any factual record had been developed.

Greer was another *qui tam* action, filed in the District of Minnesota in 2007. The government again did not intervene. That complaint largely alleged the same fraudulent pricing scheme and use of marketing techniques as in the other two proceedings, including the use of a "Practice Management Program" and other methods to encourage physicians' use of Remicade. (*Greer* Compl., Def. Ex. O). That action was eventually dismissed in 2011, again for failure to prosecute and before any factual record had been developed.

B. <u>Prior Public Disclosure of Fraud</u>

"A prior, public disclosure of fraud occurs 'when the essential elements exposing the particular transaction as fraudulent find their way into the public domain.'" *Poteet*, 619 F.3d at 110 (quoting *U.S. ex rel. Ondis v. City of Woonsocket*, 587 F.3d 49, 54 (1st Cir. 2009)). "A prior public disclosure may occur through any public document available on the docket in a civil

hearing." *U.S. ex rel. Est. of Cunningham v. Millennium Lab'ys of California, Inc.*, 713 F.3d 662, 670 (1st Cir. 2013). That disclosure must contain either "(1) a direct allegation of fraud, or (2) both a misrepresented state of facts and a true state of facts so that the listener or reader may infer fraud." *Poteet*, 619 F.3d at 110 (citations omitted). Those facts "may originate in different sources, as long as they 'lead to a plausible inference of fraud' when combined." *Winkelman*, 827 F.3d 201 at 208 (quoting *Ondis*, 587 F.3d at 54). "However, there is no public disclosure when the essential background information is publicly available but no allegation of fraud or true state of facts has been made publicly available." *U.S. ex rel. Nowak v. Medtronic, Inc.*, 806 F. Supp. 2d 310, 328 (D. Mass. 2011) (quotation omitted). "The ultimate inquiry . . . is whether the government has received fair notice, prior to the suit, about the potential existence of the fraud." *Winkelman*, 827 F.3d 201 at 208-09.

Defendant contends that *AWP*, *Heineman*, and *Greer* together disclosed two of the complaint's core allegations: that it helped establish infusion suites so that physician practices would administer its products, and that it helped those practices operate the infusion businesses. (Def. Mem. at 19-20). To support that contention, it points to 16 quotations, all of which appear to support the same basic background narrative—that defendant helped establish and operate infusion suites for medical practices. (*Id.* at 19-21).[3] According to defendant, that information, combined with the fact that "such education could have substantial independent value," and that the physicians who benefited from them "submitted claims to Medicare," are sufficient to infer the fraud alleged in this action. (Reply at 6).

[3] Those quotations are drawn from an assortment of pleadings, exhibits, trial exhibits, deposition testimony, and memoranda.

The basic problem with that argument is that it equates any prior disclosure of its marketing techniques to physicians with the disclosure of the kickback scheme alleged here. While it is correct that a prior disclosure need not spell out an allegation of fraud in precise terms, the facts disclosed must at least be sufficient to put the public on notice of the perpetration of the specific fraud at issue. Not all pharmaceutical marketing practices, of course, are fraudulent. Nor is it true that pharmaceutical companies cannot provide any assistance to physicians under any circumstances. And nothing in *AWP*, *Heineman*, or *Greer* provided clear evidence, much less a direct allegation, that the services defendant allegedly provided constituted unlawful kickbacks. Those disclosures did not allege that the services had independent value to prescribing physicians; that defendant targeted certain physicians with those services; or even that the services were provided free of charge to those physicians—all of which are key facts alleged in the complaint here. Instead, each of the prior proceedings was concerned with the practice of marketing the "spread" that physicians could achieve by purchasing and prescribing Remicade, not the provision of free business services.

It is true, of course, that the provision of any services, of any kind, by a pharmaceutical company to physicians raises the possibility that a kickback was paid. But information that merely raises a possible or potential concern cannot alone meet the requirements of the public-disclosure bar because without more it cannot lead to a "plausible inference of fraud." *Winkelman*, 827 F.3d at 208 (quoting *Ondis*, 587 F.3d at 54). Here, a reasonable individual considering all of the disclosures together—itself an unlikely prospect given the highly piecemeal nature of the information—would have had to guess that the disclosed services might be fraudulent, and conduct significant additional investigation to ascertain whether that was true. There was neither a direct allegation of the kind of fraud alleged here, nor a misrepresented state

of facts alongside a true state of facts that would have allowed an investigator to infer fraud from the materials alone. *See Nowak*, 806 F. Supp. 2d at 328.

In sum, disclosures of defendant's marketing practices in *AWP*, *Heineman*, and *Greer* were not sufficient to trigger the FCA's public-disclosure bar because they would not have put the government or any reasonable person on fair notice of the fraud alleged here. Accordingly, the motion will be denied.[4]

IV. Conclusion

For the foregoing reasons, defendant's motion for judgment on the pleadings is DENIED.

So Ordered.

/s/ F. Dennis Saylor IV
F. Dennis Saylor IV
Chief Judge, United States District Court

Dated: February 15, 2024

[4] Because the Court has determined that there was no prior public disclosure of fraud, it does not reach the remaining issues raised by the parties, including whether the relators in *Heineman* and *Greer* were "agents" of the government. However, the Court notes that even if the previous actions could be considered to be "prior public disclosures," they certainly do not contain "substantially similar" allegations that "ultimately target the same fraudulent scheme" alleged in this action, such that it is "based upon" any of those purported prior disclosures. *See Banigan*, 950 F.3d at 143 (quotations omitted).