**UNITED STATES DISTRICT COURT**
**MIDDLE DISTRICT OF FLORIDA**
**TAMPA DIVISION**

**UNITED STATES OF AMERICA,**
**et al., ex rel. SUNIL PATEL,**

**Plaintiffs,**

**v.** **Case No. 8:14-cv-120-T-33TGW**

**GE HEALTHCARE, INC.,**

**Defendant.**
_____/

**ORDER**

This matter comes before the Court upon consideration of Defendant GE Healthcare, Inc.'s ("GE") Motion to Dismiss the Third Amended Complaint and request for oral argument, filed on August 25, 2017 (Doc. # 77), GE's Unopposed Request for Judicial Notice, also filed on August 25, 2017 (Doc. # 78), and Relator Sunil Patel's ("Patel") Response in Opposition, filed on September 6, 2017 (Doc. # 80). The Request for Judicial Notice and the Motion to Dismiss are **GRANTED** as set forth more specifically below. The request for oral argument is **DENIED.**

## I. Background

GE operates 31 nuclear pharmacies in the United States. (Doc. # 73 at ¶ 7). Patel is a board-certified nuclear pharmacist who worked at GE's nuclear pharmacy in Tampa. (Id. at ¶ 6). In this action, Patel alleges that GE violated the

False Claims Act, 31 U.S.C. § 3729(a)(1), and parallel state statutes, by selling diluted and expired drugs and by artificially inflating the price of certain drugs. The relevant facts follow.

**A. Drug allegations**

A majority of Patel's allegations relate to the manner in which GE compounded and labeled radiopharmaceuticals. In the practice of pharmacy, "compounding" refers to "incorporating ingredients to create a finished product for dispensing to a patient or for administration by a practitioner." (Doc. # 73 at ¶ 28 (citing Fla. Admin. Code § 64B16-27.700)). Relevant here, the term "includes the preparation of nuclear pharmaceuticals[.]" (Id.).

Patel alleges that GE's nuclear pharmacies produce the radiopharmaceuticals at issue by "compounding an NDA reagent kit with an NDA radionuclide or an elution from an NDA generator." (Id. at ¶ 27). For instance, GE manufactures the drug Myoview by injecting radioactive Technetium 99 into cold vials to activate the drug. (Id. at ¶ 51). Unit doses are drawn from the vials, which are then sent to physicians and hospitals for use in cardiac imaging scans. (Id.).

The FDA-approved package insert for Myoview requires that the radioactivity injected into Myoview kits be limited to "up to 240 mCi [millicuries]." (Id. at ¶ 52). Nonetheless, GE

routinely injects radioactivity of up to and greater than 500 millicuries into Myoview kits. (Id. at ¶ 54).

Patel raises similar allegations with respect to six other radiopharmaceuticals that are also used as imaging agents: Sestamibi, MAG3, MAA, MDP, Mebrofenin, and HDP. (Id. at ¶¶ 68, 80, 88, 98, 106, 124). Patel maintains that GE's motive for injecting excess radioactivity is profit; the practice allows GE to obtain extra doses from each kit to sell to physicians and hospitals. (E.g., Id. at ¶ 55).

GE also routinely labels radiopharmaceuticals with an expiration time that is well beyond the time specified by the package insert, including the drugs Myoview, Sestamibi, MAG3, MAA, MDP, Sulfur Colloid, and HDP. (Id. at ¶¶ 68, 80, 88, 98, 114, 124, 143). In a similar vein, Patel alleges that GE uses expired Iodine-131 stock solution to make diagnostic capsules for thyroid uptake tests. (Id. at ¶ 133).

Patel maintains that the radiopharmaceuticals subject to the foregoing practices are not reimbursable by government programs because the drugs are compounded in violation of GE's state license (Id. at ¶¶ 41-43), the drugs are not safe, effective, or FDA-approved (Id. at ¶¶ 9, 12, 18, 46-47), and the drugs are "misbranded" and "adulterated" in violation of the Food, Drug and Cosmetic Act, 21 U.S.C. § 352(a) (Id. at ¶¶ 32, 34).

Because the radiopharamceuticals are not reimbursable, Patel alleges in Count I of the Third Amended Complaint that

GE caused physicians and hospitals to submit "false claims" for the drugs, in violation of 31 U.S.C. § 3729(a)(1)(A). (Doc. # 73 at ¶¶ 153-255). In Count II, Patel alleges that GE's labels and invoices falsely indicated that the drugs were FDA-approved, which constitutes a "false record or statement" material to a false claim, in violation of 31 U.S.C. § 3729(a)(1)(B). (Doc. # 73 at ¶¶ 256-267).

**B. Pricing allegations**

Within Count I, Patel further alleges that GE artificially inflated the reimbursement rate for Myoview and other drugs by providing false sales data to Medicare. (Doc. # 73 at ¶¶ 168, 183, 196, 210, 224, 235, 254).

Medicare determines the reimbursement rate for radiopharmaceuticals "based on the lower of the billed charge or 95 percent of the average wholesale price (AWP) as reflected in published sources (e.g., Red Book, Price Alert, etc.)." (Id. at ¶ 148). According to Patel, GE submitted false AWP data for Myoview to the Red Book. (Id. at ¶¶ 148-149). GE also provided false information about the number of unit doses obtained from a Myoview kit, which is used to calculate the per-unit reimbursement rate. (Id. at ¶ 150).

**II. Procedural History**

On January 17, 2014, Patel filed this action under seal as relator for the United States and Florida, California,

Colorado, Connecticut, Delaware, District of Columbia, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Washington, and Wisconsin (collectively, "the States"). (Doc. # 1).

On March 23, 2017, the United States and the States declined to intervene. (Doc. ## 23, 25). After the Court lifted the seal, GE filed a Motion to Dismiss the Second Amended Complaint. (Doc. ## 24, 49). Before the Court ruled on the Motion, Patel requested and was granted leave to amend. (Doc. ## 70, 71).

On August 16, 2017, Patel filed the Third Amended Complaint ("TAC"), which is the operative pleading. (Doc. ## 71, 73). As noted, the TAC asserts two counts, each of which is brought pursuant to the federal False Claims Act and the States' parallel false claims acts. (Doc. # 73 at ¶¶ 153-267).

On August 25, 2017, GE filed the instant Motion to Dismiss with Prejudice. (Doc. # 77). Patel responds in opposition. (Doc. # 80). On September 7, 2017, the Court denied GE's request to file a reply. (Doc. ## 81, 82). Accordingly, the Motion to Dismiss is ripe for review.

## III. Legal Standard

On a motion to dismiss, the Court accepts as true all allegations in the complaint and construes the facts in the light most favorable to the plaintiff. Jackson v. Bellsouth Telecomms., 372 F.3d 1250, 1262 (11th Cir. 2004). Further, the Court favors the plaintiff with all reasonable inferences from the allegations in the complaint. Stephens v. Dep't of Health & Human Servs., 901 F.2d 1571, 1573 (11th Cir. 1990). However, the Supreme Court explains that:

> While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do. Factual allegations must be enough to raise a right to relief above the speculative level.

Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007) (internal citations omitted). A court is not "bound to accept as true a legal conclusion couched as a factual allegation." Papasan v. Allain, 478 U.S. 265, 286 (1986).

Rule 9(b) of the Federal Rules of Civil Procedure imposes more stringent pleading requirements on claims alleging fraud. Clausen v. Lab. Corp. of Am., Inc., 290 F.3d 1301, 1305 (11th Cir. 2002). The complaint must allege "facts as to time, place, and substance of the defendant's alleged fraud, specifically the details of the defendant['s] allegedly

fraudulent acts, when they occurred, and who engaged in them." Hopper v. Solvay Pharm., Inc., 588 F.3d 1318, 1324 (11th Cir. 2009).

## IV. Discussion

Enacted in 1863, the False Claims Act ("FCA"), 31 U.S.C. §§ 3729, et seq., "was originally aimed principally at stopping the massive frauds perpetrated by large contractors during the Civil War." Universal Health Servs., Inc. v. U.S. ex. rel. Escobar, 136 S. Ct. 1989, 1996 (2016) (internal quotation marks omitted). "Since then, Congress has repeatedly amended the Act, but its focus remains on those who present or directly induce the submission of false or fraudulent claims." Id. The FCA's civil penalties are "essentially punitive in nature" and subject defendants to treble damages plus penalties of up to $10,000 per claim. Id. (internal quotation marks omitted).

The FCA may be enforced by the government or by a relator through a qui tam action brought "in the name of the Government." 31 U.S.C. § 3730(b); Kellogg Brown & Root Servs., Inc. v. U.S. ex rel. Carter, 135 S. Ct. 1970, 1973 (2015). If a qui tam action results in recovery for the government, the relator shares in the award.

### A. Public-disclosure bar

A relator's ability to bring an FCA action is subject to certain limitations, including the public-disclosure bar in 31

U.S.C. § 3730(e)(4), which endeavors "to strike a balance between encouraging private persons to root out fraud and stifling parasitic lawsuits." Schindler Elevator Corp. v. U.S. ex rel. Kirk, 563 U.S. 401, 413 (2011).

In its current iteration, the public-disclosure bar requires a court to dismiss an FCA action "if substantially the same allegations or transactions" were previously disclosed in a prior federal action, in the news media, or in other specified sources. 31 U.S.C. § 3730(e)(4)(A) (2016). The current version applies to FCA claims that arise from billing on or after March 23, 2010. U.S. ex rel. Saldivar v. Fresenius Med. Care Holdings, Inc., 841 F.3d 927, 932 n.1 (11th Cir. 2016).

A number of Patel's allegations pertain to conduct commencing as early as 2004, and therefore implicate the prior version of the statute. (E.g., Doc. # 73 at ¶¶ 165, 183). That version imposes a jurisdictional bar when an FCA action is "based upon the public disclosure of allegations or transactions" in similar enumerated sources. 31 U.S.C. § 3730(e)(4)(A) (2009). Because the prior version is jurisdictional, the Court addresses the public-disclosure bar at the outset of this analysis. U.S. ex rel. Osheroff v. Humana Inc., 776 F.3d 805, 810 (11th Cir. 2015).

To determine whether the public-disclosure bar applies under either version of the statute, the Court considers:

(1) whether the allegations made by the relator have been publicly disclosed; (2) if so, whether the allegations are based on (or substantially the same as) the publicly-disclosed allegations; and (3) if so, whether the relator is an "original source" of the information as that term is defined in the FCA. Id. at 812, 814.

GE argues that Patel's allegations overlap with a federal action filed by relator James Wagel in 2006. (Doc. # 77 at 24). In the earlier action, Wagel, a sales representative for a competing pharmaceutical company, alleged that GE encouraged various healthcare providers to inject excess Technetium into Myoview when the providers prepared doses on-site. (Doc. # 78-2 at ¶¶ 7, 45-47, 52, 60, 67-74). Wagel alleged that GE artificially inflated the reimbursement rate for Myoview by failing to report the extra doses yielded by this practice. (Id. at ¶¶ 59-60).

Ultimately, the United States settled Wagel's action for $30 million. (Doc. # 78-4 at 1). The Department of Justice issued a press release stating that GE violated the FCA "by causing Medicare to overpay for Myoview." (Id.).[1]

The pleadings from Wagel's case and the press release are public disclosures within the meaning of § 3730(e)(4).

[1] GE submits an Unopposed Request for Judicial Notice of Wagel's pleadings and the news articles. (Doc. # 78). GE's request is granted. Osheroff, 776 F.3d at 811-812.

However, the Court finds that Patel's allegations are not "based on" or "substantially the same as" the allegations in the prior public disclosures.

Wagel's action challenged GE's practices as a manufacturer. Specifically, Wagel alleged that GE encouraged healthcare providers to inject excess radioactivity into Myoview at the providers' offices in order to obtain additional doses. By contrast, this action alleges that GE itself injected excess radioactivity, in GE's capacity as a nuclear pharmacy. As a result, the public-disclosure bar does not apply because the prior action did not allege that GE "in its capacity as a [pharmacy] actually engaged in wrongdoing." Cooper v. Blue Cross & Blue Shield of Fla., Inc., 19 F.3d 562, 567 (11th Cir. 1994) (holding that action against primary insurer was not barred by prior allegations against insurer in its role as payment intermediary).

Because Patel's allegations are not based on, or substantially the same as, the publicly-disclosed allegations, the Court is not required to reach the third question of whether Patel is an original source. U.S. ex rel. Williams v. NEC Corp., 931 F.2d 1493, 1500 (11th Cir. 1991). But even if the original-source inquiry were determinative, Patel qualifies as an original source.

The prior version of the FCA defined an "original source" as "an individual who has direct and independent knowledge of

the information on which the allegations are based." 31 U.S.C. § 3730(e)(4)(B) (2009). The Eleventh Circuit has interpreted the phrase "direct and independent knowledge" to require first-hand knowledge. Saldivar, 841 F.3d at 936. Here, the TAC demonstrates Patel's first-hand knowledge of GE's nuclear pharmacy scheme based on Patel's first-hand experience as a GE nuclear pharmacist. (E.g., Doc. # 73 at ¶¶ 54, 69-73, 80, 90, 133, 142-144).

The current version of the FCA defines an original source as someone "who has knowledge that is independent of and **materially adds** to the publicly disclosed allegations or transactions[.]" 31 U.S.C. § 3730(e)(4)(B) (2016) (emphasis added). The Court finds that Patel's allegations "materially add" to Wagel's action in part because Patel alleges that GE effectively continued the fraudulent scheme – through its own nuclear pharmacies – after settling Wagel's action. Jacobs v. Bank of Am. Corp., No. 1:15-CV-24585-UU, 2017 WL 2361943, at *7 (S.D. Fla. Mar. 21, 2017) (holding that allegations of continuing violations following a consent judgment materially added to prior public disclosures). Moreover, the TAC includes extensive allegations relating to GE's sale and use of expired radiopharmaceuticals, which is a separate pharmacy scheme that was not at issue Wagel's case.

Based on the foregoing, the Court holds that the instant action is not subject to the public-disclosure bar.

**B. Statute of limitations**

GE alternatively moves to dismiss a portion of the TAC as time-barred. Because this action was not filed until January 17, 2014, GE argues that claims prior to January 17, 2008 are barred pursuant to the FCA's six-year statute of limitations. (Doc. # 77 at 7-8); see 31 U.S.C. § 3731(b)(1) (stating that an FCA action may not be brought "more than 6 years after the date on which the violation of section 3729 is committed.").

In response, Patel contends that the FCA's ten-year tolling provision governs. (Doc. # 80 at 18-20). Pursuant to 31 U.S.C. § 3731(b)(2), an FCA action may be brought within:

> 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed[.]

31 U.S.C. § 3731(b)(2).

Courts are split as to whether the tolling provision applies to cases in which the government has declined to intervene, such as the instant case. United States v. Cochise Consultancy, Inc., No. 5:13-CV-02168-RDP, 2016 WL 1698248, at *2-3 (N.D. Ala. Apr. 28, 2016) (identifying a three-way split in authority); U.S. ex rel. Wood v. Allergan, Inc., No. 10-CV-5645 (JMF), 2017 WL 1233991, at *16-18 (S.D.N.Y. Mar. 31, 2017) (same); see also Stephen S. Stallings, Laura E. Caravello, Wait Not, Want Not: The Importance of the Statute

of Limitations in Qui Tam False Claims Act Cases, 7 Pitt. J. Envtl. Pub. Health L. 245, 259-272 (2013). The Eleventh Circuit has not issued a published decision addressing the issue.

GE fails to acknowledge, let alone address, the tolling provision. GE also concedes that some of the State's false claims acts include at least a ten-year limitations period. (Doc. # 77 at 8 n.10). Accordingly, absent a more focused challenge, the Court declines to dismiss at this juncture.

**C. Presentment of a false claim (Count I)**

GE next moves to dismiss Count I for failure to state a claim. In Count I, Patel alleges that GE violated 31 U.S.C. § 3729(a)(1)(A), which creates a right of action against any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." To establish a violation of § 3729(a)(1)(A), Patel must prove three elements: "(1) a false or fraudulent claim, (2) which was presented, or caused to be presented, for payment or approval, (3) with the knowledge that the claim was false." U.S. ex rel. Phalp v. Lincare Holdings, Inc., 857 F.3d 1148, 1154 (11th Cir. 2017).

The key issue under § 3729(a)(1)(A) is whether the defendant "presented or caused to be presented" a false claim. Urquilla-Diaz v. Kaplan Univ., 780 F.3d 1039, 1052 (11th Cir.

2015) (quoting Hopper, 588 F.3d at 1325-26). Patel "must allege the actual presentment of a claim . . . with particularity, meaning particular facts about the 'who,' 'what,' 'where,' 'when,' and 'how' of fraudulent submissions to the government." Id. at 1052 (internal quotation marks omitted).

"Providing exact billing data — name, date, amount, and services rendered — or attaching a representative sample claim is one way a complaint can establish" presentment of a false claim. U.S. ex rel. Mastej v. Health Mgmt. Assocs., Inc., 591 F. App'x 693, 704 (11th Cir. 2014). "However, there is no per se rule that an FCA complaint must provide exact billing data or attach a representative sample claim." Id. (citing Clausen, 290 F.3d at 1312 & n.21). Rather, a complaint must contain "some indicia of reliability" that a false claim was actually submitted. Clausen, 290 F.3d at 1311. For instance, a relator with first-hand knowledge of the defendant's billing practices may possess a sufficient basis for alleging that the defendant submitted false claims. Mastej, 591 F. App'x at 704.

At its most detailed, the TAC alleges that Patel spoke with two nuclear technicians who worked for two of GE's physician customers. (Doc. # 73 at ¶¶ 60, 62). One technician, Renee, worked for Dr. Ramulu Eligetti in Ocala. (Id. at ¶ 60). Renee told Patel that approximately 85% of Dr.

Eligetti's patients were comprised of Medicare and Medicaid beneficiaries. (Id.). Another technician, Toni, who worked for Dr. Sami Elchahal in North Tampa, told Patel that a "majority" of Dr. Elchahal's patients were comprised of Medicare and Medicaid beneficiaries. (Id. at ¶ 62).

Both Dr. Eligetti and Dr. Elchahal purchased Myoview from GE's Tampa pharmacy, and Patel alleges that the Myoview contained excess radioactivity because all Myoview was compounded with excess radioactivity. (Id. at ¶¶ 61, 63). Because Dr. Eligetti and Dr. Elchahal purchased Myoview for patients, and because a substantial number of their patients were Medicare or Medicaid beneficiaries, Patel argues that false claims were necessarily presented for payment to Medicare and Medicaid. (Doc. # 80 at 8-9).

These allegations fall well short of alleging "exact billing data." Mastej, 591 F. App'x at 704. Patel identifies no "particular facts about the 'who,' 'what,' 'where,' 'when,' and 'how' of fraudulent submissions to the government." Urquilla-Diaz, 780 F.3d at 1052 (quoting Hopper, 588 F.3d at 1325-26).

Instead, Patel contends that his allegations possess other "indicia of reliability" because he personally participated in GE's fraudulent scheme. (Doc. # 80 at 9). Yet, the Eleventh Circuit has repeatedly held that knowledge of an underlying scheme – even detailed knowledge – is not

sufficient to allege presentment. E.g., U.S. ex rel. Atkins v. McInteer, 470 F.3d 1350, 1358-59 (11th Cir. 2006); Clausen, 290 F.3d at 1311-12.

Patel relies on two other Eleventh Circuit cases, but each is readily distinguishable. In Matheny, the Eleventh Circuit held that a relator's allegations possessed the requisite indicia of reliability because the relator "personally participated in the manipulation" of account data submitted to the government, and the relator provided "detailed allegations of the accounting records . . . and his involvement with the patient accounts." U.S. ex rel. Matheny v. Medco Health Sols., Inc., 671 F.3d 1217, 1221, 1230 (11th Cir. 2012). Likewise, in Walker, the relator alleged that she received direct instructions about how to bill services and also had at least one personal conversation about the defendant's billing practices with an office manager. U.S. ex rel. Walker v. R&F Props. of Lake Cty., Inc., 433 F.3d 1349, 1360 (11th Cir. 2005). But in this case, the TAC pleads no similar facts demonstrating that Patel is familiar with the claims and billing process.

Perhaps recognizing the deficiency of his allegations under Eleventh Circuit precedent, Patel suggests that a "more flexible" pleading standard should apply when a qui tam defendant causes a third party to file false claims, as GE allegedly did in this case. (Doc. # 80 at 8). Patel relies

on cases from the First Circuit holding that a relator can satisfy Rule 9(b) "by providing factual or statistical evidence to strengthen the inference of fraud beyond possibility." U.S. ex rel. Duxbury v. Ortho Biotech Prods., 579 F.3d 13, 29 (1st Cir. 2009) (internal quotation marks omitted).

Patel fails to acknowledge that the Eleventh Circuit has rejected this approach. In Hopper, the relators alleged that the defendant's illegal marketing campaign for the drug Marinol induced physicians to write off-label prescriptions, which in turn caused pharmacies to submit false claims for reimbursement. 588 F.3d at 1326. Although the relators possessed no billing or claims data, they presented what they described as a "highly-compelling statistical analysis [that] renders inescapable the conclusion that a huge number of claims for ineffective off-label uses of Marinol resulted" from the illegal marketing campaign. Id. The Eleventh Circuit acknowledged the First Circuit line of cases, but held that the relators' failure to identify a single prescription or claim with particularity was fatal to their cause of action. Id. at 1326-27; accord U.S. ex rel. Keeler v. Eisai, Inc., 568 F. App'x 783, 796-798 (11th Cir. 2014).

Patel identifies no basis for this Court to depart from Hopper by applying a more lenient standard.[2] Moreover, even

[2] For this same reason, the Court rejects Patel's (continued...)

under the First Circuit's more flexible pleading standard, Patel's allegations are insufficient. In a recent case, the First Circuit emphasized that a relator must generally plead "specific medical providers who allegedly submitted false claims, the rough time periods, locations, and amounts of the claims, and the specific government programs to which the claims were made." U.S. ex. rel. Kelly v. Novartis Pharm. Corp., 827 F.3d 5, 13 (1st Cir. 2016). The First Circuit rejected as speculative a claim which – similar to Count I in this case — was premised on the bare facts that certain doctors received services from the defendants, the doctors were enrolled in federal reimbursement programs, and the doctors prescribed the drug at issue. Id. at 15.

Patel attempts to buttress his claim by alleging that two of the drugs at issue, Myoview and Sestamibi, are used for cardiac tests and "heart disease is the leading cause of death for Americans over the age of 65, the point at which Medicare coverage begins." (Doc. # 73 at ¶ 64). Patel also submits a report from the U.S. Government Accountability Office, which states that Myoview and Sestamibi were the two

[2](...continued)
reliance on a Fifth Circuit case, U.S. ex rel. Grubbs v. Kanneganti, 565 F.3d 180, 192 (5th Cir. 2009), which also announced a more lenient pleading standard. See Keeler, 568 F. App'x at 797 n.19 ("Although the Fifth Circuit in Grubbs criticized the stringent requirements of Clausen, subsequent cases decided by the Eleventh Circuit emphatically reaffirms the holding as binding precedent.")

radiopharmaceuticals that Medicare spent the most money on between 2003 and 2004. (Doc. # 80 at 10 n.5; Doc. # 80-1 at 4). Based on these facts, Patel argues that "many, if not most," of the Myoview and Sestamibi doses sold to Dr. Eligetti and Dr. Elchahal "likely were for Medicare beneficiaries and were billed to the Medicare program." (Doc. # 80 at 10).

To state a plausible claim under § 3729(a)(1)(A), Patel must do more than allege that it is "likely" that false claims were submitted to the government. Clausen, 290 F.3d at 1313. Once again, Patel's argument rests on "mere conjecture" and is not sufficient to allege presentment under Rule 9(b) pleading standards. Id.

Based on the foregoing, Count I is due to be dismissed. Because Patel fails to allege the presentment of any claim with particularity, the Court is unable to meaningfully address whether Patel adequately alleges that such a claim was "false" under the Ninth Circuit's recent decision in United States ex rel. Campie v. Gilead Sciences, Inc., 862 F.3d 890 (9th Cir. 2017), or based on another theory of falsity. The Court therefore declines to reach GE's alternative arguments regarding the element of falsity. (See Doc. # 77 at 12-16).

GE requests that Count I be dismissed with prejudice. (Doc. # 55 at 17-18). In response, Patel requests leave to amend. (Doc. # 80 at 6 n.3).

Pursuant to Fed. R. Civ. P. 15(a)(2), "[t]he court should freely give leave [to amend] when justice so requires." In light of the liberal policy favoring amendment, and because this Court has not previously issued any substantive ruling in this action, the Court will grant Patel one – and very likely only one – opportunity to amend. However, Patel is cautioned that he may only amend Count I if he is able to allege presentment of actual claims in good faith under Eleventh Circuit pleading standards.

**D. False statement material to a false claim (Count II)**

In Count II, Patel alleges a violation of 31 U.S.C. § 3729(a)(1)(B), which was formerly codified at 31 U.S.C. § 3729(a)(2). The prior version applies to claims for payment submitted before June 7, 2008, and therefore covers a portion of Patel's claim. Hopper, 588 F.3d at 1327 n.3. That version creates a cause of action against any person who "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government." 31 U.S.C. § 3729(a)(2) (2008).

Under this version of the statute, a relator is not required to allege presentment because the statutory language includes no express presentment requirement. Hopper, 588 F.3d at 1328. But a relator is required to allege that (1) the defendant intended that the government pay a false claim, and

(2) the government actually paid a false claim. Id. at 1327-28.

GE argues that Patel fails to allege with particularity either intent or actual payment of a false claim. (Doc. # 77 at 17-19). On the element of payment, Patel correctly points out that in Hopper, the Eleventh Circuit suggested that the First Circuit's more lenient pleading standard could apply to allegations of payment. 588 F.3d at 1329 (holding that Clausen and its progeny "do not necessarily foreclose the possibility that, for claims under subsection (a)(2), general allegations of improper government payments to third parties, supported by factual or statistical evidence to strengthen the inference of fraud . . . could satisfy the particularity requirements of Rule 9(b)").

But here, similar to Hopper, the Court need not resolve this issue because Patel fails to allege any facts sufficient to support the element of intent. Id. at 1329-30. Patel includes no allegations relevant to intent within Count II. (Doc. # 73 at ¶¶ 256-267). And in response to the Motion to Dismiss, Patel identifies no such allegations within the TAC. (Doc. # 80 at 11-12).

GE appears to suggest that the same elements of intent and payment are required under the current version of the statute, § 3729(a)(1)(B), which creates a cause of action against any person who "knowingly makes, uses, or causes to be

made or used, a false record or statement material to a false or fraudulent claim." (Doc. # 77 at 18 n.18). In contrast to § 3729(a)(2), the current version omits any reference to payment or intent.

In Hopper, the Eleventh Circuit declined to address the elements of a claim under the current version. 588 F.3d at 1329 n.4; see also Mastej, 591 F. App'x at 710 (again declining to address the issue). But in a recent published decision, the Eleventh Circuit held that "[t]o prove a claim under § 3729(a)(1)(B), a relator must show that: (1) the defendant made (or caused to be made) a false statement, (2) the defendant knew it to be false, and (3) the statement was material to a false claim." Phalp, 857 F.3d at 1154. Consistent with the revised statutory language, the Eleventh Circuit omitted any intent or payment requirement. Accordingly, absent some contrary authority, the Court is not persuaded that the requirements under § 3729(a)(2) are applicable to the portion of Patel's claims brought under § 3729(a)(1)(B).

GE alternatively argues that Patel fails to allege that the false statements or records were "material" to a false claim. (Doc. # 77 at 21-22). In particular, GE contends that a heightened materiality standard applies under Escobar, a 2016 Supreme Court decision. (Id. at 22).

In Escobar, the Supreme Court addressed the viability of the so-called "implied false-certification" theory of liability under § 3729(a)(1)(A) – not § 3729(a)(1)(B), which is the subsection at issue in Count II.[3] 136 S. Ct. at 1999. The Supreme Court first confirmed the prevailing view among the Circuits that a plaintiff could establish a "false claim" under § 3729(a)(1)(A) by showing that a defendant omitted information material to a claim. Id. Resolving a Circuit split, the Supreme Court also held that materiality is assessed under a "demanding" and "rigorous" standard. Id. at 2003-2004 & n.6.

In an implied-false certification case under § 3729(a)(1)(A), the materiality requirement is a judicially-imposed doctrine, which is designed to ensure that only significant omissions trigger the FCA's considerable penalties. But here, Patel brings Count II under § 3729(a)(1)(B), which expressly requires that false statements or records be "material" to a false claim. Notably, for this provision, the FCA specifically defines "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or

[3] In connection with the instant Motion, neither side addresses the viability of an implied-certification theory under § 3729(a)(1)(B), likely because GE does not directly challenge Patel's pleading of the "falsity" element for this claim.

property." 31 U.S.C. § 3729(b)(4); Rutledge v. Aveda, No. 2:14-CV-00145-AKK, 2015 WL 2238786, at *5 (N.D. Ala. May 12, 2015); U.S. ex rel. St. Joseph's Hosp., Inc. v. United Distributors, Inc., 918 F. Supp. 2d 1306, 1315 (S.D. Ga. 2013).

GE cites no case holding that Escobar's heightened definition of materiality applies to a claim under § 3729(a)(1)(B). Indeed, the Fourth Circuit has declined to alter its analysis under § 3729(a)(1)(B) following Escobar. United States v. Triple Canopy, Inc., 857 F.3d 174, 179 (4th Cir. 2017) (holding that the court's prior opinion, which applied § 3729(b)(4)'s materiality standard to a claim under § 3729(a)(1)(B), was not impacted by Escobar).

For the present, the Court reserves ruling on this unbriefed issue in light of a more fundamental problem with the TAC. As discussed, Count II implicates two versions of the statute, which in turn possess separate elements of proof. Accordingly, the Court dismisses Count II sua sponte in order for Patel to re-plead his claim in separate counts and to otherwise cure the deficiencies identified above. See U.S. ex rel. Graves v. Plaza Med. Ctrs. Corp., No. 10-23382-CIV, 2014 WL 5040284, at *4 (S.D. Fla. Oct. 8, 2014) (ordering relator to plead separate counts for each version of the statute). GE may renew its arguments, with citation to persuasive authority, on a subsequent motion.

**E. State claims**

In addition to alleged violations of the FCA, Patel alleges parallel violations of the States' false claims laws. GE moves to dismiss those claims for the same reasons identified above, and Patel offers no opposition. (Doc. # 77 at 27). Accordingly, the state-law claims in Counts I and II are dismissed without prejudice. Keeler, 568 F. App'x at 803.

**V. Conclusion**

Based on the foregoing, it is **ORDERED, ADJUDGED,** and **DECREED** that:

(1) GE's Unopposed Request for Judicial Notice (Doc. # 78) is **GRANTED**;

(2) GE's Request for Oral Argument (Doc. # 77 at 28) is **DENIED**;

(3) GE's Motion to Dismiss the Third Amended Complaint (Doc. # 77) is **GRANTED** as set forth more specifically herein. Counts I and II are dismissed without prejudice. Patel may file a Fourth Amended Complaint on or before **October 26, 2017**.

**DONE** and **ORDERED** in Chambers in Tampa, Florida, this 28th day of September, 2017.