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

UNITED STATES OF AMERICA, et al., ex rel. SALLY SCHIMELPFENIG and JOHN SEGURA,	:	
Plaintiffs,	:	
	:	**CIVIL ACTION**
v.	:	**NO. 11-4607**
	:	
DR. REDDY'S LABORATORIES LIMITED, et al.,	:	
Defendants.	:	

Jones, II J.

March 27, 2017

MEMORANDUM

Plaintiffs bring state and federal anti-fraud claims against Defendants on behalf of the United States, alleging that Defendants fraudulently submitted claims for federal reimbursement of prescription medication packaged and labeled in violation of federal statutes. Defendants move to dismiss Plaintiffs' Second Amended Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6). For the reasons that follow, this Court will GRANT Defendants' Motions to Dismiss the Second Amended Complaint.

BACKGROUND

Plaintiffs are qui tam relators who bring the present action on behalf of the United States under the False Claims Act and related state statutes pursuant to 31 U.S.C. § 3729. In their Second Amended Complaint, relators Sally Schimelpfenig and John Segura allege Defendants collectively dispensed prescription drugs that were in violation of the Poison Prevention Packaging Act and the Consumer Product Safety Improvement Act of 2008. (Dkt No. 26, ¶ 2).

For the purposes of the present action, the defendants (collectively "Defendants") are divided into two distinct categories. Manufacturing Defendants – Defendant Dr. Reddy's Laboratories and its United States subsidiaries – are responsible for the manufacture of the allegedly noncompliant prescription drugs at issue in this case. (Dkt No. 26, ¶ 14). Retail Defendants – CVS, Walgreens, and Walmart – are the pharmacies who received the noncompliant prescription drugs from Manufacturing Defendants, provided said drugs to the ultimate beneficiaries, and thereafter sought reimbursement for the drugs from one of numerous federal health care programs. (Dkt No. 26, ¶ 15). All Defendants are approved federal health care providers subject to federal statutes and regulations. (Dkt No. 26, ¶ 16-21).

The Poison Prevention Packaging Act (15 U.S.C. §§1471-77) (hereinafter "PPPA") was enacted in 1970 to "provide for special packaging to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting, household substances." (Dkt No. 26, ¶ 25). The PPPA requires that any prescription drug for human use that is in dosage form intended for oral administration be packaged in special packaging designed to make it difficult for young children to open and ingest the contents. (Dkt No. 26, ¶32-36). With the passage of the Consumer Product Safety Act of 1970 (hereinafter "CPSA"), Congress created the Consumer Protection Safety Commission (hereinafter "CPSC"), which was charged with the administration and enforcement of the PPPA and related regulations. (Dkt No. 26, ¶27-30). In 2008, Congress passed the Consumer Product Safety Improvement Act (hereinafter "CPSIA") to supplement and amend the CPSA. (Dkt No. 26, ¶ 74). The CPSIA requires manufacturers of imported goods to certify that their products comply with all rules and regulations enforced by the CPSC – which includes the PPPA. (Dkt No. 26, ¶75). Products without the requisite

certification cannot be imported or distributed in commerce in the United States. (Dkt No. 26, ¶ 80).

As a corporation based out of India, Defendant Dr. Reddy's Laboratories is subject to the CPSIA. (Dkt No. 26, ¶ 75). As approved federal health care program participants, all Defendants are subject to the PPPA. (Dkt No. 26, ¶ 113). Manufacturing Defendants did not test the packaging of the drugs imported and distributed in America for child resistance. (Dkt No. 26, ¶ 135). For years, Manufacturing Defendants failed to issue general conformity certificates for the prescription drugs imported and distributed in America, in violation of the CPSIA. (Dkt No. 26, ¶ 172). Thereafter, Manufacturing Defendants made false express representations to Retail Defendants that their drugs were in compliance with all federal laws. (Dkt No. 26, ¶ 208). Manufacturing Defendants did not disclose their drugs' noncompliance with the PPPA and CPSIA to the Retail Defendants. (Dkt No. 26, ¶ 176). Retail Defendants were responsible for ensuring that Manufacturing Defendants' products complied with the relevant packaging and certification statutes. (Dkt No. 26, ¶ 48-50). As a result of Defendants' collective noncompliance with the PPPA and CPSIA prescription drugs that were not packaged according to federal requirements were dispensed to federal health care recipients. (Dkt No. 26, ¶ 116). As a result of Defendants collective noncompliance with the PPPA and CPSIA, Retail Defendants submitted claims to Government payers for federal reimbursement of the noncompliant drugs dispensed to patient-beneficiaries. (Dkt No. 26, ¶ 116).

Based on the above-described conduct, the Second Amended Complaint brings claims against Manufacturing and Retail Defendants under the False Claims Act and related state laws. Presently before this Court are Manufacturing Defendants' and Retail Defendants' individually filed Motions to Dismiss and all respective responses and replies thereto.

The United States of America declined to intervene in the present action. (Dkt No. 27).

LEGAL STANDARD

In deciding a motion to dismiss pursuant to Rule 12(b)(6), courts must "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." Phillips v. Cnty. of Allegheny, 515 F.3d 224, 233 (3d Cir. 2008) (internal quotation marks omitted). After the Supreme Court's decision in Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007), "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. at 678 (citing Twombly, 550 U.S. at 556). This standard, which applies to all civil cases, "asks for more than a sheer possibility that a defendant has acted unlawfully." Id. at 678; accord Fowler v. UPMC Shadyside, 578 F.3d 203, 210 (3d Cir. 2009) ("[A]ll civil complaints must contain more than an unadorned, the-defendant-unlawfully-harmed-me accusation.") (internal quotation marks omitted).

Because the False Claims Act and related state law claims allege fraud, they are subject to the heightened pleading requirements of Federal Rule of Civil Procedure 9(b). United States ex rel. Whatley v. Eastwick Coll., 657 F. App'x. 89, 94 (3d Cir. 2016). "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). The aim of this heightened pleading standard is to "place the defendants on

notice of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges of immoral and fraudulent behavior." Seville Indus. Mach. Corp. v. Southmost Mach. Corp., 7 742 F.2d 786 (3d Cir. 1984). "Rule 9(b) requires, at minimum, that plaintiffs support their allegations of…fraud with all of the essential background facts that would accompany the first paragraph of any newspaper story – that is the who, what, when, where, and how, of the events at issue." In re Rockefeller Ctr. Props. Sec. Litig., 311 F.3d 198, 217 (3d Cir. 2002) (internal citations omitted).

DISCUSSION

The first four of the thirty-four total claims against Defendants allege violations of the False Claims Act (hereinafter "FCA"). (Dkt No. 26, ¶ 206-217). As these are the only claims over which the Court has original jurisdiction, the Court begins its analysis there. "The primary purpose of the FCA is to indemnify the government – through its restitutionary penalty provisions – against losses caused by a defendant's fraud." United States ex rel. Wilkins v. United Health Grp. Inc., 659 F.3d 295, 304 (3d Cir. 2011). "The FCA makes it unlawful to knowingly submit a fraudulent claim to the [G]overnment." United States ex rel. Whatley v. Eastwick Coll., 657 F. App'x. 89, 93 (3d Cir. 2016). "To that end, the Act contains a qui tam provision that permits private parties (known as 'relators') to bring suit on behalf of the United States against anyone submitting a false claim to the Government," and where the qui tam suit is successful, the relator can share in any recovery. Id. "In order to establish a prima facie FCA violation under [§] 3729(a)(1), [a plaintiff] must prove that (1) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent." Wilkins 659 F.3d at 304-305 (internal citations omitted).

For the reasons that follow, this Court finds that Plaintiffs fail to plead sufficient facts to allege violations of the FCA, and this Court declines to exercise supplemental jurisdiction over the remaining state law claims.

I. Plaintiffs Fail to Plead Sufficient Facts to Establish a FCA Claim for Factual Falsity

The second prong of the prima facie standard for FCA claims requires proof that the defendant's claim was false or fraudulent. Id. Under the FCA there are two categories of false claims: that which are factually false and that which are legally false. Wilkins, 659 F.3d at 305. "A claim is factually false when the claimant misrepresents what goods or services that it provided to the Government." Id. Alternatively, "a claim is legally false when the claimant knowingly falsely certifies that it has complied with a statute or regulation[,] the compliance with which is a condition for Government payment." Id. Counts I through IV of the Second Amended Complaint (hereinafter "SAC") allege that Defendants' federal reimbursement requests for drugs packaged and labeled in violation of the PPPA and CPSIA were both legally and factually false claims in violation of the FCA. (Dkt No. 26, ¶ 206-217). According to Plaintiff, Defendants' claims for Government reimbursement were factually false for two reasons: (1) the claims failed to disclose noncompliance with federal packaging and labeling requirements and (2) the drugs' packaging was materially different than that which was required by contract and law, and thus that which the Government reasonably expected to be distributed. (Dkt No. 53, 15-16). Defendants move to dismiss each count of the SAC that alleges Defendants knowingly submitted – or caused to be submitted – factually false claims to the Government. Defendants contend that these allegations are not cognizable as claims of factual falsity and are more aptly characterized as FCA violations based on the *legal* falsity theory of liability. (Dkt No. 50, 18); (Dkt No. 51, 11). This Court agrees.

Courts of all circuits generally agree that "application of the False Claims Act in factually false cases is 'fairly straightforward.'" United States ex rel. Phalp v. Lincare Holdings, Inc., 116 F. Supp. 3d 1326, 1344-45 (S.D. Fla. 2015) (citing United States ex rel. Connor v. Salina Reg'l Health Ctr., Inc., 543 F.3d 1211(10th Cir. 2008) and United States ex rel. Kirk v Schindler Elevator Corp., 601 F.3d 94 (2nd Cir. 2010)). "In a run-of-the-mill factually false case…[a] relator must generally show that the [G]overnment payee has submitted an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided." United States ex rel. Connor v. Salina Reg'l Health Ctr., Inc., 543 F.3d 1211, 1217 (10th Cir. 2008) (internal citations omitted). This standard for establishing a FCA claim of factual falsity holds true within the Third Circuit. See Lyttle v. AT&T Corp., 2012 U.S. Dist. LEXIS 183022 *1, *69 (W.D. Pa. November 15, 2012) ("To make a claim of factual falsity, the [plaintiff] must show that the defendant submitted an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided.") (internal citations omitted); Wilkins 659 F.3d at 305 (holding that the court did not need to consider factual falsity, "as appellants do not contend that appellees did not deliver the services for which they sought payment.").

Here, Plaintiffs neither allege that Defendants dispensed drugs different than that for which Defendants sought federal reimbursement, nor do Plaintiffs allege that Defendants sought reimbursement for drugs or services that were not at all provided. Nowhere in the 116 page long SAC do Plaintiffs allege that Defendants provided the Government with any description of Defendants' drugs, incorrect or otherwise. The only alleged falsity Plaintiffs identify is Defendants' failure to disclose their drugs' lack of compliance with the PPPA and CPSIA. Such an argument is quintessentially legal falsity under the FCA. Plaintiffs did not reference a single

instance in the Third Circuit where the court permitted a FCA claim of *factual* falsity based solely on a failure to divulge a lack of statutory compliance. Plaintiffs cannot circumvent the requirements for proving legal falsity under the FCA by repurposing their claims as ones for factual falsity. The SAC simply does not allege sufficient facts to support finding Defendants liable for submitting factually false claims to the Government in violation of the FCA. This Court therefore grants Defendants' Motions to Dismiss Plaintiffs' FCA claims to the extent that the claims are based on the factual falsity theory of FCA liability.

II. Plaintiffs Fail to Plead Sufficient Facts to Establish a FCA Claim for Legal Falsity

A FCA claim based on legal falsity arises from a "false certification" theory of liability. Wilkins, 659 F.3d at 305. Where a claimant falsely certifies that it has complied with a federal statute or regulation, compliance with which is a condition of Government payment, the payee's claim is legally false and actionable under the FCA. Id. A claimant's false certification of statutory or regulatory compliance can either be express or implied. Id. Applying the "express false certification" theory, an entity is liable under the FCA where said entity falsely certifies that it is "in compliance with regulations which are prerequisites to Government payment in connection with the claim for payment of federal funds." Id. Under the "implied false certification" theory of FCA liability, implicit in each claim for federal reimbursement is a certification of compliance with all conditions of Government payment, such that a knowing failure to disclose violations affecting the claimant's eligibility for payment renders the claim legally false. See id. Because Plaintiffs do not allege that Defendants expressly certified compliance with all federal statutes and regulations in their claims for reimbursement[1], it is

[1] Plaintiffs allege that the Manufacturing Defendants falsely and expressly represented to their "contract partners" – i.e., the Retail Defendants in the present action – that the drugs complied with all federal laws. The relevant inquiry when determining liability under the express certification theory, however, is whether warranties of statutory and

presumably under the latter theory of liability that Plaintiffs allege Defendants submitted legally false claims for Government reimbursement and violated the FCA.

The "false certification" theory of FCA liability underwent an overhaul of sorts in the recent Supreme Court case United Health Services v. United States ex rel. Escobar. 136 S. Ct. 1989 (2016). In Escobar, relators filed a qui tam suit against a mental health facility alleging violations of the FCA where the facility repeatedly sought federal reimbursement for counseling services provided by unlicensed, unsupervised personnel. Id. In determining the facility's liability under the FCA, the Court clarified the circumstances under which the FCA imposes liability for false or fraudulent claims for federal reimbursement. With specific respect to the "implied false certification" theory of FCA liability, the Court in Escobar held that "the implied certification theory can be a basis for [FCA] liability, at least where two conditions are satisfied: first the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." Escobar, 136 S. Ct. at 2001.

Applying this standard to the case at bar, this Court finds that the SAC fails to plead sufficient facts to support a finding of FCA liability. Plaintiffs do not allege that Defendants made any specific representations about the goods it provided for government reimbursement and Plaintiffs do not allege sufficient facts to establish that Defendants' failure to disclose noncompliance with the PPPA and CPSIA was material to the Government's payment decision. Because Plaintiffs did not allege FCA liability under the express certification theory of legal falsity, and failed to allege sufficient facts to support a finding of FCA liability under the implied

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regulatory compliance were made to the Government payer. Wilkins, 659 F.3d at 305. Plaintiffs do not so allege in the Second Amended Complaint.

certification theory of legal falsity, this Court must grant Defendants' Motions to Dismiss Counts I through IV of the Second Amended Complaint to the extent that they allege FCA liability for the submission of legally false claims.

A. Plaintiffs do not Allege Defendants Made Specific Representations in Connection with Defendants' Requests for Federal Reimbursement

"When…a defendant makes representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements, those omissions can be a basis for liability if they render the defendant's representations misleading with respect to the goods or services provided." Escobar, 136 S. Ct. at 1999. As discussed above, the Supreme Court held that the implied certification theory could be the basis of FCA liability, "at least where two conditions are satisfied: first the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." Id. at 2001. In Escobar, the mental health facility charged with violating the FCA made specific representations about the services it provided when the facility sought federal reimbursement, so the facts of the case fit squarely in the Court's delineated standard for determining FCA liability under the implied certification theory of legal falsity. Id. at 2000 ("The claims in this case do more than merely demand payment. They fall squarely within the rule that half-truths – representations that state the truth only so far as it goes, while omitting critical qualifying information – can be actionable misrepresentations.").

The present case does not so harmoniously conform to the Court's standard, as Plaintiffs do not allege that Defendants made specific representations about the products for which they sought Government reimbursement. The Supreme Court in Escobar specifically declined to address the issue of whether the submission of a claim or bill is itself a representation of legal

entitlement to Government payment. Id. ("We need not resolve whether all claims for payment implicitly represent that the billing party is legally entitled to payment.") In their Supplemental Brief Addressing the Supreme Court's Escobar Decision, Defendants interpret the Supreme Court's decision as an unwillingness to adopt a broad rule that holds all claims for Government payment constitute an implicit representation by the claimant that the claimant is legally entitled to the payment it seeks. (Dkt No. 67, 6). Defendants contend that because the Third Circuit has also never so broadly held, this Court should require Plaintiffs to allege a specific representation Defendants made in their claims for federal reimbursement. (Dkt No. 67, 6). In contrast, in its Statement of Interest Addressing the Supreme Court's Escobar Decision, the United States of America argues that the Third Circuit in Wilkins found that a defendant could be held liable for violating the FCA under the implied certification theory absent a showing of a separate false statement. (Dkt No. 80). The United States argues that "nothing in Escobar purports to overrule preexisting cases like Wilkins that affirmed a broader view of implied certification than the Supreme Court needed to address in Escobar." (Dkt No. 80, 4).

This Court does not need to address the issue of whether Escobar overrules any number of earlier cases that adopted a broad interpretation of the implied certification theory of FCA liability for legally false claims. This Court agrees with the United States that prior to the Court's holding in Escobar, the Third Circuit's approach to the implied certification theory did not require a showing of express representations by the claimant to the Government payer, false or otherwise. But ultimately that fact is irrelevant, because it would appear that the Third Circuit has since changed its approach to the implied certification theory of FCA liability in the wake of Escobar. In United States ex rel. Whately v. Eastwick College, the Third Circuit appears to interpret Escobar as requiring specific representations that, in conjunction with the claimant's

purposeful omissions, renders the ensuing claims legally false. 657 F. App'x 89, 94 (3d Cir. 2016) (citing to Escobar and holding that "[u]nder the express false certification theory, a claimant is liable under the FCA for falsely certifying that it is in compliance with a material statute, regulation, or contractual provision. By contrast, implied false certification liability attaches when a claimant makes specific representations about the goods or services provided and the claimant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths.") (internal citations omitted). The Third Circuit quoted the Escobar standard without qualifying it as being one of multiple avenues by which to establish FCA liability and without addressing the purportedly unresolved issue of whether all claims for reimbursement are implicit representations of legal entitlement to Government payment. Id. This Court therefore interprets the language of Whately to mean the Third Circuit intended to present the Escobar standard – requiring proof of specific representations made to the Government payer regarding the goods or services provided – as being the only one available for proving FCA liability for legally false claims under the implied certification theory.

Under that reading of Whately, this Court must dismiss all of Plaintiffs' claims against Defendants which allege FCA liability for the submission of legally false claims under the implied certification theory. Plaintiffs do not allege that Defendants made specific representations about their products that would, in conjunction with Defendants' failure to disclose noncompliance with the PPPA and CPSIA, render their claims "misleading half-truths" subject to FCA liability.

B. Plaintiffs do not Sufficiently Allege Materiality

Even if the Third Circuit retained its previously broad view of the implied certification theory, Plaintiffs fail to allege sufficient facts for this Court to find that Defendants' failure to disclose their noncompliance with the PPPA and CPSIA was material to the Government's decision to pay the requested reimbursements. The FCA defines "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). "[A] misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be *material* to the Government's payment decision in order to be actionable under the False Claims Act." Escobar, 136 S. Ct. at 2002 (emphasis added).

In Wilkins, the Third Circuit held that "to plead a claim upon which relief could be granted under a false certification theory, either express or implied, a plaintiff must show that compliance with the regulation which the defendant allegedly violated was a condition of payment from the Government." Wilkins, 659 F.3d at 309. Since Escobar, the focus of the court's analysis has shifted from determining whether compliance with a particular statute or regulation was a "condition of payment" to whether compliance was "material to the payment decision." Despite this shift, the Court believes the Third Circuit's general instruction requiring a showing of materiality remains intact. To survive Defendants' Motions to Dismiss, Plaintiffs must show that Defendants' claimed compliance with the federal packaging requirements influenced or was capable of influencing the Government's decision to provide the reimbursements for Defendants' products. For the reasons that follow, this Court finds that Plaintiffs fail to allege the materiality of PPPA and CPSIA compliance.

Prior to the Court's holding in Escobar, many courts only found materiality where the Government expressly designated the relevant statute or regulation as a condition of payment. Escobar, 136 S. Ct. at 1998. But instead of limiting FCA liability under the implied certification theory to violations of statutes or regulations explicitly identified as conditions of Government payment, the Court in Escobar concluded that "[w]hat matters is not the label the Government attaches to a requirement, but whether the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision." Id. Escobar calls for a "holistic approach to determining materiality in connection with a payment decision, with no one factor being necessarily dispositive." United States ex rel. Escobar v. Universal Health Servs., 842 F.3d 103, 109 (on remand from Universal Health Servs. v. United States ex rel. Escobar, 136 S. Ct. 1996 (2016)); Escobar, 136 S. Ct. at 2001 ("[M]ateriality cannot rest on a single fact or occurrence as always determinative.") (internal citations omitted). In Escobar, the Court provided examples of factors lower courts should consider when determining whether a statute, regulation, or contract provision is material to the Government's payment decision. First, while not dispositive, whether the Government labeled a statutory, regulatory, or contractual provision a condition of payment is relevant to the materiality inquiry. Escobar 136 S. Ct. at 2001. Second, "[p]roof of materiality can include…evidence…that the Government consistently refuses to pay claims…based on noncompliance with the particular statutory, regulatory, or contractual requirement." Id. at 2003. Third, "if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material." Id. at 2004.

Beyond broad conclusory statements, the SAC does little to allege the materiality of PPPA and CPSIA compliance to the Government's decision to accept Defendants' claims for

reimbursement. Plaintiffs do not identify a single statutory, regulatory, or contractual provision identifying compliance with federal packaging requirements as a condition of Government payment; Plaintiffs do not allege an instance wherein the Government refused payment of a claim on the basis of noncompliance with federal packaging requirements; and Plaintiffs do not allege an instance wherein the Government initiated an action to recover monies paid for goods noncompliant with federal packaging requirements. Plaintiffs merely plead an abundance of research highlighting the importance of child-proofing prescription medications and note Congress's decision to regulate the issue of child safety in drug manufacturing. (SAC, ¶191-204). Neither is sufficient to allege materiality. That the Government or a federal agency found a particular issue important enough to regulate speaks little to the intended consequence of noncompliance. See e.g., Wilkins, 659 F.3d at 310 n. 17 (concluding that the CMS statement 'protecting people with Medicare from deceptive or harmful practices is among our highest priorities at CMS' demonstrates "only that CMS considers the marketing regulations to be very important" and that the court "would not regard the statement as indicating what the consequence of noncompliance should be."). Ultimately, the relevant inquiry is whether the Government's payment decision was influenced by claimant's purported compliance with a particular requirement, not whether a given issue has been deemed worthy of regulation.

Presumably because Plaintiffs cannot demonstrate materiality by any of the means described in Escobar, Plaintiffs repeatedly assert that drugs packaged in contravention of the PPPA are necessarily not covered for reimbursement by federal healthcare programs. To the extent possible, this Court understands Plaintiffs' argument to be the following: (1) drugs noncompliant with the PPPA are misbranded; (2) misbranded drugs are not "safe and effective" under the Federal Food, Drug, and Cosmetic Act; (3) because misbranded drugs are not "safe

and effective," misbranded drugs cannot be "reasonable and necessary" as required by the Center for Medicare and Medicaid Services; and (4) because misbranded drugs are neither "safe and effective" nor "reasonable and necessary," the sale of misbranded drugs in interstate commerce is unlawful. (Dkt No. 54, 14-15); (Dkt No. 53, 23-29). Plaintiffs' syllogism fails because nearly all of their propositions are without statutory support. [2] Construing the SAC *very* liberally, the most Plaintiffs allege is that misbranding is a basis upon which the Government would have the option to refuse payment of Defendants' claims, which is insufficient to show materiality. Escobar, 136 S. Ct. at 2003. Plaintiffs' circular logic and unsupported legal conclusions simply cannot save their FCA claims, even on the most favorable reading of the SAC.

Third Circuit precedent also weighs in favor of granting Defendants Motions to Dismiss. In the Third Circuit, that the Government established an administrative mechanism for addressing violations of the statutes or regulations at issue is also relevant to the materiality inquiry. See Wilkins, 659 F.3d at 310 ("Further, considering that the Government has established an administrative mechanism for managing and correcting Medicare marketing violations other than the withholding of payment otherwise due, it is clear that…it does not require perfect compliance as an absolute condition for receiving Medicare payments for services rendered.") (internal citations omitted). Here, Plaintiffs' own pleadings reflect the existence of federal agencies equipped with the administrative power to address Defendants' statutory and regulatory violations. (SAC, ¶ 29-30). To allow Plaintiffs to bring suit based on Defendants'

[2] In Plaintiffs' Brief in Opposition to the Retail Defendants' Motion to Dismiss (Dkt No. 54) Plaintiffs assert "when a drug is *misbranded* it is not covered for reimbursement by federal programs such as Medicare, Medicaid, The Civilian Health and Medical Program of the Uniformed Services (a/k/a Tricare), and The Federal Employees Health Benefits Program." The purported authority for this assertion is 15 U.S.C. § 1473(b) and 21 U.S.C. §352(p). 15 U.S.C. § 1473(b) states only that drugs in noncompliant packages may only be dispensed when so directed by the prescribing physician or so requested by the recipient, and 21 U.S.C. §352(p) states that drugs that don't comply with the PPPA are misbranded. Neither speaks to noncompliant or misbranded drugs' eligibility for federal reimbursement. Plaintiffs likewise fail to provide legal authority for their conclusion that misbranded drugs cannot be "safe and effective" for the purposes of the FDCA or "reasonable and necessary" for the purposes of the CMS.

noncompliance with federal packaging requirements would mean to "short-circuit the very remedial process the Government has established to address noncompliance with those regulations." Wilkins, 659 F.3d at 310. "The False Claims Act is not an all-purpose antifraud statute, or a vehicle for punishing garden-variety breaches of contract or regulatory violations." Escobar, 136 S. Ct. at 2003. Absent a showing that compliance with the PPPA and CSIPA is material to the Government's decision to grant reimbursements for Defendants' products, this Court is unwilling to undermine the well-established regulatory procedures in place for addressing Defendants' exact kind of noncompliance.

Defendants advance numerous other arguments in support of their Motions to Dismiss Plaintiffs' federal FCA claims which the Court need not reach today. Plaintiffs' inability to establish the materiality of PPPA and CPSIA compliance is fatal to all of Plaintiffs' FCA claims of legal falsity. The Supreme Court explicitly rejected the notion that materiality is too fact sensitive to consider at the motion to dismiss stage and held that Federal Rules 8 and 9(b) require FCA plaintiffs to "[plead] facts to support allegations of materiality." Escobar, 136 S. Ct. at 2004 n. 6. Because Plaintiffs failed to allege facts sufficient to find Defendants liable under the FCA for either the submission of factually false claims or the submission of legally false claims, this Court has no choice but to grant Defendants' Motions to Dismiss Counts I through IV of the Second Amended Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6).

Having dismissed all of Plaintiffs federal claims against Defendants, this Court declines to exercise supplemental jurisdiction over Plaintiffs' remaining state law claims pursuant to 28 U.S.C. §1367(c)(3) ("The district courts may decline to exercise supplemental jurisdiction over a claim…if…the district court has dismissed all claims over which it has original jurisdiction….").

CONCLUSION

Plaintiffs fail to plead a cognizable claim of factual falsity under the False Claims Act, and absent a showing of materiality, Defendants cannot be found liable under the False Claims Act for failing to disclose noncompliance with the PPPA and CPSIA. It is not lost upon this Court the danger of distributing prescription medications that are not packaged in accordance with the Poison Prevention Packaging Act. But based on the pleadings presently before us, the False Claims Act is not the appropriate mechanism by which to sanction Defendants for their violations. For this and all of the forgoing reasons, this Court grants Defendants' Motions to Dismiss Plaintiffs' Second Amended Complaint without prejudice and with leave to amend in the next thirty days.

An appropriate Order follows.

BY THE COURT:

/s/ C. Darnell Jones, II

C. Darnell Jones, II J.