NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES of AMERICA, et al., *Ex rel.* Laurie Simpson, Plaintiff / Relator, v. BAYER CORP., et al., Defendants.	Civil Action No. 05-3895 (JLL) (JAD) **OPINION**

LINARES, District Judge.

This matter comes before the Court by way of Bayer AG, Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., and Bayer Healthcare LLC (collectively "Bayer")'s motion to dismiss Relator Laurie Simpson ("Simpson")'s Ninth Amended Complaint (ECF No. 155) pursuant to Federal Rule of Civil Procedure 12(b)(6). (ECF No. 168). The Court has considered the parties' submissions in support of and in opposition to the instant motion and decides this matter without oral argument pursuant to Federal Rule of Civil Procedure 78. For the reasons set forth below, the Court **grants** Bayer's motion in part and **denies** Bayer's motion in part.

I. BACKGROUND[1]

Simpson brings this *qui tam* action against Defendant Bayer, her former employer, under the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.*, and similar state and local statutes. (Compl. ¶¶ 4-8). Bayer employed Simpson from April 27, 1998 until January 1, 2005. (*Id.* at ¶

[1] The following facts are taken as true solely for the purposes of this motion.

101). As an employee of Bayer, Simpson helped market one of Bayer's prescription drugs, Trasylol. (*See id.* at ¶¶ 101-108). Simpson alleges, in short, that Bayer "engaged in unlawful marketing, including off-label marketing and payment of kickbacks, in order to increase the market shares of its prescription drugs Trasylol and Avelox." (*See Id.* at ¶187). Moreover, Simpson alleges that Bayer illegally promoted Trasylol by "engag[ing] in a campaign of concealment and disinformation concerning Trasylol's safety and efficacy that continued at least until May 2008, when Bayer recalled Trasylol from the market." (*Id.* at ¶ 9). These promotional activities, according to Simpson, violated the Food Drug and Cosmetic Act (the "FDCA")'s prohibition against "misbranding." (*Id.* at ¶ 13).

A. The FDCA's Prohibition Against Misbranding

"The FDCA regulates the manufacturing, marketing and sale of prescription drugs," and explicitly prohibits "misbranded" drugs from entering interstate commerce. *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 239-40 (3d Cir. 2012) (citations omitted). A drug is misbranded if its labeling is "false or misleading in any particular." 21 U.S.C. § 352(a). Likewise, a drug is misbranded if its "labeling, which under the statute includes all drug manufacturer promotional and advertising material, describes any intended uses for the drug not approved by the [Food and Drug Administration ("FDA")]." *Ironworkers Local Union 68 v. AstraZeneca Pharm., LP*, 634 F.3d 1352, 1357 n.5 (11th Cir. 2011) (citations omitted). Thus, the FDCA "generally restricts pharmaceutical manufacturers—and all those within their chain of distribution—from promoting a drug's potential off-label uses to . . . physicians." *Id.* (citations omitted); *see also In re Schering Plough Corp.*, 678 F.3d at 240 ("[T]he FDCA's regulatory regime prohibits manufacturers from directly advertising off-label uses, such as through labeling claims or explicit statements made by sales representatives.").

B. Bayer's Alleged Misbranding of Trasylol

Simpson generally alleges that Bayer misbranded Trasylol by promoting off-label uses of the drug. (Compl. ¶¶ 143). The FDA approved Trasylol for administration to patients undergoing coronary artery bypass graft surgery using a cardiopulmonary bypass pump (hereinafter "on-pump CABG surgery") to prevent excess bleeding. (*See id.* at ¶110; 118). Simpson alleges that Bayer disregarded the limited scope of the FDA's approval by promoting the use of Trasylol in: (1) valve replacement surgeries; (2) off-pump CABG surgeries; (3) surgeries involving pediatric patients; (4) surgeries involving patients on the antiplatelet drug Plavix; (5) orthopedic surgeries; and (6) liver transplant surgeries. (*Id.* at ¶¶ 151-175). She further alleges that Bayer failed to update Trasylol's label to provide relevant safety and efficacy information concerning such off-label uses. (*Id.*).

C. Avelox

Avelox is Bayer's trade name for moxifloxacin hydrochloride, an antibiotic. (*Id* at ¶ 3). Simpson generally alleges that Bayer illegally provided kickbacks to providers to induce them to use Avelox. (*Id.).* She asserts that Bayer's marketing department engaged in several programs that were designed to improperly benefit prescribing physicians in order to induce them to prescribe Avelox. (*Id.* at ¶ 251). Among these schemes were: (1) Cash honoraria paid to Avelox key opinion leaders; (2) Honoraria paid to doctors as Avelox "Consultants" to Bayer; (3) Bayer paid honoraria for attendance at Avelox promotions; and (4) Other kickbacks. (*Id. at* ¶¶ 252-276). Simpson also alleges that: (1) Bayer funded and sponsored biased continuing medical education and other programs with kickbacks to promote Avelox; and (2) Bayer paid Kaiser Permanente to influence physicians to increase prescriptions of Avelox. (*Id* at ¶ 277-282).

D. Retaliation

Simpson alleges that in response to the concerns that she expressed about the drugs and Bayer's actions, Bayer engaged in threats, harassment, discrimination, and other negative employment actions directed at Simpson. (*Id.* at ¶ 292). After Bayer withdrew its drug "Baycol" from the market, allegedly as a result of 31 deaths associated with the drug, Simpson alleges she experienced overwhelming emotional stress as she "tried to cope with the distress of having worked on a product that had caused avoidable patient deaths and harm while simultaneously assisting Bayer's defense of thousands of Baycol lawsuits." (*Id.* at ¶¶ 293-305).

After the withdrawal of Baycol in August 2001, Simpson was reassigned to Trasylol in mid-2002. (*Id.* at ¶ 306). Promotional efforts for Trayslol marketing were centered around a Cardiac Team, however, Simpson alleges that she came to realize that the team meetings "were a sham and that she had been assigned to Trasylol to help Bayer make these promotional efforts look legitimate." (*Id.* at ¶ 307). Simpson's alleges that her reassignment to work on Trasylol exacerbated her emotional distress when she realized that Bayer's management was still engaging in fraudulent and illegal marketing practices that put patients at risk. (*Id.*at ¶ 307). Simpson allegedly spoke to several Bayer company members to discuss her concerns that the Cardiac Team Meetings were fraudulent, promotional in nature (including off-label promotion), involved kickbacks, violated Bayer's Corporate Compliance policy, and were illegal. (*Id.* at ¶¶ 309-328). After a series of alleged negative employment actions taken toward Simpson, Simpson was notified that she was being terminated on because of a workforce reduction implemented. (*Id.* at ¶ 326). Ms. Simpson was terminated by Bayer effective January 1, 2005. (*Id.*). Simpson alleges that she was replaced by another Bayer employee, who was less qualified and had less experience in market research and the therapeutic area than Simpson. (*Id.* at ¶ 327).

E. Causes of Action

The causes of action that Bayer now moves to dismiss in their entirety fall into several categories. Counts I through VI fall within the first category, alleging that all Trasylol claims violated the FCA based upon Bayer's alleged marketing violations. (Id. at ¶¶ 329-391). Counts VII and VIII fall within the second category; alleging that Bayer caused the submission of claims for Trasylol uses that were not "reasonable and necessary". (*Id.* at ¶¶ 392-403). Counts IX-XII fall within a third category, alleging that Bayer paid kickbacks to promote sales of Trasylol and Avelox, which resulted in violation of the Anti-Kickback Statute. (*Id.* at ¶¶ 404-432). Counts XIII-XXXIII fall into a fourth category, which allege Bayer violated various state and local law claims. (*Id.* at ¶¶ 433-561). Finally, Counts XXXIV and XXXV allege a retaliation claim against Simpson under the FCA and NY state law, respectively.

II. LEGAL STANDARD

For a complaint to survive dismissal, it "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) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.*

In determining the sufficiency of a complaint, the Court must accept all well-pleaded factual allegations in the complaint as true and draw all reasonable inferences in favor of the non-moving party. *See Phillips v. County of Allegheny*, 515 F.3d 224, 234 (3d Cir. 2008). But, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Iqbal*, 556 U.S. at 678. Thus, legal conclusions draped in the

guise of factual allegations may not benefit from the presumption of truthfulness. *Id.*; *In re Nice Sys., Ltd. Sec. Litig.*, 135 F. Supp. 2d 551, 565 (D.N.J. 2001).

Additionally, in evaluating a plaintiff's claims, generally "a court looks only to the facts alleged in the complaint and its attachments without reference to other parts of the record." *Jordan v. Fox, Rothschild, O'Brien & Frankel*, 20 F.3d 1250, 1261 (3d Cir. 1994). However, "a document integral to or explicitly relied on in the complaint may be considered without converting the motion [to dismiss] into one for summary judgment." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (internal quotation marks omitted and alteration in the original)

III. DISCUSSION

A. Motions Before the Court

1. Bayer's Motion to Dismiss

Defendant Bayer argues that the Court should dismiss Simpson's Ninth Amended Complaint on the following grounds: (1) Simpson's misbranding counts still fail to state a claim upon which relief can be granted, specifically; (a) Simpson still has not connected Bayer's alleged misbranding to false claims for payment, (b) Simpson cannot allege that Bayer caused the submission of any Medicare claims for payment, (c) Simpson cannot establish that Trasylol use was material under the payment systems at issue, and (d) Simpson's claims under the FCA fail because she has not alleged a false express certification; and (2) Counts alleges pursuant to state and local law should be dismissed.

2. Simpson's Opposition

Relator Simpson opposes Bayer's Motion to Dismiss by arguing: (1) the Complaint adequately alleges conditions of payment for Simpson's first six causes of action, specifically,

(a) Simpson has adequately alleged that Government could withhold payment on direct purchases of Trasylol, (b) Simpson has adequately alleged the Government could withhold payment for Trasylol under TRICARE and CHAMPVA, (c) Simpson has adequately alleged the Government could withhold payment for Trasylol under Medicaid, (d) Simpson has adequately alleged the Government could withhold payment under Medicare; (2) Simpson's Amended Complaint adequately alleges that the authoritative drug compendia did not support off-label uses; (3) Bayer cannot use the Government's payment systems to avoid liability; and (4) Simpson may pursue the State claims for those state that have declined to intervene.

B. Counts 1-6

> Sections 3729(a)(1) and (2) of the FCA impose liability on any person who:
>
> (1) knowingly presents, or causes to be presented, [to the United States Government] a false or fraudulent claim for payment or approval; [or]
>
> (2) 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)(1)-(2) (pre-FERA). Based on this language, the Third Circuit has concluded that a plaintiff must plead three elements to state a claim under section 3729(a)(1) of the FCA: "(1) the defendant presented or caused to be presented to an agent of the United States a claim for payment;[2] (2) the claim was false or fraudulent; and (3) the defendant knew the claim was false or fraudulent." *U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 242 (3d Cir. 2004) (quotation marks and citation omitted). A plaintiff must plead the same three elements to state a claim under section 3729(a)(2) of the FCA along with a fourth element, *i.e.*, "that the defendant

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[2] The FCA defines a claim in pertinent part as a "request or demand . . . for money or property that . . . is presented to an officer, employee, or agent of the United States . . . ." 31 U.S.C. § 3729(c) (pre-FERA).

made or used (or caused someone else to make or use) a false record in order to cause the false claim to be actually paid or approved." *Id.* (citation omitted).

The Third Circuit has held that there are two categories of false or fraudulent claims under the FCA: factually false claims and legally false claims. *U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 305 (3d Cir. 2011) (citing *U.S. ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1217 (10th Cir. 2008)). "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.* "A legally false FCA claim is based on a 'false certification' theory of liability." *Id.* (citation omitted).

There are two "false certifications" theories of liability: the express false certification theory and the implied false certification theory. *Id.* (citation omitted). "Under the 'express false certification' theory, an entity is liable under the FCA for falsely certifying that it is in compliance with regulations which are prerequisites to Government payment in connection with the claim for payment of federal funds." *Id.* (citation omitted). On the other hand, under the implied false certification theory, an entity is liable if it "seeks and makes a claim for payment from the Government without disclosing that it violated regulations that affected its eligibility for payment." *Id.* (citation omitted).

To plead an implied false certification theory, "a plaintiff must show that compliance with the regulation which the defendant allegedly violated was a *condition of payment* from the Government." *Id.* at 309 (emphasis added and citations omitted); *see also Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001) ("[A] claim for reimbursement made to the government is not

legally false simply because the particular service furnished failed to comply with the mandates of a statute, regulation or contractual term that is only tangential to the service for which reimbursement is sought."). Whether a defendant's compliance with a statute or regulation is a "condition of payment" from the Government is distinct from whether such compliance is "material" to the Government. *See Mikes*, 274 F.3d at 697 (explaining that a condition of payment requirement is distinct from a materiality requirement); *see also Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 793 (4th Cir. 1999) ("The prerequisite standard in the false certification cases is essentially a heightened materiality requirement: the government must have conditioned payment of the claim upon certification of compliance with the provision of the statute, regulation, or contract at issue.").

A defendant's compliance with a statute or regulation is a condition of payment when knowledge of the defendant's failure to comply "'might cause [the Government] to actually refuse payment.'" *Wilkins*, 659 F.3d at 309 (quoting *Conner*, 543 F.3d at 1220). In contrast, a defendant's compliance with a statute or regulation is material to the Government when the defendant's failure to comply "has a natural tendency to influence agency action or is capable of influencing agency action." *Harrison*, 176 F.3d at 785 (quotation marks and citation omitted). A defendant's failure to comply with a statute or regulation when submitting a claim for payment to the Government may induce the Government to act in a manner other than refusing to pay the claim. *See Wilkins*, 659 F.3d at 309 (noting that the defendant's noncompliance with Medicare marketing regulations could induce the Government to eventually bar the defendant from participating in the Medicare program, but that it did not necessarily provide the Government with a reason to refuse the defendant's requests for payment).

Bayer argues that Counts 1-6 should be dismissed because Simpson still does not identify any law that would have enabled the government reimbursement programs at issue to withhold payment based upon Bayer's alleged marketing violations. Bayer states that Simpson alleges that Bayer's marketing violations ran afoul of various program requirements that generally require compliance with unspecified laws. However, Bayer asserts, none of the provisions cited by Simpson mention the Food Drug and Cosmetic Act ("FDCA"), let alone compliance with its misbranding provisions.

Bayer gives two reasons why these 6 Counts should be dismissed. First, Bayer cites Third circuit case law for the proposition that Simpson cannot file suit based upon the violations of regulations "which may be corrected through an administrative process and which are not directly related to the Government's payment of a claim". *United States ex rel. Wilkins v. United Health Group, Inc.,* 659 F.3d 295, 310-11 (3d. Cir. 2011). Bayer also contends that Simpson still does not dispute that Trasylol was approved by the FDA at all times nor does she allege that Bayer defrauded the FDA. Second, Bayer argues that Simpson misinterprets the program requirements upon which she tries to base her claim, namely: (1) Medicare; (2) Medicaid; and (3) TRICARE/CHAMPUS and CHAMPVA.

Simpson responds to Bayer's argument by stating that although Bayer argues that Simpson has failed to identify a provision that authorized the Government to refuse payment for a misbranded drug, it is of little consequence because the Court has never required an express provision specifically referencing misbranding as a basis for refusing payment. Simpson argues that the Court could "reasonably infer" that the Government might refuse payment because Trasylol, as a misbranded drug, was not merchantable or fit for its particular purpose in treating patients and therefore could not be sold or supplied to government agencies in compliance with

federal and state laws. Therefore, Simpson asserts, each claim for payment submitted by Bayer to the VA or any government agencies for Trasylol was false.

In its previous Opinion, this Court held that:

> It can be reasonably inferred from [Simpson's] allegation that the Government may eventually sue a drug manufacturer for failing to comply with the FDCA's misbranding provisions. It does not follow, however, that the Government conditions its payments for pharmaceuticals on a drug manufacturer's compliance with the FDCA's misbranding provisions... Therefore, Simpson's allegations concerning the materiality of the FDCA's misbranding provisions to the Government do not allege the existence of a condition of payment.

U.S. ex rel. Simpson v. Bayer Corp., No. 05-3895 JLL, 2014 WL 1418293, at *5 (D.N.J. Apr. 11, 2014) *reconsideration denied*, No. 05-3895 JLL, 2014 WL 2112357 (D.N.J. May 20, 2014). While Simpson is correct in noting that the Court never required an express provision specifically referencing misbranding as a basis for refusing payment in order for her claims to survive dismissal, Simpson has still not identified a provision which would allow the Court to "reasonably infer" that the Government might refuse payment because Trasylol, as a misbranded drug, was not merchantable or fit for its particular purpose in treating patients and therefore, could not be sold or supplied to government agencies in compliance with federal and state laws. Simpson has still failed to adequately allege that Bayer's compliance with the FDCA's misbranding provisions was a condition of payment from the Government. While Simpson's allegation that, "[i]f the United States had known that Trasylol was misbranded and prohibited from interstate commerce, it would not have paid for it," is well taken, the Court cannot allow that claim to proceed without applicable case law or statute which would allow the Court to "reasonably infer" that the government might refuse payment because of misbranding violations. (*See Com.* at ¶¶ 338, 350). Even if the Court were to accept Simpson's contention that Trasylol

was not was not merchantable or fit for its particular purpose in treating patients, Simpson's claims could not proceed without the requisite provision that identified this allegation as a condition of payment by the Government.

The Court now considers whether Simpson otherwise alleges the existence of a condition of payment in her causes of action involving payments from: (1) Medicare (V-VI); (2) Medicaid (Counts III-IV); and (3) TRICARE/CHAMOUS and CHAMPVA (Counts I-II).

1. Medicare

Bayer argues that while Bayer's alleged marketing violations caused hospitals to violate their obligations to comply with federal laws, these requirements are conditions of participation, which are eligibility requirements that Medicare addresses through administrative mechanisms, not by refusing to pay claims. As a result, Bayer asserts, participation conditions are treated as distinct from payment conditions and do not give rise to FCA liability. Additionally, Bayer states that while Simpson asserts that Bayer's alleged conduct violated a payment condition based upon a Medicare regulation that authorizes the program to suspend payment while investigating suspected violations, this regulation only provides a procedural mechanism for addressing violations and does not establish that an FDCA misbranding violation constitutes an actionable fraud or misrepresentation, warranting nonpayment of a claim.

Simpson responds to Bayer's arguments by asserting that she has provided a "broader context" that would allow the Court to "reasonably infer" that the Government can and might refuse to pay Medicare reimbursements for Trasylol. Simpson states that the following four allegations support the conclusion that the fact that a drug is misbranded violates a condition of payment: (1) a claim for payment violates a certification in the Medicare enrollment form; (2) a claim for payment violates a certification in hospital cost reports; (3) Medicare is empowered to

withhold funds based on fraud; and (4) Medicare cannot expend funds for items prohibited by law.

Additionally, Simpson points out that she has amended her Complaint to identify conditions of payment, including that Bayer caused hospitals to violate certifications contained in the CMS-855 Medicare enrollment form. Simpson cites a recent District Court opinion for the proposition that a CMS-855 form establishes a condition of payment. *See United States ex. rel. Dalitz v. Amsurg Corp.,* No. 12-2218, 2014 WL 7336671, at *7 (E.D. Cal. Dec. 24, 2014).

Bayer responds to Simpson's arguments by stating that none of the case law offered by Simpson rehabilitates her theory that a healthcare provider has been caused to violate a condition of payment if it signs the Medicare enrollment form, treats a patient with a particular medicine, and the pharmaceutical company which sold the medicine violated an FDA marketing regulation. Bayer attempts to distinguish *Dalitz* by noting that the case dealt with a provider who allegedly billed for services that were not provided. Bayer argues that the court in *Dalitz* did not consider whether Medicare regulations, who generally state that providers should follow the law, are conditions of payment and incorporate other federal regulations, including FDA marketing requirements, as conditions of payment.

In its previous Opinion, the Court held that it "cannot reasonably infer that the Government would refuse to pay Medicare reimbursements for Trasylol due to Bayer's noncompliance with the misbranding provisions of the FDCA." *Citing Cf. Wilkins,* 659 F.3d at 309–10 ("[T]he fundamental flaw in appellants' allegations is that the amended complaint does not cite to any regulation demonstrating that a participant's compliance with Medicare marketing regulations is a condition for its receipt of payment from the Government."). *U.S. ex rel. Simpson v. Bayer Corp.,* No. 05-3895 JLL, 2014 WL 1418293, at *7 (D.N.J. Apr. 11, 2014)

reconsideration denied, No. 05-3895 JLL, 2014 WL 2112357 (D.N.J. May 20, 2014). The Court of Appeals for the Tenth Circuit explained the difference between conditions of participation and conditions of payment: "Conditions of participation ... are enforced through administrative mechanisms, and the ultimate sanction for violation of such conditions is removal from the government program," while "[c]onditions of payment are those which, if the government knew they were not being followed, might cause it to actually refuse payment." Conner, 543 F.3d at 1220.

Simpson has still failed to identify how her allegations regarding Bayer's misbranding should be considered a condition of payment as opposed to a condition of participation. Nowhere in her Amended Complaint, nor in the accompanying briefs does Simpson indicate that by submitting the alleged claims, Medicare would refuse to pay Medicare reimbursements for Trasylol due to Bayer's noncompliance with the misbranding provisions of the FDCA." Although Simpson cites to an Eastern District of California case for the proposition that a certification contained in the CMS-855 form is a condition of payment that could form the basis of an implied false certification claim; that case dealt with a provider that allegedly billed for non-provided services. This case deals with, as Bayer properly points out, whether providers should follow FDA marketing requirements as conditions of payment. As the Court has already noted in its previous Opinions, as well as above, the Court cannot reasonably infer, based upon Simpson's allegations, that FDA marketing requirements are conditions of payment under Medicare requirements. Therefore, the Court dismisses Counts V and VI with prejudice.

2. Medicaid

Simpson's argument as to Medicaid is that the program generally requires costs submitted for reimbursement to be incurred in compliance with applicable state and local law,

and that Bayer caused hospitals submitting claims to violate this requirement because misbranding is prohibited under various state statutes. Bayer asserts that this argument fails because none of the provisions Simpson cites authorizes the government to refuse payment for an FDA-approved drug based upon suspected misbranding. Bayer argues that most of the state misbranding prohibitions Simpson cites do not apply to the facts alleged in her Complaint.

Simpson responds to Bayer's argument by citing case law for the proposition that Bayer's argument that the federal government was not authorized to withhold payment, despite Trasylol being a prohibited item, fails because that interpretation of the relevant statute would be "absurd". Simpson furthers her argument by stating that the almost all state prohibitions on misbranded drugs apply to hospitals.

In its previous Opinion, the Court held that: "the Court cannot plausibly infer from [Simpson's] allegation that the Government would refuse to pay Medicaid reimbursements for Trasylol based on Bayer's noncompliance with the misbranding provisions of the FDCA. Such an inference would be speculative at best." The Court observed that "the [FCA] was not designed for use as a blunt instrument to enforce compliance with all medical regulations—but rather only those regulations that are a precondition to payment." *Mikes*, 274 F.3d at 699.

The Court is cognizant that federal law only allows funds to be used for Medicaid if the costs are not for items prohibited under state and local laws or regulations. In addition, the Court is aware that nearly every state prohibits the manufacture, sale, receipt, and/or distribution of a misbranded drug. However, nowhere is her Amended Complaint does Simpson point to a specific provision that would allow the government to refuse payment for an FDA-approved drug based upon suspected misbranding. Based on the pleadings within the Complaint, the Court cannot reasonably infer whether Medicaid costs for a misbranded drug would be remedied by an

administrative mechanism or through refusal to pay a claim. Without a provision pointing to Simpson's contention, the Court cannot allow her claims to proceed. Therefore, Counts III and IV are dismissed with prejudice.

3. TRICARE/CHAMOUS and CHAMPVA

Simpson's argument as to TRICARE/CHAMPUS and CHAMPVA is that for direct purchases by these programs, compliance with the misbranding provisions was a condition of payment based on general contractual provisions requiring (1) compliance with laws "applicable to its performance under this contract"; and (2) a general warranty of merchantability and fitness "for the particular purpose described in this contract." Bayer argues that these allegations fail to identify a relevant payment condition because Simpson cites only general provisions requiring compliance with unspecified laws, without identifying any provision that authorized the government to refuse payment for an FDA-approved drug based upon suspected misbranding. Moreover, Bayer asserts, Simpson does not allege that any product supplied to the government under the contract was unusable or differed from the contract description, as is required to violate the warranty of merchantability and fitness. Finally, Bayer states that to the extent Simpson alleges that payment was conditioned on the use being medically necessary or accepted, these allegations fail because Simpson has not plausibly alleged that claims were submitted for Trasylol uses that failed this standard.

The Court agrees with Bayer. Nowhere in Simpson's Amended Complaint do her allegations identify a relevant payment condition. The only provisions that Simpson points to in her argument are general in nature and do not address any specific provision that authorized the government to refuse payment for an FDA-approved drug based upon suspected misbranding. Simpson again alleges that, "[i]f the United States had known that Trasylol was misbranded and

prohibited from interstate commerce, it would not have paid for it." (*See* Comp. at ¶¶ 338, 350). This bare legal conclusion does not adequately plead the existence of a condition of payment. *Cf. Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) (noting that conclusory or bare-bones allegations do not survive a motion to dismiss). While the Court is cognizant that TRICARE and CHAMPVA condition payment for drugs on the requirement that they are "medically necessary", it cannot allow Simpson's claims to proceed without identification of a specific provision that authorized the government to refuse payment for an FDA approved drug based on the alleged misbranding. The Court cannot allow Simpson's claims to proceed. Therefore, Counts I and II are dismissed with prejudice.

C. Counts 7-8

The Medicare statute explicitly empowers the Secretary of Health and Human Services to decide one's entitlement to Medicare benefits. 42 U.S.C. § 1395ff(a)(1)(A). In doing so, the Medicare statute authorizes the Secretary "to determine whether the numerous medical services and items covered by Medicare are 'reasonable and necessary' in particular circumstances." *Willowood of Great Barrington, Inc. v. Sebelius*, 638 F. Supp. 2d 98, 105 (D. Mass. 2009) (citing *Goodman v. Sullivan*, 891 F.2d 449, 450 (2d Cir. 1989)). The Secretary sets forth such determinations in "both formal regulations and informal policy manuals." *Id.*

A defendant falsely certifies compliance with the Medicare statute if it submits, or causes to be submitted, a claim for Medicare reimbursement of a drug when the use of that drug was not "*reasonable and necessary* for the diagnosis or treatment of illness or injury . . . ." 42 U.S.C. § 1395y(a)(1)(A) (emphasis added); *Mikes*, 274 F.3d at 700. Thus, whether Counts VII and VIII may proceed hinges on whether the Complaint alleges that the off-label uses of Trasylol that Bayer promoted were not "reasonable and necessary." *Mikes*, 274 F.3d at 700.

Counts VII and VIII allege that Bayer's conduct led to the submission of claims involving Trasylol uses that were not "reasonable and necessary" and therefore not covered under Medicare. Bayer argues that the allegations in the Amended Complaint are identical to the previous Complaint, except for two new paragraphs. Bayer asserts that the new allegations do not cure Simpson's previous pleading deficiencies regarding these Counts. Bayer goes on to identify how each specific use of Trasylol is supported by compendia. Finally Bayer cites a statute for the proposition that even if a particular claim failed the "reasonable and necessary" requirement, the government would still be required to pay the claim, so long as the patient and provider reasonably understood the use in question to be "reasonable and necessary." Bayer contends that Simpson does not allege that any patient or provider knew or could have known that any claim was not reimbursable.

Simpson refutes Bayer's arguments by stating that the Amended Complaint adequately alleges that the authoritative drug compendia did not support off-label uses. Simpson then lists the alleged off-label uses that Bayer promoted, including: (1) off-pump CABG surgery; (2) pediatric surgery; (3) other pediatric surgery; (4) orthopedic surgery; (5) use with Plavix; and (6) valve surgery. Simpsons then explains in detail how the 2000 DRUGDEX entry fails to support each of these uses, except for valve surgery (which Simpson argues Bayer influenced the entry of through its alleged fraud). Bayer then cites case law for the proposition that a compendia listing, alleged to be the result of fraud, cannot support a finding of reasonable and necessary use.

In its previous Opinion, this Court held, "As it stands, Simpson's Complaint does not plausibly allege that the off-label uses of Trasylol that Bayer promoted lacked medical acceptance. This conclusion stems from the Court's inability to reasonably infer from the Complaint which particular off-label uses of Trasylol the 2000 DRUGDEX entry considers

unsupported." *U.S. ex rel. Simpson v. Bayer Corp.,* No. 05-3895 JLL, 2014 WL 1418293, at *7 (D.N.J. Apr. 11, 2014*) reconsideration denied,* No. 05-3895 JLL, 2014 WL 2112357 (D.N.J. May 20, 2014).

The Court, at this stage of the litigation, is not to test the sufficiency of the evidence underlying Simpson's allegations. As long as Simpson alleges facts plausibly suggesting that the uses at issue were not "medically accepted," the Court must accept her allegations as true. *See* e.g. *U.S. ex rel. Brown v. Celgene Corp.,* No. 10-3165, 2014 WL 3605896, at *6 (C.D. Cal. July 10, 2014) Simpson's allegations in the Amended Complaint meet this plausibility threshold here. The Complaint alleges, *inter alia*: (i) Bayer communicated and marketed Trayslol for uses other than those approved by the FDA and outside of the FDAMA's limited exception of off-label marketing materials (¶ 394); (ii) that the uses lacked sufficient medical support as reflected by the listings for Trasylol in the major drug compendia (*Id.*); (iii) that Bayer knew of these risks, yet encouraged off-label uses by physicians and hospitals (*Id.*) and (iv) how each off-label use was unreasonable, unnecessary and unsupported by the 2000 DRUGDEX entry. These allegations are sufficient to give rise to a plausible inference that Bayer promoted off-label uses that were not supported by the compendia. Based on the foregoing, the Court finds it inappropriate, at this stage of the litigation, to dismiss Counts VI and VII. Therefore, Bayer's motion is denied as to these Counts.

D. Counts 13-33

In Counts XIII-XXXIII, Simpson brings causes of action under the false claims acts of twenty-one states and the District of Columbia. (*Id.* at ¶¶433-568). Bayer contends that this Court must dismiss these causes of action as premature because not all of these jurisdictions have

validly declined to intervene. In its previous Opinion, this Court declined to dismiss these causes of action with prejudice, because without proper intervention from each state, dismissing the causes of action would be premature. To date, the Court is not aware of nor has it received a declination of intervention from the state of Delaware. Once again, each jurisdiction's false claims act requires either the jurisdiction or an official thereof to notify the Court of that jurisdiction's decision to decline intervention. Without all of the States declination at hand, the Court finds that these actions are premature. Therefore, consistent with its previous holding, the Court dismisses Counts XIII-XXXIII without prejudice.

E. Count 35

Bayer argues that Simpson's Count XXXV New York State retaliation claim fails to state a claim because the state, N.Y. State Fin. Law. § 191, was not enacted until April 2007, which was more than two years after Simpson's employment with Bayer ended. Bayer cites case law for the proposition that although the statute generally purports to apply to claims filed or presented prior to April 1, 2007, its retaliation provision is effective only on or after April 1, 2007. *See* 2007 N.Y. Sess. Laws 58, §93(5); *See Bowen v. Georgetown University Hosp.*, 488 U.S. 204, 208-9 (1988); *Majewski v. Broadalbin-Perth Cent. Sch. Dist.*, 91 N.Y.2d 577, 584 (1998)("It is a fundamental canon of statutory construction that retroactive operation is not favored by courts and statutes and will not be given such construction unless the language expressly or by necessary implication requires it."). Simpson does not address these arguments in her briefs. Therefore, because Simpson has not made any attempt to refute Bayer's argument and the relevant statute and case law indicate that retaliation claims may not be brought retroactively under N.Y State Fin. Law. §191, Count XXXV is dismissed with prejudice.

IV. CONCLUSION

For the reasons set forth above, the Court **GRANTS** Bayer's motion to dismiss Counts I through VI. In doing so, the Court dismisses those causes of action **with prejudice**. As to Counts VI and VIII, the Court **DENIES** Bayer's motion. As to Counts XIII-XXXIII, the Court **GRANTS** Bayer's motion. In doing so, the Court dismisses those causes of action **without prejudice.** Simpson may amend her Complaint within thirty days if she chooses, but only for the purpose of allowing the State of Delaware to submit its intervention in this action or declination thereof to this Court. As to Count XXXV, the Court **GRANTS** Bayer's motion to dismiss. Count XXXV is dismissed **with prejudice**.

An appropriate Order accompanies this Opinion.

DATED: 13 of March, 2015.

JOSE L. LINARES
U.S. DISTRICT JUDGE