UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 22-CV-60160-RAR

UNITED STATES OF AMERICA,
ex rel., **PATRICIA CROCANO**,

Plaintiff-Relator,

v.

TRIVIDIA HEALTH INC.,

Defendant.
_____/

ORDER GRANTING MOTION TO DISMISS

The False Claims Act prohibits people from submitting claims to the federal government for amounts it does not owe. It is not a catch-all statute targeting any conceivable form of misconduct connected with the government's spending programs—particularly when such misconduct is proscribed by separate enforcement regimes. Here, Relator alleges a pattern of illicit behavior concerning Defendant's response to a serious defect in its products. But she alleges no conduct expressly contemplated by the False Claims Act, and the Court must rein in Relator's expansive view of the statute. For the reasons set forth herein, it is hereby **ORDERED AND ADJUDGED** that Defendant's Motion is **GRANTED**.

BACKGROUND

The United States government funds and operates several health insurance programs designed to assist various subsets of the American population. *E.g.*, Am. Compl. [ECF No. 43] ¶ 14. The governments of the several states fund similarly administered programs that cover state employees. *Id.* ¶¶ 50, 51. Each of these programs provides for reimbursement of glucose test strips, which are used by diabetic patients in conjunction with blood glucose meters to monitor their blood glucose levels and govern their intake of insulin. *Id.* ¶¶ 8, 16, 17, 37, 46, 51.

Defendant is a manufacturer of glucose test strips, including the TRUEtest product, which are subject to reimbursement claims submitted to government health insurance programs and marketed to recipients of those programs. Am. Compl. ¶¶ 8, 27, 38, 47. Between 2013 and 2016, thousands of test strips manufactured by Defendant were rendered defective, presumably due to a change in packaging equipment at Defendant's manufacturing facility. *Id.* ¶¶ 82, 97. As a result of the defect, the test strips were insufficiently sealed in their vials, causing them to become adulterated by ambient air and report inaccurate readings of patient glucose levels. *Id.* ¶¶ 83, 84. Diabetic patients relied on the inaccurate test strip readings to govern their insulin intake and consequently took too much or too little insulin, resulting in adverse patient outcomes including a lost pregnancy. *Id.* ¶¶ 87, 112.

In response to its product defect, on June 28, 2016, Defendant recalled 5,527,921 units of test strips manufactured between April 16, 2015, and July 30, 2015. Am. Compl. ¶¶ 233–36. Contemporaneous with the product recall, Defendant issued a press release that resulted in limited media coverage. *See* [ECF No. 96-1]. The U.S. Food and Drug Administration ("FDA") acknowledged Defendant's product recall by issuing a series of public notices in September 2016. *See* [ECF No. 96-2].

Relator is a licensed nurse and compliance specialist and a former employee of Defendant's Customer Care Department and Post Market Compliance Department. Am Compl. ¶ 6. Relator alleges that Defendant "knowingly presented, or caused to be presented, false or fraudulent claims for payment to federal healthcare programs," *id.* ¶ 258, in violation of the False Claims Act, 31 U.S.C. §§ 3729(a)(1)(A)–(B), and "knowingly presented or caused to be presented . . . false or fraudulent claims for payment or approval" in violation of the false or fraudulent claim acts of twenty-seven states, *e.g., id.* ¶ 264. Consequently, the government health insurance programs "paid for claims that otherwise would not have been allowed." *E.g., id.* ¶ 259.

Specifically, Relator alleges that Defendant "knowingly manufactured, sold, and distributed into interstate commerce defective, adulterated, and misbranded TRUEtest diabetic blood-test strips." Am. Compl. ¶ 80. Relator alleges that Defendant's "scheme" began sometime in 2013, when Defendant introduced new packaging machines into its manufacturing line that caused the defect in the test strip vials. *Id.* ¶¶ 82, 88. Relator further alleges that Defendant knew of the defect years before the product recall but engaged in various fraudulent practices aimed to continue placing its product into the stream of commerce covered by the government health insurance programs. *Id.* ¶ 86. Those practices included failing to investigate a high volume of customer complaints about the test strips, *id.* ¶¶ 94–121; manipulating customer complaint and laboratory testing data to conceal the product defect, *id.* ¶¶ 122–47; hiding, falsifying, and failing to submit medical device reports to the FDA, *id.* ¶¶ 148–76; excluding many defective units from the eventual product recall, *id.* ¶¶ 233–43; and violating the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, *id.* ¶¶ 244–53.[1]

Relator brings no specific allegation that Defendant directly submitted any false claims to a government health insurance program. Rather, Relator cites various sources reporting that Defendant's test strips composed a significant share of such products reimbursed by those programs, *e.g.*, Am. Compl. ¶ 28, and that Defendant "knew [g]overnment [h]ealth [i]nsurance [p]rograms would and, in fact, did pay" for them, *id.* ¶ 252.

Relator initially brought this *qui tam* action in the U.S. District Court for the District of South Carolina on February 2, 2017. *See generally* Compl. [ECF No. 1]. On September 10, 2021, the United States filed a notice on behalf of itself and all twenty-seven Plaintiff states declining to

[1] Although not necessary to her Amended Complaint, Relator also peers into Defendant's intent behind this alleged behavior, claiming Defendant was motivated by "greed," Am. Compl. ¶ 223, and that it "chose not to issue a recall because it would hurt profitability and the company's ability to pay Christmas bonuses, *id.* ¶ 225. Plaintiff also alleges that Defendant feared disclosure of its product defect would jeopardize its acquisition by a Chinese medical products firm. *Id.* ¶ 228.

intervene in this action, *see* [ECF No. 40], and the District of South Carolina unsealed the case three days later, *see* [ECF No. 41]. Relator filed her Amended Complaint on November 18, 2021 [ECF No. 43], and the District of South Carolina transferred the case to this Court on January 20, 2022 [ECF No. 64]. Defendant filed the instant Motion to Dismiss the Amended Complaint ("Motion") [ECF No. 95] on March 25, 2022.[2] The United States filed a statement of interest in this case on June 3, 2022, advising the Court as to its position on certain legal arguments presented in the Motion. *See* [ECF No. 124].

Upon motions by the parties, [ECF Nos. 96, 110], the Court has taken judicial notice of Defendant's press release following its product recall, two media reports of the recall, and several reports issued by the Office of Inspector General ("OIG") of the U.S. Department of Health and Human Services ("HHS"). [ECF Nos. 125–26]. The Court also has taken judicial notice of the existence of various documents located on the HHS and FDA websites. *Id.*

LEGAL STANDARD

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is plausible on its face when a plaintiff "pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* Additionally, Federal Rule of Civil Procedure 9(b) requires a party "alleging fraud . . . [to] state with particularity the circumstances constituting fraud." To satisfy this heightened pleading requirement in a *qui tam* action, "a relator must allege the actual submission of a false claim because the False Claims Act does not create liability merely for a health care provider's disregard of government

[2] The Motion has been fully briefed and is ripe for judicial review. *See* Resp. in Opp'n to Def.'s Mot. to Dismiss ("Response") [ECF No. 109]; Def.'s Reply in Supp. of Mot. to Dismiss Am. Compl. ("Reply") [ECF No. 117].

regulations or improper internal policies unless the provider asks the government to pay amounts it does not owe." *Carrel v. AIDS Healthcare Found., Inc.*, 898 F.3d 1267, 1275 (11th Cir. 2018) (cleaned up). When reviewing a motion to dismiss, courts should limit their "consideration to the well-pleaded factual allegations, documents central to or referenced in the complaint, and matters judicially noticed." *La Grasta v. First Union Secs., Inc.*, 358 F.3d 840, 845 (11th Cir. 2004).

ANALYSIS

I. False Claims Act (Count I)

The False Claims Act allows private persons, known as relators, to bring civil actions, known as *qui tam* suits, on the United States' behalf for fraudulent claims. *United States ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1307 (11th Cir. 2002). Its purpose is to place the federal government on notice of potential fraudulent claims in relation to its assistance and other spending programs. *See United States ex rel. Zafirov v. Fla. Med. Assocs. LLC*, No. 19-1236, 2021 WL 4443119, at *7 (M.D. Fla. Sept. 28, 2021); *United States ex rel. Cho v. H.I.G. Capital, LLC*, No. 17-983, 2020 WL 5076712, at *11 (M.D. Fla. Aug. 26, 2020). False Claims Act cases are often brought under two separate causes of action: presentment under section 3729(a)(1)(A) and false statement or document under section 3729(a)(1)(B). To establish a presentment claim, a relator 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. 31 U.S.C. § 3729(a)(1)(A). To prove a false statement or document claim, 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. *Id.* § 3729(a)(1)(B).

Defendant argues that Relator's Amended Complaint must be dismissed because it is barred by the False Claims Act's public disclosure bar, it fails to satisfy the heightened pleading

requirements of Rule 9(b), and it fails to state a claim under the statute. The Court addresses each argument in turn.

A. The Amended Complaint Is Not Barred by the Public Disclosure Bar

The False Claims Act requires a court to dismiss an action or claim if substantially the same allegations were publicly disclosed before the *qui tam* action was initiated. *See* 31 U.S.C. § 3730(e)(4)(A). An exception arises if the relator is an original source of the information. *See id.* Courts typically employ a three-part inquiry to determine whether the public disclosure bar applies: (1) Before the filing of the *qui tam* complaint, had the plaintiff's allegations been publicly disclosed? (2) If so, are the plaintiff's allegations substantially the same as those described in the public disclosure? (3) If yes, is the complaint nonetheless allowed because the relator is an original source of the information? *United States ex rel. Osheroff v. Humana, Inc.*, 776 F.3d 805, 812 (11th Cir. 2015) (citing *Cooper v. Blue Cross Blue Shield of Fla., Inc.*, 19 F.3d 562, 565 n.4 (11th Cir. 1994)).

The first prong of the *Cooper* test looks at whether information has been disclosed in a federal court proceeding; "a congressional, Government Accountability Office, or other federal report, hearing, audit, or investigation"; or the news media. 31 U.S.C. § 3730(e)(4)(A); *Osheroff*, 776 F.3d at 812. The Eleventh Circuit has held that these sources include publicly available websites. *Osheroff*, 776 F.3d at 813. The "sources of public disclosure in § 3730(e)(4)(A) . . . suggest that the public disclosure bar provides a broa[d] sweep." *Schindler Elevator Corp. v. United States ex rel. Kirk*, 563 U.S. 401, 408 (2011) (quotations omitted).

Here, the facts at the heart of Relator's allegations were publicly disclosed though (1) Defendant's press release, (2) FDA notices, and (3) media reports on Defendant's product recall. Mot. at 5. Defendant's press release—on which Relator relies as evidence, *see* Am. Compl. ¶ 233—disclosed the product defect that forms the basis for Relator's claim—*i.e.*, that open test

strips had been placed into the marketplace and could cause low blood glucose test results. *Id.* at 6. Defendant's public announcement stated that the recalled strips "may include open test strip vials within the sealed test strip vial boxes." *Id.* (quoting Am. Compl. ¶ 234). Defendant's announcement also explained that the defective strips may be exposed to the environment, which "can affect strip performance." *Id*. The announcement further stated that "[i]f a user . . . uses the strips to measure blood glucose, the meter may provide incorrect low blood glucose results." *Id*. (quoting [ECF No. 96-1]). Much of this was repeated in the media reports. *Id.* In September 2016, the FDA provided public notices of Defendant's recall on its website. Mot. at 6. The FDA's notices described the reason for the recall as "[p]roduct gives incorrect low blood glucose levels" and the FDA-determined cause as "Nonconforming Material/Component." *Id*. (quoting [ECF No. 96-2]). Relator does not dispute these disclosures but rather focuses on the second two prongs of the inquiry.

The second step of the *Cooper* test asks whether Relator's allegations are "substantially the same" as those publicly disclosed. *Osheroff*, 776 F.3d at 814. This prong is satisfied if Relator bases her claim "in any part on . . . publicly disclosed information." *Id.* (emphasis omitted). This prong does not require a "complete identity" of allegations; rather, "[t]he key inquiry is whether the disclosures could have put the government on notice of the fraud alleged in the *qui tam* complaint." *Zafirov*, 2021 WL 4443119, at *7 (quoting *United States ex rel. Maur v. Hage-Korban*, 981 F.3d 516, 523 (6th Cir. 2020)). This test is a "quick trigger" to reach the more exacting original source inquiry. *Osheroff*, 776 F.3d at 814.

Relator argues that the facts contained in Defendant's product recalls, as well as the resulting FDA notices and media coverage, are not substantially the same as her allegations because those disclosures did not directly allege fraud against the government. Resp. at 10–12. In

support, Relator cites the Eleventh Circuit's holding in *United States ex rel. Bibby v. Mortgage Investors Corp.* that, to bar a *qui tam* action, a public disclosure must

> present a submitted statement or claim (X) and the true set of facts (Y), which shows that X is untrue. These two things together allow the conclusion (Z) that fraud has occurred. There is no allegation of fraud under this formula unless each variable is present. Where only one element of the fraudulent transaction is in the public domain (*e.g.*, X), the *qui tam* plaintiff may mount a case by coming forward with either the additional elements necessary to state a case of fraud (*e.g.*, Y) or allegations of fraud itself (*e.g.*, Z).

987 F.3d 1340, 1353–54 (11th Cir. 2021) (cleaned up).

This passage comes from a discussion in which the Eleventh Circuit clarified the definition of "allegations" to use in the *Cooper* test. *Bibby*, 987 F.3d at 1353–54. The *Bibby* court noted that "the *Cooper* test does not further define 'allegations'" and thus borrowed a formula from the D.C. Circuit in which allegations are defined as a "true set of facts (Y)" for purposes of public disclosure analysis. *Id.* at 1353. In applying this fact-based standard, the Court notes that Relator's claim rests quite heavily on facts that were publicly available long before Relator filed this action.[3] Indeed, the introductory paragraphs of the Amended Complaint state that a "manufacturing defect caused [Defendant] to produce thousands of vials with contaminated test strips that would not produce an accurate reading." Am. Compl. at 2. The Amended Complaint continues that Defendant "manufactured, sold, and distributed into interstate commerce defective, adulterated, and misbranded TRUEtest diabetic blood-test strips." *Id.* ¶ 80. Per the Amended Complaint, the strips would result in inaccurate blood glucose results because they were shipped in unsealed or open vials. *Id.* ¶¶ 81–86. These facts are substantially the same as those Defendant announced in June 2016 and the FDA announced in September 2016 and thus were in the public domain well before Relator filed her initial complaint in February 2017.

[3] As mentioned *supra*, Relator even relies on Defendant's press release as evidence of her claims. *See* Am. Compl. ¶ 233.

Having found that Y was in the public domain, the Court turns to X, a false statement or claim. As an initial matter, the Court notes that upon the release of the information disclosed in Defendant's product recall and the subsequent FDA notices and media coverage, the government was in full possession of each element from which fraud might be inferred. Specifically, the government was now aware that Defendant "manufactured, sold, and distributed into interstate commerce defective, adulterated, and misbranded TRUEtest diabetic blood-test strips." Am. Compl. ¶ 80. It was aware that the strips would result in inaccurate blood glucose results because they were shipped in unsealed or open vials. *Id.* ¶¶ 81–86. And it was aware of the extent to which Defendant's products were covered by its own health insurance programs and the volume of claims the products represented; indeed, the Amended Complaint points to data from HHS, the parent department of both the FDA and the Centers for Medicare & Medicaid Services, as evidence for the filing of fraudulent claims. *See id.* ¶ 28.

It is difficult to square the spirit of the False Claims Act—*i.e.*, to "put the government on notice" of potential fraud, *Zafirov*, 2021 WL 4443119, at *7 —with the letter of the law—*i.e.*, that "[t]here is no allegation of fraud under this formula unless each variable is present," *Bibby*, 987 F.3d at 1353–54. Theoretically, the government should have no need for Relator to come along and connect the dots between X and Y for them. *Cf. United States ex rel. Winkelman v. CVS Caremark Corp.*, 827 F.3d 201, 209 (1st Cir. 2016) (holding that the public disclosure bar applied where "[e]nough was revealed in the [public] disclosures to put the government on notice of the potential fraud without the aid of these relators"). But under the *Bibby* formula, the standard is not whether each element of the fraudulent transaction is in the government's possession but rather whether each "element of the fraudulent transaction is in the public domain." 987 F.3d at 1354. And the simple fact is that Defendant's product recall, the FDA notices, and the media coverage contained no information about X, a false or fraudulent claim submitted to the government.

Therefore, the Court must conclude that only one element of the fraudulent transaction, Y, is present. And "[w]here only one element of the fraudulent transaction is in the public domain (*e.g.*, X), the *qui tam* plaintiff may mount a case by coming forward with either the additional elements necessary to state a case of fraud (*e.g.*, Y) or allegations of fraud itself (*e.g.*, Z)." *Bibby*, 987 F.3d at 1354 (alteration in original). Plaintiff takes the second option by alleging fraud itself on the part of Defendant. *See* Resp. at 10–12. As a matter of law, this allegation is sufficient to survive the *Cooper* test under the *Bibby* standard.[4] Consequently, the Court need not address whether Relator is an original source under the third prong of the *Cooper* analysis.

B. The Amended Complaint Fails to Satisfy the Heightened Pleading Requirements of Rule 9(b)

As discussed *supra*, a False Claims Act claim can be brought under either section 3729(a)(1)(A) (presentment) or section 3729(a)(1)(B) (false statement or document). Although Relator lumps both causes of action into a single count, each type of claim raises separate concerns as to the pleading requirements of Rule 9(b). The Court therefore addresses each claim individually.

1. Presentment Claim (Section 3729(a)(1)(A))

"Because the submission of an actual claim to the government for payment is 'the *sine qua non*' of [a False Claims Act] violation, a plaintiff-relator must 'plead the submission of a false claim with particularity.'" *United States ex rel. Mastej v. Health Mgmt. Assocs., Inc.*, 591 F. App'x 693, 703 (11th Cir. 2014) (quoting *Clausen*, 290 F.3d at 1311; *United States ex rel. Matheny v. Medco Health Sols. Inc.*, 671 F.3d 1217, 1225 (11th Cir. 2012)). "[A False Claims Act] complaint satisfies Rule 9(b) if it sets forth facts as to time, place, and substance of the defendant's alleged

[4] As discussed *supra*, a relator's claims are barred if they are based "in any part on . . . publicly disclosed information." *Osheroff*, 776 F.3d at 814. Although Relator's factual allegations rest heavily on publicly disclosed information, her operative allegation under the *Bibby* formula of fraud itself does not. So it is not barred.

fraud, specifically the details of the defendants' allegedly fraudulent acts, when they occurred, and who engaged in them." *Hopper v. Solvay Pharm., Inc.*, 588 F.3d 1318, 1324 (11th Cir. 2009). In other words, a relator must provide the "who, what, where, when, and how of fraudulent submissions to the government." *Corsello*, 428 F.3d at 1014 (internal quotation marks omitted). Allegations of "[u]nderlying improper practices alone are insufficient to state a claim under the False Claims Act absent allegations that a specific fraudulent claim was in fact submitted to the government." *Id.*

Relator's allegations of false claims boil down to the following: Defendant manufactured adulterated test strips. Resp. at 14. Defendant did not properly report the adulteration to the FDA. *Id.* A device becomes "misbranded" if its manufacturer does not properly report adverse events. *Id.* Therefore, all test strips manufactured while Defendant knew of the adulteration were misbranded. *Id.* Misbranded medical devices cannot be sold in the United States. *Id.* Devices that cannot be sold are ineligible for government reimbursement. *Id.* Therefore, any claim for reimbursement of Defendant's test strips during this period was false. *Id.* Defendant's test strips were among the products reimbursable through government health insurance providers during this period. Am. Compl. ¶ 27. According to the OIG of HHS, TRUEtest composed 14.7 percent of all Medicare claims for diabetes test strips in 2013 and maintained a substantial portion of the overall share through 2016. *Id.* ¶¶ 28, 30. Therefore, all of these claims must have been false. Resp. at 14.

These allegations lack any of the details required to satisfy particularity. They do not provide the dates any claims were submitted, the name of any individual or individuals who submitted the claims, or copies of a single bill or payment. "In short, [Relator] provide[s] the who, what, where, when, and how of improper practices, but [s]he fail[s] to allege the who, what, where, when, and how of fraudulent submissions to the government." *Corsello*, 428 F.3d at 1014.

While seemingly admitting that her Amended Complaint lacks these important details, Relator nonetheless argues that her serpentine allegations have sufficient "indicia of reliability" because (1) she logically infers from the government's own data that Defendant's products made up a significant portion of reimbursed test strips during the relevant period and therefore must have been subject to fraudulent claims, and (2) she "alleges extensive personal knowledge of the fraudulent conduct." Resp. at 31–32. But even these allegations fail to allege "an actual false claim for payment." *Clausen*, 290 F.3d at 1311. A relator may not "point to improper practices of the defendant to support the inference that fraudulent claims were submitted because submission cannot be inferred from the circumstances." *Carrel*, 898 F.3d at 1275 (cleaned up). At most, Relator's allegations regarding Defendant's specific conduct are consistent with the allegation that Defendant submitted a false claim to the government. But Rule 9(b) requires more than inferences, consistencies, and suppositions. It is not enough for a relator to simply allege that fraudulent claims "must have been submitted, were likely submitted[,] or should have been submitted." *Clausen*, 290 F.3d at 1311.

Relator argues, correctly, that the Eleventh Circuit has instructed its courts to be "more tolerant toward complaints that leave out some particularities of the submissions of a false claim if the complaint also alleges personal knowledge or participation in the fraudulent conduct." *Matheny*, 671 F.3d at 1230; Resp. at 32. But Relator's Amended Complaint does not merely "leave out some particularities of the submissions of a false claim." It lacks any particularities at all. And although Relator alleges personal knowledge of various improper practices by Defendant, as described *supra* Background, she does not allege personal knowledge of any fraudulent submissions themselves. It seems awfully difficult for her to do so successfully as an outsider of the entities responsible for processing and submitting claims. But these are the "specific details" about false claims that establish "the indicia of reliability necessary under Rule 9(b)." *United*

States ex rel. Sanchez v. Lymphatx, Inc., 596 F.3d 1300, 1302 (11th Cir. 2010) (internal quotation marks omitted).

The Eleventh Circuit's analyses in two cases are instructive here. First, in *Hopper*, the court rejected a claim where, as here, the relator failed to specify any false claim that had in fact been submitted to the government. 588 F.3d at 1322. The relator alleged that the defendant, Solvay, had illegally marketed its FDA-approved drug, Marinol, for off-label uses and that "sales generated from the marketing scheme caused the government to pay false claims through Medicaid and other programs." *Id.* As to submission of claims, the court noted the following:

> The relators allege that the marketing campaign convinced doctors to prescribe Marinol for off-label uses, and claims were ultimately submitted by state health programs and other third parties to the federal government to pay for some of those prescriptions. The relators do not allege that Solvay itself submitted any false claims. Rather, they allege that every time federal funds were used to pay for an off-label prescription, the third party who requested payment from the government made a false claim. . . . Those false claims were attributable to Solvay, according to the relators, because the off-label marketing campaign caused the claims to be submitted against federal funds and because Solvay intended that its campaign cause the filing of false claims. . . . To support their allegations that the government paid false claims, the relators point to a marked increase in prescriptions for [the drug] and an increase in Medicaid payments for [the drug] between 2001 and 2005, years in which Solvay is alleged to have engaged in the marketing campaign.

Id. After reviewing these allegations, the Eleventh Circuit affirmed the district court's dismissal for failure to satisfy Rule 9(b). *Id.* at 1322. In particular, the court noted that the "relator failed to allege specific fraudulent submissions to the government." *Id.* at 1325. While the complaint offered "detailed allegations of an illegal scheme to cause the government to pay amounts it did not owe" and, as described by the relator, "a highly-compelling statistical analysis" showing "a huge number of claims for ineffective off-label uses" for the drug at issue, the complaint did "not allege the existence of a single actual false claim." *Id.* at 1326.

Second, the Eleventh Circuit recently affirmed *Cooper*'s instruction that evidence of shady business practices coupled with evidence of Medicare claims by the defendant, without specific claims evidence, is not enough. *Estate of Helmy v. Bethany Hospice & Pallative Care of Coastal Ga., LLC*, 853 F. App'x 496, 502 (11th Cir. 2021). In *Estate of Helmy*, the relator alleged, in part, that the defendant's "doctors referred significant numbers of Medicare recipients, that 'all or nearly all' of [the defendant's] patients were Medicare recipients, and that Medicare claims data shows that [the defendant] billed the government for their patients." *Id.* at 501. The court found this was not enough without allegations of an actual claim, noting that "relators cannot 'rely on mathematical probability to conclude that [a defendant] surely must have submitted a false claim at some point.'" *Id.* (quoting *Carrel*, 898 F.3d at 1277).

Here, as in *Hopper* and *Estate of Helmy*, Relator identifies no specific claim submitted for a defective (or "misbranded") product. The Amended Complaint merely alleges that a subset of the strips was defective because of the open vials, *see* Am. Compl. ¶¶ 80–86, 177, 183, 251, 107–11, 114, and that the submission or caused submission of a claim for these products violated the False Claims Act, *id.*, ¶¶ 254–61. But, as discussed *supra*, the Amended Complaint fails to allege the necessary who, what, where, when, and how of any claim for such defective products submitted to the government.

Relator argues that the holdings in *Hopper* and *Estate of Helmy* are irrelevant here because "Relator does not rely on statistical analyses to establish falsity." Resp. at 30. But where a relator fails to allege the details necessary to establish the submission of false claims to the government, a strict application of Rule 9(b) requires that logical inference can fare no better than statistical analysis. *See Carrel*, 898 F.3d at 1275; *Corsello*, 428 F.3d at 1013 ("Although we construe all facts in favor of the plaintiff when reviewing a motion to dismiss, we decline to make inferences about the submission of fraudulent claims because such an assumption would strip all meaning

from Rule 9(b)'s requirements of specificity."). Accordingly, Plaintiff's presentment claim must be dismissed.

2. False Statement or Document Claim (Section 3729(a)(1)(B))

To satisfy the heightened pleading requirements of Rule 9(b), a false statement or document claim under section 3729(a)(1)(B) must be pled with particularity regarding the document and statement alleged to be false, who made or used it, when the statement was made, how the statement was false, and what the defendants obtained as a result. *United States ex rel. Pepio v. Prometheus Labs., Inc.*, 2020 WL 6203527, at *5 (M.D. Fla. Oct. 22, 2020). In short, the false statement must be "material" to a claim for payment. *United States ex rel. Phalp v. Lincare Holdings, Inc.*, 857 F.3d 1148, 1154 (11th Cir. 2017). "Material" in this context means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 192 (2016). Thus, the false statement or document must play a meaningful role in causing payment of a specific claim. *E.g.*, *United States ex rel. v. Huntington Ingalls Inds.*, No. 14-1256, 2021 WL 4307510, at *5 (M.D. Fla. Sept. 22, 2021) ("[U]nder § 3729(a)(1)(B), . . . relators must still plead that the false statement was connected to an actual false claim.").

Under this standard, Relator fails to specify any false document or statement that had the "natural tendency to influence" the payment of a claim or link such statements to an actual claim. The Amended Complaint includes references to Medical Device Reports, *e.g.*, Am. Compl. ¶¶ 160–64; customer support call scripts, *e.g.*, *id.* ¶¶ 125–28; "memos," *e.g.*, *id.*, ¶¶ 239–40; and customer complaint tracking records, *e.g.*, *id.* ¶¶ 107–09, some of which Relator alleges contained false statements. But the Amended Complaint does not allege how they had a natural tendency to influence the payment of any claim or are material to a false or fraudulent claim as required by

section 3729(a)(1)(B). Accordingly, Relator's false statement or document claim must be dismissed.

Ordinarily, a plaintiff whose complaint falls short of the heightened pleading requirements of Rule 9(b) would be afforded leave to amend. But as discussed *infra* Analysis I.C, the Court finds that Relator's failure to state a claim for falsity under the False Claims Act is ultimately fatal to her case.

C. The Amended Complaint Fails to State a Claim under the False Claims Act

Defendant attacks Relator's claims as to falsity as a matter of law. Mot. at 16. At the outset, the Court notes that the False Claims Act is not a catch-all statute for targeting weaselly behavior. *Universal Health*, 579 U.S. at 194. Rather, it has the singular purpose of placing the federal government on notice of potential fraudulent claims in relation to its assistance and other spending programs. *See Zafirov*, 2021 WL 4443119, at *7; *Cho*, 2020 WL 5076712, at *11. There is no question that Relator alleges a cornucopia of weaselly practices on the part of Defendant. *See supra* Background. But, at bottom, these allegations amount to a series of regulatory violations whose connection to claims for payment by the government is tenuous at best. To be clear, a regulatory violation can rise to the level of creating liability under the False Claims Act. Indeed, if a statute governing certain claims expressly conditions reimbursement on compliance with specific regulatory obligations, violation of said obligations is "material" to the claims and therefore relevant to a defendant's liability. *See Universal Health*, 579 U.S. at 194–95 (defining "material" as discussed *supra* Analysis I.B.2). But allowing a "theory of liability based merely on a regulatory violation . . . would sanction use of the [False Claims Act] as a sweeping mechanism to promote regulatory compliance, rather than a set of statutes aimed at protecting the financial resources of the government from the consequences of fraudulent conduct." *United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 702 (4th Cir. 2014).

As to falsity, Relator brings a number of arguments in support of her claims, none of which are persuasive. Primarily, she claims that all of Defendant's test strips manufactured during the period when Defendant knew of the product defect were statutorily ineligible for reimbursement and accordingly false because they were misbranded and adulterated. Resp. at 13–16. This argument fails because none of the alleged regulatory violations resulting in "misbranded and adulterated" test strips were material to any claim for payment.

Relator does not allege that the statutes governing Medicare and other government health insurance programs prohibit reimbursement for adulterated or misbranded medical products. Rather, her central argument hangs on alleged violations of the FDCA and of FDA regulations promulgated thereunder. Am. Compl. ¶¶ 244–53; Resp. at 14. The FDCA prohibits the "introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded." 21 U.S.C. § 331(a). A device is "misbranded" if "there has been a failure or refusal to give required notification or to furnish required material or information." *Id.* § 352(t). Relator alleges that Defendant failed to provide the FDA such notification pursuant to regulations promulgated under the authority granted by this statute—specifically, the requirement "to investigate each adverse event, evaluate its causes, and furnish particular information to the FDA within 30 days of receiving or otherwise becoming aware of information 'from any source' that 'reasonably suggests that a device' a manufacturer markets '[m]ay have caused or contributed to a death or serious injury' or '[h]as malfunctioned and . . . would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.'" Resp. at 14 (quoting 21 C.F.R. §§ 803.50(1)–(2) (alterations in original)). Thus, says Relator, all test strips placed into the stream of commerce while Defendant was breaching this regulatory obligation were misbranded. *Id.* And because they were misbranded, the logic goes, they were ineligible for reimbursement by Medicare and other government health insurance

programs, so any claims for any test strip manufactured during this period were necessarily false. *Id.*

This is where Relator's argument falls apart. Even if Defendant's test strips manufactured between 2013 and 2016 were misbranded, as Relator argues, Relator cites no portion of the FDCA closing the circuit between misbranding and claims for reimbursement from the government. All Relator offers is the conclusory assertion that Defendant's alleged misbranding "would be material to a decision to pay for the defective product" because a "defect rendering a product worthless and unmarketable—and even requiring its removal from the market—necessarily is an important [*sic*] to any decision to pay for the product." Resp. at 25.

The Court finds *Rostholder*, a similar case out of the Fourth Circuit, particularly instructive. 745 F.3d 694. In that case, the relator filed a *qui tam* action against his former employer, a manufacturer of penicillin. *Id.* at 697. The relator relied on another provision of the FDCA, section 335, which covers requirements for approval and marketing of new drugs. *Id.* at 701. The relator alleged that the defendant violated regulations the FDA promulgated under section 355 by failing to package its penicillin in isolation from non-penicillin products made at the same facility. *Id.* The relator argued that penicillin manufactured in violation of FDA regulations was not eligible for Medicare or Medicaid reimbursement, so "any claims presented to the government for reimbursement for these drugs were false under the [False Claims Act]." *Id.* The defendant filed a motion to dismiss, which the district court granted. *Id.*

On appeal, the relator asserted that any submitted claim was false because the penicillin was manufactured in violation of FDA regulations promulgated under the FDCA and therefore was adulterated, and Medicare reimbursement is not permitted for adulterated materials. *Rostholder*, 745 F.3d at 701. The court rejected this argument, noting that neither section 355 nor the statutes governing Medicare and Medicaid "provide that when an already-approved drug has

been produced or packaged in violation of FDA safety regulations, that particular drug may not be the proper subject of a reimbursement request under Medicare and Medicaid." *Id.* The relator further maintained "he adequately ha[d] pleaded a false claim because compliance with [FDA regulations] is material to the government's decision to provide reimbursement for regulated drugs." *Id.* at 702. The court rejected this "false certification" argument as well, noting that "because compliance with the [FDA regulations] is not required for payment by Medicare and Medicaid, [the defendant] ha[d] not falsely stated such compliance to the government, as contemplated by the [False Claims Act]." *Id.*

In addition, *Rostholder*'s relator had not otherwise "identified any false statement or other fraudulent misrepresentation that [the defendant] made to the government," 745 F.3d at 702, and the court affirmed the district court's holding that he "did not adequately allege a false statement, or a fraudulent course of conduct as required for a [False Claims Act] claim," *id.* at 700. In affirming, the court noted that the FDA "has broad powers to enforce its own regulations," and "allowing [False Claims Act] liability based on regulatory non-compliance could short-circuit the very remedial process the [g]overnment has established to address non-compliance with those regulations." *Id.* at 702 (internal quotations and citations omitted).

Here, the Amended Complaint suffers from these same shortcomings. Similar to *Rostholder*'s relator, Relator identifies no statutory condition tying adverse event reporting to eligibility for reimbursement. In other words, no statute cited by Relator provides that once a medical device "has been produced or packaged in violation of FDA safety regulations," it "may not be the proper subject of a reimbursement request under Medicare and Medicaid." *Rostholder*, 745 F.3d at 701. Relator also floats a "false certification" argument, Resp. at 15–16, but because compliance with FDA regulations "is not required for payment by Medicare and Medicaid, [Defendant] has not falsely stated such compliance to the government," *Rostholder*, 745 F.3d at

702. Finally, Relator "has not identified any false statement or other fraudulent misrepresentation that Defendant made to the government." *Id.* What she alleges is a long pattern of shady behavior designed to conceal a serious product defect from the relevant governing body. But unless such violations are material to the alleged fraudulent claims, they do not create liability under the False Claims Act. They are proscribed by other statutes subject to their own enforcement regimes. The Court will not expand the scope of the False Claims Act into the realm of regulatory enforcement.[5]

Relator attempts to salvage her claims by cloaking them in two additional theories of pleading. First, Relator claims that Defendant's allegedly adulterated and misbranded test strip units were statutorily ineligible for reimbursement because their defect rendered them not "reasonable and necessary" as defined under 42 U.S.C. § 1395y(a)(1)(A). Resp. at 17–21. This argument fails because the "reasonable and necessary" standard is applied at the product level, not the unit level. *See* Medicare Program Integrity Manual, CMS Pub. 100-08, ch. 13, § 13.5.4 (describing the process by which Medicare contractors determine whether a device or service is reasonable and necessary). Indeed, in every case Relator cites in support of her argument, the court determined that a device or service itself was categorically not reasonable and/or necessary

[5] Relator relies heavily on a case from within this circuit for the proposition that Defendant's allegedly adulterated and misbranded test strips were statutorily ineligible for reimbursement and accordingly false. Resp. at 14–15 (citing *United States ex rel. Wallace v. Exactech, Inc.*, No. 18-01010, 2020 WL 4500493 (N.D. Ala. Aug. 5, 2020)). But *Wallace* is unpersuasive for three reasons. First, the *Wallace* court did not analyze whether the defendant's alleged regulatory violations were material to its alleged claims. The Court finds the Fourth Circuit's framework in *Rostholder* to be more consistent with the spirit of the False Claims Act—*i.e.*, "protecting the financial resources of the government from the consequences of fraudulent conduct." 745 F.3d at 702. Second, the *Wallace* court found that the defendant's claims were false because the actual product was "materially different" from that approved by the FDA owing to changes in the defendant's "manufacturing and engineering process." 2020 WL 4500493, at *13. Here, no such change is alleged. Relator alleges that Defendant replaced a packaging machine in its production line. Am. Compl. ¶ 82. But equipment turnover does not equate to a change in the FDA-approved manufacturing process. Finally, *Wallace*'s relators alleged far more than just the regulatory violations. The *Wallace* court noted that the relators' allegations of claims included names, dates, times, locations, serial numbers, and dollar amounts. 2020 WL 4500493, at *13. But here, as discussed *supra* Analysis I.B.1, Relator's Amended Complaint identifies no actual claims for reimbursement by Defendant.

for a given treatment.[6] Because Relator alleges only that certain units of Defendant's products manufactured over a discrete period—rather than Defendant's products in general—were not reasonable and necessary for the treatment of diabetic patients, this theory is irrelevant to this case.

Second, Relator argues that "[w]hen a supplier knowingly provides worthless product of no medical value to obtain government reimbursement, the claim for reimbursement is factually false and actionable under the [False Claims Act]." Am. Compl. ¶ 75. This argument fails for the simple reason that Relator attempts to expand case law concerning "worthless services" theory under the False Claims Act into the realm of "worthless products."[7] The Eleventh Circuit has not endorsed this view, and the Court declines to do so here.[8]

For the foregoing reasons, the Court finds that Relator fails to state a claim upon which relief may be granted. "Ordinarily, a party must be given at least one opportunity to amend before

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[6] Resp. at 17–21 (citing *Almy vs. Sebelius*, 679 F.3d 297, 301 (4th Cir. 2012) (discussing a finding by the Secretary of HHS that a particular arthritis treatment system "was not 'reasonable and necessary' and was therefore excluded from the statutory coverage of Medicare Part B"); *Wallace*, 2020 WL 4500493, at *13 (holding that changes in the defendant's manufacturing process rendered its product a "materially different device" that was not reasonable and necessary); *United States ex rel. Dildine v. Pandya*, 389 F. Supp. 3d 1214, 1220–21 (N.D. Ga. 2019) (holding that certain types of cataract procedures and glaucoma diagnoses and tests were categorically not medically reasonable and necessary for a class of patients); *United States v. Gen. Hosp. Corp.*, 394 F. Supp. 3d 174, 182 (D. Mass. 2019) (holding that unnecessarily prolonged administrations of anesthesia were not reasonable and necessary); *United States ex rel. Cestra v. Cephalon, Inc.*, No. 14-1842, 2015 WL 3498761, at *8–11 (analyzing whether off-label prescriptions of a certain drug were reasonable and necessary); *United States ex rel. Bergman v. Abbot Labs.*, 995 F. Supp. 2d 357, 369, 373 (E.D. Pa. 2014) (same); *United States ex rel. Galmines v. Novartis Pharm. Corp.*, No. 06-3213, 2013 WL 2649704, at *12 (E.D. Pa. June 13, 2013) (same)).

[7] Am. Compl. ¶¶ 75–76 (citing *United States ex rel. Jackson v. DePaul Health Sys.*, 454 F. Supp. 3d 481, 494 (E.D. Pa. 2020) (discussing "worthless services" theory); *United States ex rel. Spay v. CVS Caremark Corp.*, 913 F. Supp. 2d 125, 158 (E.D. Pa. 2012) (same); *United States ex rel. Davis v. U.S. Training Ctr., Inc*., 498 F. App'x 308, 315 n.11 (4th Cir. 2012) (same)); Resp. at 26–29 (citing *United States ex rel. Roop v. Hypoguard USA Inc.*, 559 F.3d 818 (8th Cir. 2009) (discussing "worthless services" theory); *United States v. Crumb*, No. 15-0655, 2016 WL 4480690, at *24 (S.D. Ala. Aug. 24, 2016) (same); *United States ex rel. Vainer v. Davita, Inc.*, No. 07-2509, 2012 WL 12832381, at *5 (N.D. Ga. Mar. 2, 2012) (same)).

[8] The Court notes that this theory apparently has not been endorsed by any other circuit either. The Fifth Circuit has contemplated adopting a "worthless goods" theory of False Claims Act liability but declined to do so. *See United States ex rel. Steury v. Cardinal Health, Inc.*, 735 F.3d 202, 207–08 (5th Cir. 2013) ("We again do not reach the issue of whether [a False Claims Act] claim may be viable under a worthless goods theory in this circuit . . . .").

the district court dismisses the complaint." *Corsello*, 428 F.3d at 1014. "[A] district court, however, need not 'allow an amendment (1) where there has been undue delay, bad faith, dilatory motive, or repeated failure to cure deficiencies by amendments previously allowed; (2) where allowing amendment would cause undue prejudice to the opposing party; or (3) where amendment would be futile.'" *Id.* (quoting *Bryant v. Dupree*, 252 F.3d 1161, 1163 (11th Cir. 2001)). The Court agrees with the Fourth Circuit's reasoning in *Rostholder* that "any amendment would [be] futile in light of [the] holding that adulterated [devices] are not barred from reimbursement by Medicare and Medicaid and, therefore, claims for reimbursement for these [devices] cannot be 'false' under the [False Claims Act]." 745 F.3d at 703. Even upon viewing the Amended Complaint's well-pleaded allegations in the light most favorable to Relator, the Court cannot draw the reasonable inference that they fit into the statutory framework established by Congress. Accordingly, any further amendment by Relator in this case would be futile, so Count I is **DISMISSED *with prejudice***.[9]

II. State False Claim Statutes (Counts II–XXVIII)

What remain are Relator's claims brought under the false or fraudulent claim statutes of twenty-seven states. "The doctrine of supplemental jurisdiction . . . permits 'federal courts to decide certain state-law claims involved in cases raising federal questions' when doing so would promote judicial economy and procedural convenience." *Ameritox, Ltd. v. Millennium Labs., Inc.*, 803 F.3d 518, 530 (11th Cir. 2015) (quoting *Carnegie–Mellon Univ. v. Cohill*, 484 U.S. 343, 348–49 (1988)). This doctrine, codified at 28 U.S.C. § 1367, "grants federal courts the power to

[9] The Court also notes that Relator has not moved for leave to amend, either within her Response or by separate motion. The Eleventh Circuit has made clear that a district court has no obligation to *sua sponte* grant leave to amend when it is not requested. *See, e.g.*, *Sanchez*, 596 F.3d at 1303 ("A district court is not required to grant a plaintiff leave to amend his complaint *sua sponte* when the plaintiff, who is represented by counsel, never filed a motion to amend or requested leave to amend before the district court." (quoting *Wagner v. Daewoo Heavy Indus. Am. Corp.*, 314 F.3d 541, 542 (11th Cir. 2002) (*en banc*)) (alteration omitted)).

exercise jurisdiction over claims 'that are so related to claims in the action within such original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution.'" *Id.* at 531 (quoting 28 U.S.C. § 1367(a)). Although section 1367 "mandates that district courts—at least initially—exercise jurisdiction over those supplemental claims that satisfy the case or controversy requirement," *id.*, a court has the authority to dismiss any pendant state law claims if "the district court has dismissed all claims over which it has original jurisdiction," 28 U.S.C. § 1367(c).

Because the Court has dismissed the federal False Claims Act claims, it declines to exercise jurisdiction over Relator's state law claims, pursuant to section 1367(c)(3). "The Eleventh Circuit has a stated policy in favor of dismissing state law claims under these circumstances." *Clarke v. Two Is. Dev. Corp.*, No. 15-21954, 2016 WL 659580, at *2 (S.D. Fla. Feb. 18, 2016); *see also Raney v. Allstate Ins. Co.*, 370 F.3d 1086, 1088–89 (11th Cir. 2004) ("The decision to exercise supplemental jurisdiction over pendant state claims rests within the discretion of the district court. We have encouraged district courts to dismiss any remaining state claims when, as here, the federal claims have been dismissed prior to trial.") (citations omitted). Accordingly, Counts II–XXVIII are **DISMISSED *without prejudice***.

CONCLUSION

To be clear, the Court does not condone Defendant's alleged violations of the FDA's reporting requirements and other practices designed to illicitly protect itself from the consequences of placing potentially dangerous medical products into the stream of commerce. But the Court is convinced that the False Claims Act is not the proper avenue for holding Defendant accountable for this behavior and is confident that the FDA's use of its regulatory enforcement powers may be exercised fully to ensure further compliance. Accordingly, for the foregoing reasons, it is hereby

ORDERED AND ADJUDGED as follows:

1. Defendant's Motion [ECF No. 95] is **GRANTED**.

2. Count I is **DISMISSED** ***with prejudice***.

3. Counts II–XXVIII are **DISMISSED** ***without prejudice***.

4. The Clerk of Court is directed to **CLOSE** this case.

5. Any other pending motions are **DENIED** as moot.

DONE AND ORDERED in Fort Lauderdale, Florida, this 18th day of July, 2022.

RODOLFO A. RUIZ II
UNITED STATES DISTRICT JUDGE