

NOT FOR PUBLICATION**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

<p>UNITED STATES of AMERICA, <i>ex rel.</i> LAURIE SIMPSON, et al.,</p> <p style="text-align: center;">Plaintiff / Relator,</p> <p>v.</p> <p>BAYER CORP., et al.,</p> <p style="text-align: center;">Defendants.</p>	<p style="text-align: center;">Civil Action No. 05-3895 (JLL) (JAD)</p> <p style="text-align: center;">OPINION</p>
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LINARES, District Judge.

This matter comes before the Court by way of Relator Laurie Simpson (“Simpson”)’s motion for reconsideration of this Court’s April 11, 2014 Opinion and Order. 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 **DENIES** Simpson’s motion.

I. BACKGROUND¹

The Food, Drug, and Cosmetic Act (the “FDCA”) generally prohibits “misbranded” drugs from entering interstate commerce. 21 U.S.C. § 331(a)-(b). As is relevant here, a drug is misbranded when its manufacturer promotes it for off-label uses, *i.e.*, uses that the Food and Drug Administration did not approve. *Ironworkers Local Union 68 v. AstraZeneca Pharm., LP*, 634 F.3d 1352, 1357 n.5 (11th Cir. 2011) (citations omitted). According to Simpson’s Eighth

¹ The Court declines to set forth the facts of this case at length since it has already done so and writes only for the parties. The Court, instead, recounts the portions of its April 11, 2014 Opinion that are relevant to Simpson’s motion for reconsideration.

Amended Complaint,² Bayer³ misbranded one of its prescription drugs, Trasylol, by promoting off-label uses of the drug. (Compl. ¶¶ 134, 136-37, 143, 145, 148, 151-52, 157, 164).

The first six counts of Simpson’s Complaint, which this Court dismissed in its April 11, 2014 Opinion and Order, allege that Bayer violated sections 3729(a)(1) and (2) of the False Claims Act (the “FCA”), 31 U.S.C. § 3729(a)(1)-(2). (*Id.* at ¶¶ 318-52(II)).⁴ To state a claim under either section, a plaintiff must allege, among other things, the existence of a false or fraudulent claim for payment. *U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 242 (3d Cir. 2004) (citation omitted). Each of the first six counts of Simpson’s Complaint alleges that each claim for payment for Trasylol was “false or fraudulent in implying that the drug was not misbranded and was permitted in interstate commerce.” (Compl. ¶¶ 324, 334, 342, 352(I), 360(I), 351(II)). Based on this common allegation, the Court previously concluded that the first six counts of Simpson’s Complaint rely on an implied false certification theory. *U.S. ex rel. Simpson v. Bayer Corp.*, No. 05-3895, 2014 WL 1418293, *4 (D.N.J. Apr. 11, 2014). The Court then held that the first six counts of Simpson’s Complaint had failed to state a claim under that theory. *Id.* at *5-7. Simpson now moves the Court to reconsider its holding on two bases: (1) the Court overlooked controlling Third Circuit law; and (2) the Court incorrectly characterized a factual allegation as a legal conclusion.

II. LEGAL STANDARD

In this District, motions for reconsideration are governed by Local Civil Rule 7.1(i), and “[r]econsideration is an extraordinary remedy, that is granted ‘very sparingly.’” *Brackett v.*

² All further references to Simpson’s Complaint refer to the Eighth Amended Complaint.

³ All further references to Bayer refer to Defendants Bayer Corporation, Bayer Healthcare Pharmaceuticals, Inc., and Bayer Healthcare, LLC.

⁴ Simpson’s Complaint uses the numbers 346 through 365 twice when numbering paragraphs. When this Court cites to the first instance in which a number is used for a paragraph, the Court follows that number with a (I). When this Court cites to the second instance in which a number is used for a paragraph, the Court follows that number with (II).

Ashcroft, No. 03-3988, 2003 WL 22303078, *2 (D.N.J. Oct. 7, 2003) (quoting *Interfaith Cmty. Org. v. Honeywell Int'l Inc.*, 215 F. Supp. 2d 482, 507 (D.N.J. 2002)). The purpose of such a motion “is to correct manifest errors of law or fact or to present newly discovered evidence.” *Jill Pharm. USA, Inc. v. Chertoff*, 447 F.3d 196, 199 n.4 (3d Cir. 2006) (quoting *Harsco Corp. v. Zlotnicki*, 779 F.2d 906, 909 (3d Cir. 1985)). As such, a movant may not use a motion for reconsideration to relitigate old matters or to raise new matters that could have been raised before the court reached its original decision. *P. Schoenfeld Asset Mgmt. LLC v. Cendant Corp.*, 161 F. Supp. 2d 349, 352 (D.N.J. 2001) (citation omitted). To prevail on a motion for reconsideration, the movant “must satisfy a high burden, and must ‘rely on one of three major grounds: (1) an intervening change in controlling law; (2) the availability of new evidence not available previously; or (3) the need to correct clear error of law or prevent manifest injustice.” *Leja v. Schmidt Mfg., Inc.*, 743 F. Supp. 2d 444, 456 (D.N.J. 2010) (quoting *N. River Ins. Co. v. CIGNA Reins. Co.*, 52 F.3d 1194, 1218 (3d Cir. 1995)).

III. DISCUSSION

A. Whether the Court Overlooked Controlling Precedent

Simpson contends that this Court overlooked controlling Third Circuit law when it held that the first six counts of her Complaint failed to state a claim under the implied false certification theory. (Pl.’s Br. 1-2, ECF No. 149-1). To state such a claim, the Third Circuit has explained that “a plaintiff must show that compliance with the regulation which the defendant allegedly violated was a condition of payment from the Government.” *U.S. ex rel. Wilkins v. United Health Grp. Inc.*, 659 F.3d 295, 309 (3d Cir. 2011) (citations omitted). Such conditions “are those which, if the government knew they were not being followed, might cause it to actually refuse payment.” *Id.* (quoting *U.S. ex rel. Conner v. Salina Reg’l Heath Ctr., Inc.*, 543

F.3d 1211, 1220 (10th Cir. 2008)). Simpson argues, in essence, that the Court misapplied this standard when it dismissed the first six counts of her Complaint. (Pl.’s Br. 1-2). The Court briefly considers Simpson’s argument since, given the opportunity that the Court has provided Simpson to amend her Complaint, doing so will likely hasten the resolution of this case. *See Arista Records, Inc. v. Flea World, Inc.*, 356 F. Supp. 2d 411, 417 (D.N.J. 2005) (court briefly addressed movant’s arguments in favor of reconsideration for the sake of hastening the ultimate resolution of the case)

The theory underpinning the first six counts of Simpson’s Complaint is that Bayer’s compliance with the FDCA’s misbranding provisions is, in and of itself, a condition of payment. The Court again rejects this theory. *Cf. U.S. ex rel. Booker v. Pfizer, Inc.*, --- F. Supp. 2d ---, No. 10-11166, 2014 WL 1271766, *14 (D. Mass. Mar. 26, 2014) (rejecting relator’s theory that a claim is false or fraudulent because it was induced by misbranding alone). “Under an implied false certification theory, . . . ‘the analysis focuses on the underlying contracts, statutes, or regulations themselves to ascertain whether they make compliance a prerequisite to the government’s payment.’” *Wilkins*, 659 F.3d at 313 (quoting *Conner*, 543 F.3d at 1218). Here, the underlying statute—the FDCA—explicitly prohibits (a) “the introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is . . . misbranded,” and (b) the “misbranding of any . . . drug . . . in interstate commerce.” 21 U.S.C. § 331(a)-(b).⁵ It is clear from the quoted language that a drug manufacturer’s compliance with the FDCA’s misbranding provisions is a condition for a drug’s legality in interstate commerce. However, it is unclear from the quoted language that a drug manufacturer’s compliance with the FDCA’s misbranding provisions is a condition for receiving payment from the Government under CHAMPVA, the

⁵ The first six counts of Simpson’s Complaint specifically cite 21 U.S.C. § 331(a)-(b), and thus the Court focuses on that section of the FDCA. (Compl. ¶¶ 320, 329, 338, 347, 356, 346(II)).

FEHBP, Medicaid, Medicare, or TRICARE. Stated otherwise, while compliance with the FDCA's misbranding provisions is a condition, it is not a condition impacting whether the Government might actually refuse payment for a drug. Thus, the first six counts of Simpson's Complaint do not allege the existence of a condition of payment.

Simpson attempts to correct this deficiency by pointing to her Complaint's allegations that the Department of Justice ("DOJ") has pursued and obtained a number of criminal and FCA settlements against companies that misbranded drugs. (Pl.'s Br. 2). Simpson contends that these allegations "easily support the plausibility of the conclusion that the Government *might* refuse payment based on misbranding." (*Id.* (emphasis in the original)). Simpson's contention is unpersuasive for at least two reasons. First, it ignores that whether the Government "might" do something depends on whether the Government can do that thing. Critically, Simpson has not pointed the Court to any language in the FDCA's misbranding provisions that allows the Government to refuse to pay for a drug under the aforementioned healthcare programs because the drug's manufacturer failed to comply with the FDCA's misbranding provisions. *See Wilkins*, 659 F.3d at 309 ("the 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.")). Second, Simpson's contention improperly conflates the DOJ's ability to bring and settle misbranding claims against pharmaceutical companies with the Government's ability to refuse to pay for drugs under a number of Government healthcare programs. Accordingly, the first six counts of Simpson's Complaint do not adequately allege that compliance with FDCA's misbranding provisions is a condition of payment under any of the healthcare programs discussed in those counts, and her motion for reconsideration on this ground is denied.

B. Whether the Court Improperly Characterized a Factual Allegation as a Legal Conclusion

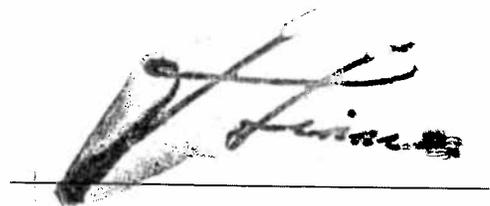
Simpson next argues that the Court erred when it characterized her allegation that “[i]f the United States had known that Trasylol was misbranded and prohibited from interstate commerce, it would not have paid for it” as a legal conclusion. The Court disagrees. At bottom, this allegation simply restates in a conclusory fashion one version of the legal standard for stating a claim under the implied false certification theory set forth in *Wilkins*: “a plaintiff must show that if the Government had been aware of the defendant’s violations of the . . . laws and regulations that are the bases of [her] FCA claims, it would not have paid the defendant’s claims.” *Id.* at 307 (citing *Conner*, 543 F.3d at 1219-20). Accordingly, the Court finds Simpson’s argument unavailing and declines to reconsider this aspect of its prior Opinion.

IV. CONCLUSION

For the reasons discussed herein, the Court **DENIES** Simpson’s motion for reconsideration.

An appropriate Order accompanies this Opinion

DATED: 20 of May, 2014.



JOSE L. LINARES
U.S. DISTRICT JUDGE