UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

UNITED STATES OF AMERICA, Ex Rel. ESTHER SULLIVAN, Relator, ET AL., **Plaintiffs,** **v.** **ATRIUM MEDICAL CORPORATION; MAQUET CARDIOVASCULAR, LLC; MAQUET CARDIOVASCULAR US SALES, LLC,** **Defendants.**	**CIVIL NO. SA-13-CA-244-OLG**

REPORT AND RECOMMENDATION OF UNITED STATES MAGISTRATE JUDGE

TO: Honorable Orlando L. Garcia
United States District Judge

Pursuant to the order of referral of the above-styled and numbered cause to the undersigned United States Magistrate Judge,[1] and consistent with the authority vested in United States Magistrate Judges under the provisions of 28 U.S.C. § 636(b)(1)(B) and Rule 1(d) and (e) of the Local Rules for the Assignment of Duties to United States Magistrate Judges, Appendix C to the Local Rules for the Western District of Texas, the following report is submitted for your review and consideration.

I. JURISDICTION

Relator Esther Sullivan has alleged subject matter jurisdiction under the False Claims

[1] Docket no. 79 (filed May 27, 2015).

Act, 31 U.S.C. § 3729, et seq., as well as under 31 U.S.C. § 1345, and 28 U.S.C. §§ 1331, 1367.[2]

II. SELECTED SUMMARY OF PROCEDURAL HISTORY

Relator Esther Sullivan initiated this case in this Court on March 26, 2013, when she filed an original complaint on behalf of the United States and 29 states, each listed as a plaintiff,[3] and which named three defendants: Atrium Medical Corporation ("Atrium"), Maquet Cardiovascular LLC (at times, "Maquet"), and "Marquet" Cardiovascular US Sales, LLC (at times, "Maquet US Sales")[4] (at times, Maquet and Maquet US Sales are referred to collectively as the "Maquet entities").[5] Plaintiffs' original complaint asserted claims in 33 counts, with each count asserted against all three defendants:

> count one—"violations of the False Claims Act related to off-label & fraudulent marketing[,] 31 U.S.C. § 3729(a)(1)(A) and 31 U.S.C. § 3729(a)(1)B) [for violations on or after June 7, 2008] [and] 31 U.S.C. § 3729(a)(1) and 31 U.S.C. § 3729(a)(2) [for violations prior to June 7, 2008];"
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> count two—"violations of the False Claims Act related to violations of the anti-kickback statute[,] 31 U.S.C. § 3729(a)(1)(A) and 31 U.S.C. § 3729(a)(1)B) [for violations on or after June 7, 2008] [and] 31 U.S.C. § 3729(a)(1) and 31 U.S.C. § 3729a)(2) [for

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[2] Docket no. 7 at 6.

[3] As noted, this qui tam action was initiated by relator Esther Sullivan on behalf of herself, the United States, and certain states. At times, this report—as the parties' submissions—refers to "plaintiffs" rather than simply relator or relator Sullivan.

[4] The caption of the original complaint and first amended complaint identify defendant Maquet US Sales as "Marquet," an apparent typographical error, as the body of each pleading refers to "Maquet Cardiovascular US Sales." Thus, this report, including its caption, refers to "Maquet US Sales."

[5] Docket no. 1. As discussed below, plaintiffs assert, "upon information and belief," that "Atrium is a business unit and/or division of Maquet Cardiovascular" (docket no. 7 at 6, ¶ 9) and, accordingly, according to plaintiffs, Atrium also could be referred to as a "Maquet entity." But, for the purposes of this report, the collective designation of "Maquet entity" does *not* include Atrium.

violations prior to June 7, 2008];"

count three—"violations of the False Claims Act related to best price violations, 31 U.S.C. § 3729(a)(1)(A)[,] 31 U.S.C. § 3729(a)(l)(B) [for violations on or after June 7, 2008] [and] 31 U.S.C. § 3729(a)(1) [and] 31 U.S.C. § 3729(a)(2) [for violations prior to June 7, 2008];"

count four—"violations of the False Claims Act arising out of defendants' conspiracy to submit false claims[,] 31 U.S.C. § 3729(a)(1)(C) [for violations on or after June 7, 2008] [and] 31 U.S.C. § 3729(a)(3) [for violations prior to June 7, 2008];"[6] and

counts five through 33—violations of specified state false claims acts, state medicaid fraud false claims acts, or other related state statutes, including a count alleging a violation of the Texas Medicaid False Claims Act (count 31).[7]

On October 18, 2013, plaintiffs filed their sealed first amended complaint which asserted three federal False Claims Act causes of action against defendants as well as violations of specified state statutes:

count one—"violations of the False Claims Act related to off-label & fraudulent marketing[,] 31 U.S.C. § 3729(a)(1)(A) and 31 U.S.C. § 3729(a)(1)B) [for violations on or after June 7, 2008] [and] 31 U.S.C. § 3729(a)(1) and 31 U.S.C. § 3729(a)(2) [for violations prior to June 7, 2008];"

count two—"violations of the False Claims Act related to violations of the anti-kickback statute[,] 31 U.S.C. § 3729(a)(1)(A) and 31 U.S.C. § 3729(a)(1)B) [for violations on or after June 7, 2008] [and] 31 U.S.C. § 3729(a)(1) and 31 U.S.C. § 3729a)(2) [for violations prior to June 7, 2008];"

count three—"violations of the False Claims Act arising out of defendants' conspiracy to submit false claims, 31 U.S.C. § 3729(a)(1)(C) [for violations on or after June 7, 2008] [and] 31 U.S.C. § 3729(a)(3) [for violations prior to June 7, 2008];"[8] and

counts four through 32—violations of specified state false claims acts, medicaid fraud false claims acts, or other related statutes, including a count alleging a violation of the

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[6] Id. at 41-46.

[7] Id. at 46-126.

[8] Docket no. 7 at 46-51.

Texas Medicaid False Claims Act (count 30).[9]

On March 31, 2014, the United States filed a notice informing both that the United States and each of the plaintiff states named in the first amended complaint elected not to intervene.[10] On April 28, 2014, the Court entered an order that, in sum and in part, unsealed plaintiffs' original and first amended complaints, the notice of election not to intervene, and all filings to be made after the date of the order.[11]

On March 18, 2015, the District Judge granted in part and denied in part defendants' joint pre-answer motion to dismiss.[12] Specifically, and in pertinent part, the District Judge dismissed defendants Maquet Cardiovascular LLC and Maquet Cardiovascular US Sales, LLC as party defendants; dismissed plaintiffs' conspiracy claim; granted defendants' motion to dismiss plaintiffs' FCA claims to the extent plaintiffs' first amended complaint alleges an FCA claim based on off-label marketing occurring on or before August 13, 2012, in any state other than Arkansas, Louisiana, Mississippi, Colorado, Texas, Oklahoma, and New Mexico; dismissed plaintiffs' claim based on the New Mexico Medicaid False Claims Act; and dismissed any claim based on state law for alleged conduct that predates the applicable limitations period under the appropriate state law.[13]

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[9] Id. at 51-131.

[10] Docket no. 14.

[11] Docket no. 16.

[12] Docket no. 68 (order adopting in full the recommendations in the undersigned's December 31, 2014 report (docket no. 58)).

[13] Id.

Thereafter, as further reflected by the docket sheets, Atrium filed an answer to plaintiffs' first amended complaint; and on May 11, 2015, Atrium filed a motion for judgment on the pleadings.[14] On May 26, 2015, the District Judge referred the motion to the undersigned.[15] The same day, plaintiffs filed (1) a motion to strike Atrium's answer to plaintiffs' first amended complaint; (2) their response to Atrium's motion for judgment on the pleadings; and (3) a motion for leave to file a second amended complaint.[16] On May 27, 2015, the District Judge referred the case for pretrial management.[17] The same day, the undersigned entered a scheduling order; setting a July 6, 2015 deadline to amend pleadings or join additional parties; a discovery deadline of October 26, 2015, a dispositive motion deadline of November 9, 2015, and a prospective date for jury selection and trial of February 22, 2016.[18] On June 1, 2015, the United States filed a "Statement of Interest."[19] On June 2, 2015, Atrium filed its reply in support of its motion for judgment on the pleadings.[20]

III. STATEMENT OF THE CASE

For the purpose of a Rule 12(c) motion to dismiss, "all factual allegations in the

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[14] Docket nos. 73, 74.

[15] Docket no. 75.

[16] Docket nos. 76, 77, 78.

[17] Docket no. 79.

[18] Docket no. 80.

[19] Docket no. 81.

[20] Docket no. 83.

complaint must be taken as true and construed favorably to the plaintiff."[21] For purposes of defendants' motion for judgment on the pleadings, unless otherwise stated, the Court accepts as true the allegations in plaintiffs' "live" pleading, plaintiffs' first amended complaint. Plaintiffs' first amended complaint sets out factual allegations in approximately 43 pages of that 131-page pleading. This portion of the report does not purport to re-state that lengthy rendition, but offers a brief summary to provide a context for the Court's discussion of the issues relating to defendants' motion.

Plaintiffs' 131-page, 504-paragraph first amended complaint is a qui tam complaint, brought by relator Esther Sullivan, a former employee of defendant Atrium, on behalf of the United States and listed states. Plaintiffs allege Atrium is a private Delaware corporation headquartered in New Hampshire that manufactures and sells medical devices, including the iCAST stent.[22] Plaintiffs allege, in sum and in part: Atrium has marketed "a balloon-expandable covered stent,"[23] called the iCAST stent; the Food and Drug Administration ("FDA") approved the iCAST stent as a Class II device to treat tracheobronchial strictures,[24] but has not approved it as a Class III vascular stent; Atrium thereafter marketed the iCAST stent for the "off label" use as vascular stent; Atrium "intended" the iCAST stent to be used for purposes other than the

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[21] Great Plains Trust Co. v. Morgan Stanley Dean Witter & Co., 313 F.3d 305, 312-13 & n. 8 (5th Cir. 2002).

[22] Docket no. 7 at 5, ¶ 7.

[23] Id. at 6, ¶ 12.

[24] Id. at 3, ¶ 1; 6, ¶ 12.

treatment of tracheobronchial strictures;[25] Atrium "exclusively promoted the iCAST stent" for uses other than the treatment of tracheobronchial strictures[26] and "almost exclusively marketed the iCAST stent to physicians and hospitals for off-label use;"[27] although relator Sullivan worked for Atrium for five years (2007-2012) as a territory business manager,[28] Atrium "never trained or instructed" relator Sullivan "to market the iCAST for use to treat tracheobronchial strictures, [and] she never sold a stent for that purpose;"[29] Atrium instructed its sales force to promote the iCAST stent as a direct competitor to the Gore Viabahn stent, a Class III medical device approved for placement in iliac arteries;[30] and "during the entire time Ms. Sullivan was employed at Atrium, she and the other sales representatives were trained and instructed by management to market the iCAST stent solely for off-label uses."[31]

Plaintiffs allege that "Atrium's off-label marketing scheme violated the False Claims Act"[32] because the FDA approved the iCAST stent as a Class II device, but "Atrium committed fraud on the FDA and fraudulently induced the FDA to approve the iCAST device by representing that its intended use was a product with substantial equivalence to a product used to

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[25] Id. at 3, ¶ 1.

[26] Id.

[27] Id. at 7, ¶ 16.

[28] Id. at 5, ¶ 4.

[29] Id. at 8, ¶ 16 (emphasis in original).

[30] Id. at 14, ¶ 31.

[31] Id. at 8, ¶ 16.

[32] Id. at 26 (title of subsection).

treat tracheobronchial strictures when, in fact, Atrium never intended the iCAST to be used for this purpose."[33] Plaintiffs allege "the vast majority of individuals with vascular blockages are over the age of 65"[34] such that Medicare and other federal payers would be asked to pay for its uses, including off-label uses.[35] Plaintiffs allege Atrium issued a guide to physicians that instructed them how to code the procedure to ensure Medicare coverage for the "off-label" procedures performed on patients covered by Medicare.[36] Plaintiffs allege off-label use of the iCAST stent "was not medically necessary because it was experimental" such that the federal government and listed states improperly paid claims for its use.[37] Further, plaintiffs allege the iCAST "was misbranded because it failed to bear adequate instruction for the off-label uses that Atrium knew and intended it be used for."[38] Plaintiffs allege the misbranding of the iCAST violated the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq.

Finally, plaintiffs further allege that to encourage health care providers to purchase the iCAST stent, Atrium used "'give-away' programs to [induce] physicians and hospitals to purchase iCAST stents and by providing preceptorships, speaker fees, referral dinners and lavish meals to physicians to induce them to purchase and use iCAST stents, mainly for off-label

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[33] Id. at 28, ¶ 67.

[34] Id. at 4, ¶ 3.

[35] Id. at 28-34, ¶¶ 68-87.

[36] Id. at 22, ¶ 52.

[37] Id. at 3, ¶ 1; 28-29, ¶ 69; 29, ¶ 71.

[38] Id. at 4, ¶ 1.

purposes,"[39] as well as providing free stents,[40] entering into "certain contracts with hospitals through Premier, a purchasing organization" that offered "better pricing going to hospitals [which] ensured that certain percentage of their grafts were Atrium grafts,"[41] and "provided grants to hospitals[] conditioned on the purchase of iCAST stents,"[42] all of which violated the Anti-Kickback statute, 42 U.S.C. § 1320a-7b.

IV. ISSUE

Whether Atrium's motion for judgment on the pleadings should be granted or denied.

V. STANDARDS

A. Motion for Judgment on the Pleadings

Rule 12(c) of the Federal Rules of Civil Procedure states: "After the pleadings are closed—but early enough not to delay trial—a party may move for judgment on the pleadings."[43] The United States Court of Appeals for the Fifth Circuit repeatedly has held that the Rule 12(c) standard is the same as the Rule 12(b)(6), standard, recently summarizing the standard as follows:

> This Court reviews a district court's grant of judgment on the pleadings under Rule 12(c) *de novo*. See Brittan Commc'ns Int'l Corp. v. Sw. Bell Tel. Co., 313 F.3d 899, 904 (5th Cir.2002); Hughes v. The Tobacco Inst., Inc., 278 F.3d 417, 420 (5th Cir.2001). A motion for judgment on the pleadings under Rule 12(c) is subject to the same standard as a motion to dismiss under Rule 12(b)(6).

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[39] Id. at 37, ¶ 98. See also id. at 41 (title of subsection).

[40] Id. at 37 (title of subsection).

[41] Id. at 38, ¶ 102.

[42] Id. at 43, ¶ 43.

[43] FED. R. CIV. P. 12(c).

> Johnson v. Johnson, 385 F.3d 503, 529 (5th Cir.2004) (citing Great Plains Trust Co. v. Morgan Stanley Dean Witter & Co., 313 F.3d 305, 313 n. 8 (5th Cir.2002)). "[T]he central issue is whether, in the light most favorable to the plaintiff, the complaint states a valid claim for relief." Hughes, 278 F.3d at 420 (internal quotations omitted). Although we must accept the factual allegations in the pleadings as true, id., a plaintiff must plead "enough facts to state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 127 S.Ct. 1955, 1974, 167 L.Ed.2d 929 (2007).[44]

If a Rule 12(c) motion (as a Rule 12(b)(6) motion) is based on extrinsic evidence, it must be converted to a motion for summary judgment.[45] If a summary judgment motion depends entirely on the pleadings and exhibits, it functions as a Rule 12(c) motion for judgment on the pleadings.[46]

B. Rule 12(b)(6) of the Federal Rules of Civil Procedure

Pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, a plaintiff must state a claim upon which relief can be granted or the complaint may be dismissed with prejudice as a matter of law.[47] When considering a motion to dismiss for failure to state a claim, the "court accepts 'all well-pleaded facts as true, viewing them in the light most favorable to the

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[44] Ackerson v. Bean Dredging LLC, 589 F.3d 196, 209 (5th Cir. 2009). See also Guidry v. Am. Pub. Life Ins. Co., 512 F.3d 177, 180 (5th Cir. 2007) (citing In re Katrina Canal Breaches Litig., 495 F.3d 191, 205 (5th Cir. 2007), cert. denied sub nom, Xavier Univ. of La. v. Travelers Cas. Prop. Co. of Am, 552 U.S. 1182, 128 S. Ct. 1230 (2008); Chehardy v. Allstate Idem. Co., 552 U.S. 1182, 128 S. Ct. 1231 (2008)); Great Plains Trust, 313 F.3d at 313 n. 8.

[45] FED. R. CIV. P. 12(d).

[46] Dyal v. Union Bag-Camp Paper Corp., 263 F.2d 387, 391 (5th Cir. 1959); Commercial Money Ctr., Inc. v. Illinois Un. Ins., 508 F.3d 327, 335-36 (6th Cir. 2007) (court can consider documents attached to pleadings and matters of public record when considering Rule 12(c) motion).

[47] FED. R. CIV. P. 12(b)(6).

plaintiff.'"[48] To withstand a Rule 12(b)(6) motion, "the plaintiff must plead 'enough facts to state a claim to relief that is plausible on its face.'"[49]

Rule 8(a)(2) of the Federal Rules of Civil Procedure sets out the fundamental pleading standard for civil litigation and governs all claims in a civil suit, requiring "a short plain statement of the claim showing that the pleader is entitled to relief."[50] Although "heightened fact pleading of specifics"[51] may not be adopted when not authorized by the Federal Rules of Civil

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[48] In re Katrina Canal Breaches Litig., 495 F.3d 191, 205 (5th Cir. 2007) (quoting Martin K. Eby Constr. Co. v. Dallas Area Rapid Transit, 369 F.3d 464, 467 (5th Cir. 2004); Jones v. Greninger, 188 F.3d 322, 324 (5th Cir. 1999); Chehardy v. Allstate Indem. Co., 552 U.S. 1182, 128 S. Ct. 1231 (2008)), cert. denied sub nom, Xavier Univ. of La. v. Travelers Cas. Prop. Co. of Am, 552 U.S. 1182, 128 S. Ct. 1230 and Chehardy v. Allstate Idem. Co., 552 U.S. 1182, 128 S. Ct. 1231 (2008).

In Katrina Canal Breaches, 495 F.3d at 205 n.10, the United States Court of Appeals for the Fifth Circuit acknowledged the United States Supreme Court's abrogation of the "no set of facts" standard for determining the adequacy of a pleading in Bell Atlantic Corp. v. Twombly, a Sherman Act case:

> We have often stated that a claim should not be dismissed under Rule 12(b)(6) unless the plaintiff would not be entitled to relief under any set of facts or any possible theory he may prove consistent with the allegations in the complaint. See, e.g., Martin K. Eby Constr., 369 F.3d at 467 (quoting Jones, 188 F.3d at 324). This standard derived from Conley v. Gibson, which stated that "a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." 355 U.S. 41, 45-46, 78 S. Ct. 99, 2 L.Ed.2d 80 (1957). But recently in Bell Atlantic, the Supreme Court made clear that the Conley rule is not "the minimum standard of adequate pleading to govern a complaint's survival." 127 S.Ct. at 1968-69.

[49] Id. at 205 (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570-72, 127 S. Ct. 1955, 1974 (2007)).

[50] FED. R. CIV. P. 8(a)(2).

[51] Twombly, 550 U.S. at 570, 127 S.Ct. at 1974.

Procedure,[52] the complaint taken as a whole "must contain either direct or inferential allegations respecting all the material elements necessary to sustain recovery under some viable legal theory"[53] and a plaintiff's pleading obligation includes the twin requirements of fact-based pleading and plausibility. More specifically, "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do."[54] "Factual allegations must be enough to raise a right to relief above the speculative level . . . on the assumption that all of the allegations in the complaint are true (even if doubtful in fact)."[55] Although the Supreme Court in Twombly stressed that it did not impose a probability standard at the pleading stage, nevertheless, the allegation of a mere possibility of relief does not satisfy the threshold requirement of Rule 8(a)(2) that the "plain statement" of a claim include factual "allegations plausibly suggesting (not merely consistent with)" an entitlement to relief.[56]

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[52] See, e.g., Fed. R. Civ. P. 9(b) (allegations of fraud or mistake to be stated with particularity); Swierkiewicz v. Sorema, N.A., 534 U.S. 506, 508, 122 S. Ct. 992 (2002) ("[A] complaint in an employment discrimination lawsuit [need] not contain specific facts establishing a *prima facie* case of discrimination under the framework set forth in McDonnell Douglas Corp. v. Green, 411 U.S. 792 [, 93 S. Ct. 1817, 36 L.Ed.2d 668] (1973).").

[53] Twombly, 550 U.S. at 562, 127 S. Ct. at 1969 (quoting Car Carriers, Inc. v. Ford Motor Co., 745 F.2d 1101, 1106 (7th Cir. 1984) (internal quotation marks omitted; emphasis and omission in original)).

[54] Id. at 555, 127 S. Ct. at 1964-65 (citing Papasan v. Allain, 478 U.S. 265, 286, 106 S.Ct. 2932, 2944 (2007)).

[55] Id. at 555, 127 S. Ct. at 1965 (as quoted in Katrina Canal Breaches, 495 F.3d at 205).

[56] Id. at 557, 127 S.Ct. at 1966. See also Ashcroft v. Iqbal, 556 U.S. 662, 684, 129 S.Ct. 1937, 1953 (2009) (rejecting the argument that the Twombly plausibility pleading standard applied only in antitrust cases and expressly holding the standard applies "all civil actions.").

When ruling on a motion to dismiss under Rule 12(b)(6), a court must accept as true all of the factual allegations contained in the complaint.[57] But, a court need not accept as true "conclusory allegations, unwarranted factual inferences, or legal conclusions," which will not defeat a Rule 12(b)(6) motion to dismiss.[58] In Iqbal, the Court formalized a two-pronged approach to apply the underlying jurisprudential principles of Twombly.[59] The first prong required the Court to separate factual allegations from legal conclusions. The Court dismissed those allegations deemed to be "conclusory" on the basis that bare legal conclusions are not entitled to the privilege that all well-pleaded facts be taken as true at the motion to dismiss stage.[60] The second prong then applied the plausibility test to the remaining allegations.[61] That

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[57] 550 U.S. at 555, 127 S.Ct. at 1965 (citing Swierkiewicz, 534 U.S. at 508 n.1, 122 S. Ct. at 996 n.1; Neitzke v. Williams, 490 U.S. 319, 326-37, 109 S.Ct. 1827, 1832 (1989); Scheuer v. Rhodes, 416 U.S. 232, 236, 94 S. Ct. 1683, 1686 (1974)).

[58] Plotkin v. IP Axess, Inc., 407 F.3d 690, 696 (5th Cir. 2005) (citing Southland Sec. Corp. v. INSpire Ins. Solutions, Inc., 365 F.3d 353, 361 (5th Cir. 2004)).

[59] Twombly, 550 U.S. at 677-79, 129 S.Ct. at 1949-50.

[60] Id. Iqbal illustrated its analysis of the first prong as follows:

> We begin our analysis by identifying the allegations in the complaint that are not entitled to the assumption of truth. Respondent pleads that petitioners "knew of, condoned, and willfully and maliciously agreed to subject [him]" to harsh conditions of confinement "as a matter of policy, solely on account of [his] religion, race, and/or national origin and for no legitimate penological interest." Complaint ¶ 96, App. to Pet. for Cert. 173a-174a. The complaint alleges that Ashcroft was the "principal architect" of this invidious policy, id., ¶ 10, at 157a, and that Mueller was "instrumental" in adopting and executing it, id., ¶ 11, at 157a. These bare assertions, much like the pleading of conspiracy in Twombly, amount to nothing more than a "formulaic recitation of the elements" of a constitutional discrimination claim, 550 U.S., at 555, 127 S.Ct. 1955, namely, that petitioners adopted a policy " 'because of,' not merely 'in spite of,' its adverse effects upon an identifiable group." Feeney, 442 U.S., at 279, 99 S.Ct. 2282. As such, the allegations are conclusory and not entitled to be assumed true. Twombly, *supra*, 550 U.S., at 554-555, 127 S.Ct. 1955. To be clear, we do not reject these

two-pronged approach is now the standard for evaluating the plausibility of a complaint under Rule 8(a)(2).

VI. DISCUSSION

A. Preliminary Matters

Before analyzing Atrium's motion, the Court must address two matters. First, plaintiffs' response attaches several exhibits, exhibits 2, 3, and 4, that are not attached to, or referenced in, the first amended complaint and one exhibit, exhibit 1, that plaintiffs argue is referenced in the complaint.[62] Plaintiffs' response makes clear plaintiffs understand the Court cannot look outside the pleadings on a 12(c) motion for judgment on the pleadings, but plaintiffs argue "where the plaintiff relies on extra-judicial pleading documents to respond to the motion, the documents may

> bald allegations on the ground that they are unrealistic or nonsensical. We do not so characterize them any more than the Court in Twombly rejected the plaintiffs' express allegation of a " 'contract, combination or conspiracy to prevent competitive entry,' " id., at 551, 127 S.Ct. 1955, because it thought that claim too chimerical to be maintained. It is the conclusory nature of respondent's allegations, rather than their extravagantly fanciful nature, that disentitles them to the presumption of truth.

Id. at 680-81, 129 S. Ct. at 1951.

[61] Id. (explaining that although the Court must "take all of the factual allegations in the complaint as true," it is "not bound to accept as true a legal conclusion couched as a factual allegation" (internal quotation marks omitted)).

[62] See docket no. 77, exhibit 1, a December 28, 1994 memorandum from Thomas A. Ault at the Department of Health & Human Services ("Ault memo"); exhibit 2, the May 21, 2015 declaration of Esther G. Sullivan ("Sullivan decl."); exhibit 3, Atrium's objections and responses to relator's first set of interrogatories; exhibit 4, the May 6, 2010 third amended complaint of relator Kevin N. Colquitt in United States ex rel. Colquitt v. Abbott Laboratories, No. 3:06-cv-1769-M (N.D. Tex.).

be considered as if they had been attached to the plaintiff's complaint," citing two cases.[63] The two cases cited by plaintiff are distinguishable. In Walch v. Adjutant General's Department of Texas, plaintiff "attached numerous exhibits to his response in opposition to the Defendants' motion to dismiss;" "[b]oth Defendants referenced some of these same documents in their motions to dismiss;" and the Fifth Circuit "rel[ied] on only two of these documents" because only those two documents "were explicitly referenced in the complaint, acknowledged in the answers, and attached to [plaintiff's] opposition to the Defendants' motion to dismiss."[64] In Colquitt, the Northern District of Texas relied on the Fifth Circuit's decision in Walch without reservation or analysis.[65]

Here, only exhibit 1, the Ault memo, is "explicitly referenced" in the first amended complaint.[66] Exhibits 2, 3, and 4 attached to plaintiffs' response to Atrium's motion for judgment on the pleadings are not referenced in the first amended complaint.[67] Under the plain language of Rule 12(d), if a Rule 12(c) motion is based on extrinsic evidence, such as exhibits 2, 3, and 4, then it either must be converted to a motion for summary judgment or the extrinsic evidence must be excluded.[68] Plaintiffs do not ask the Court to construe the motion for judgment

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[63] Id. at 7, n.2 (citing Walch v. Adjutant General's Dep't of Tex., 533 F.3d 289 (5th Cir. 2008); Colquitt, 864 F.Supp. 2d 499, 531 n.9 (N.D. Tex. 2012)).

[64] Walch, 533 F.3d at 293-94.

[65] Colquitt, 864 F.Supp. 2d at 531 n.9.

[66] Docket no. 7 at 29 § 71.

[67] See generally id.

[68] FED. R. CIV. P. 12(d).

on the pleadings as one for summary judgment. Accordingly, except to the extent exhibit 1 was referenced in the first amended complaint, the Court does not consider the exhibits attached to plaintiffs' response in making its recommended ruling on Atrium's motion for judgment on the pleadings.

Second, the United States has filed a "Statement of Interest" in support of relator's position in opposition to Atrium's motion for judgment on the pleadings.[69] The United States has not intervened in this case, filed a notice declining intervention, and has not sought to retract that decision.[70] Therefore, the United States is not a party to these proceedings. Accordingly, the statement of interest is comparable to an unsolicited amicus brief. The Court declines to consider an unsolicited statement of interest from a non-party that had the opportunity to intervene and declined to do so. Neither the United States nor relator (the party with whom the United States aligns itself) has provided any legal authority to show it would be proper for the Court to consider its "Statement of Interest" under the circumstances of this case.

B. Fraud on the FDA

1. summary of arguments

Atrium moves for judgment on the pleadings, arguing plaintiffs' fraud on the FDA claim is "not supported by the FCA" because the FCA "requires 'the alleged fraud be made as part of a claim for payment to the payor agency.'"[71] Specifically, relying on a federal case from the

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[69] Docket no. 81.

[70] Docket no. 14.

[71] Docket no. 74 at 4 (citing United States ex rel. Campie v. Gilead Sci., Inc., No. C-11-0941 EMC, 2015 U.S. Dist. LEXIS 1635, at *36 (N.D. Cal. Jan. 7, 2015)).

Northern District of California, Atrium argues "false certifications, statements, or other fraudulent conduct directed at the FDA during the approval process do not render subsequent Medicare or Medicaid reimbursement requests made to CMS 'false' under the FCA."[72] Further, Atrium argues "Relator should be foreclosed from recovering under [the fraud on the FDA] theory under her state law claims because of preemption."[73]

In response, relator argues "in the device arena, payment *is* conditioned on whether the FDA has approved a device as being sufficiently safe and effective" therefore, "where misrepresentations affect the FDA's decision about whether or not to approve a device . . . such claims are viable under the FCA."[74] Relator argues that "[b]ut for Atrium's misrepresentation about its intent with respect to marketing the device, the iCAST would not have been cleared for marketing," "[t]hus, Atrium fraudulently induced the FDA into clearing the iCAST for marketing."[75] Relator asserts "[t]he *only* way to redress this type of fraud on the FDA is through post-clearance legal action such as a[n FCA] suit," and "Atrium's fraudulent inducement of the FDA to approve its device for marketing is absolutely material to Medicare's decision about whether to pay for services and procedures."[76]

In reply, Atrium raises three arguments. First, Atrium argues "Campie is persuasive authority more analogous to the present case than any of Relator's fraudulent inducement

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[72] Id. at 3-4 (citing Campie, No. C-11-0941 EMC, 2015 U.S. Dist. LEXIS 1635, at *36).

[73] Id. at 6 (citing Buckman Co. v. Plaintiff's Legal Comm., 531 U.S. 341, 350 (2001)).

[74] Docket no. 77 at 3 (emphasis in original).

[75] Id. at 5.

[76] Id. at 6-7 (emphasis in original).

cases."[77] Second, Atrium argues the FDA has "a wide range of administrative responses and action[s]" it could have taken, including "bring[ing] an enforcement action, issu[ing] a recall or warning letter, conduct[ing] an investigation, or bring[ing] an action."[78] Atrium asserts "[t]he FDCA has clearly indicated its intent that the FDA make decisions surrounding the FDA approval process by explicitly not allowing a private right of action under the FDCA."[79] Third, Atrium argues "the mere submission of a claim for the off-label use of a medical device is not by itself a false claim."[80] Atrium argues "the doctor or hospital that elects to deploy an iCAST off-label must conclude whether it meets applicable requirements for reimbursement before potentially making a claim for reimbursement."[81]

2. analysis

The FCA states, in pertinent part, liability to attaches to any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;" or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim."[82] "The FCA permits the United States, or a private person on the government's behalf (a 'relator'), to sue a person who has presented a false claim for payment to

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[77] Docket no. 83 at 3.

[78] Id. at 6.

[79] Id. at 7.

[80] Id.

[81] Id. at 8.

[82] 31 U.S.C. §§ 3729(a)(1)(A); 3729(a)(1)(B).

the United States."[83] A violation of the FCA occurs when (1) "there was a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that caused the government to pay out money or to forfeit moneys due (*i.e.*, that involved a claim)."[84] "The [FCA] attaches liability . . . to the claim for payment, not to the underlying fraudulent activity."[85] It is undisputed that a claim for Medicare payment triggers the

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[83] United States ex rel. Parikh v. Brown, 587 F. App'x 123, 127 (5th Cir. 2014) (citing 31 U.S.C. §§ 3729(a), 3730(b)).

[84] United States v. Bollinger Shipyards, Inc., 775 F.3d 255, 259 (5th Cir. 2014) (quoting United States ex rel. Longhi v. Lithium Power Techs., Inc., 575 F.3d 458, 467 (5th Cir. 2009)).

[85] Parikh, 587 F. App'x at 128-29 (quoting Longhi, 575 F.3d 458, 467 (5th Cir. 2009) (internal quotation marks omitted)). See also United States ex rel. Grubbs v. Kanneganti, 565 F.3d 180, 188 (5th Cir. 2009). In United States ex rel. Bui v. Vascular Solutions, Inc., No. A-10-CA-883-SS (W.D. Tex. Mar. 7, 2013) (slip op.), Judge Sam Sparks denied a motion to dismiss claims under the FCA, noting the parties' "arguments essentially dovetail[ed] into a single debate about whether off-label uses of medical devices . . . are properly reimbursable by Medicare or TRICARE." Bui, No. A-10-CA-883, docket no. 44 at 6. Regarding Medicare and TRICARE coverage, in Bui, Judge Sparks stated:

> In general, the Medicare statute prohibits payments for services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. § 1395y(a)(l)(A). The Secretary of Health and Human Services has the authority to decide "whether a particular medical service is 'reasonable and necessary,'" and also has the authority to decide "the means by which she implements her decision, whether by promulgating a generally applicable rule or by allowing individual adjudication." Heckler v. Ringer, 466 U.S. 602,617(1984) (citing 42 U.S.C. § 1395ff(a)). As relevant to this case, the Secretary contracts with private insurance carriers, who in turn issue "local coverage determinations" (LCDs) with respect to particular services. See 42 U.S.C. §§ 1395u; 1395ff(f)(2)(B); 42 C.F.R. § 421.200. LCDs generally require treatments to be reasonable and necessary, and may include more specific guidelines, such as requiring a laser or RF ablation device to be FDA-approved.
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> Similarly, TRICARE excludes from its coverage umbrella "[u]nproven drugs, devices, and medical treatments or procedures." 32 C.F.R. § 199.4(g)(15). A device or procedure is considered unproven if it lacks the necessary FDA approval and clearance. Id. § 199.4(g)(15)(i)(A). TRICARE is allowed to "consider coverage of off-label uses" of medical devices, but "[a]pproval for reimbursement of off-label uses requires review for medical necessity and also

FCA.[86]

Atrium argues this Court should apply the reasoning of the Northern District of California, in United States ex rel. Campie v. Gilead Sciences, Inc., which analyzed and "expressly rejected" relator's allegation that "purported fraud during the FDA's approval process would render every subsequent payment made by another governmental entity a false claim because of the alleged original sin."[87] Relator argues the decision in Campie is distinguishable and "where misrepresentations affect the FDA's decision about whether or not to approve a device, as alleged here, such claims are viable under the FCA."[88] Relator argues this Court should apply the reasoning of the Eastern District of Pennsylvania, in United States ex rel. Krahling v. Merck & Co., Inc., which "explicitly endorsed the fraud-on-the-FDA theory," and

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> requires demonstrations from medical literature, national organizations, or technology assessment bodies that the off-label use of the drug or device is safe, effective, and in accordance with nationally accepted standards of practice in the medical community." Id. The TRICARE Policy Manual states: "If the device is used for a noncovered or excluded indication, benefits may not be allowed." Gov't Resp. [#40], Ex. A.

Bui, No. A-10-CA-883, docket no. 44 at 6-7.

The Court finds Bui distinguishable for two reasons. First, the Government intervened in Bui. Second, unlike the situation in Bui, relator does not allege that Atrium "mislead physicians into believing the" iCAST was "FDA-approved" for vascular use. Bui, No. A-10-CA-883, docket no. 44 at 9. Relator alleges Atrium trained her to promote the off-label use of the iCAST, and to inform physicians how to code the billing for such off-label use. Docket no. 7 at 8.

[86] See United States ex rel. Shupe v. Cisco Sys., Inc., 759 F.3d 379, 384 (5th Cir. 2014) (noting "[c]ourts have also identified entities that do not receive Government funds, but nevertheless are covered by the FCA because of their status as Government entities (citing United States v. Mackby, 261 F.3d 821, 824, 826 (9th Cir. 2001)).

[87] Docket no. 74 at 1 (citing Campie, No. C-11-0941 EMC, 2015 U.S. Dist. LEXIS 1635, at *36).

[88] Docket no. 77 at 3.

"rejected the argument . . . that the fraud-on-the-FDA theory is preempted."[89]

In Campie, the Northern District of California considered FCA claims brought by former employees of Gilead who alleged the pharmaceutical company violated FDA regulations in the manufacturing of "drugs for the treatment of HIV/AIDS, cystic fibrosis, and hepatitis," "failed to correct these violations," concealed the violations, and "the resulting sale of misbranded, adulterated drugs render each sale of the affected drugs 'false' for purposes of the [FCA]."[90] The court ultimately granted Gilead's motion to dismiss plaintiffs' FCA claims, but permitted plaintiffs leave to amend.[91] Specifically, in Campie, the court determined:

> Gilead's non-disclosures and misrepresentations were made to the FDA during the FDA approval process; this process preceded and was distinct to the subsequent reimbursement requests to CMS under Medicare or Medicaid. In short, the misrepresentations at issue were to the FDA, not the payor agency (CMS) and were not made as a condition of reimbursement by CMS. . . . Rather, payment is conditioned only on FDA approval of the drugs sold. Here, Gilead had obtained FDA approval of all the drugs in question.[92]

In Campie, the court noted that "[n]o circuit court, including the Ninth Circuit, has ever interpreted [the FCA's] statutory language as encompassing a false or fraudulent statement to a licensing or regulatory agency [such as the FDA]—disconnected from the request for payment—simply because that false or fraudulent statement to that licensing agency ultimately

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[89] Id. at 8 (citing United States ex rel. Krahling v. Merck & Co., Inc., 44 F.Supp.3d 581 (E.D. Pa. 2014)).

[90] Campie, No. C-11-0941 EMC, 2015 WL 106255, at *1.

[91] Id. at *15.

[92] Id. at *10.

enabled the defendant to achieve eligibility for funding from the payor agency."[93]

In Krahling, the Eastern District of Pennsylvania considered claims brought by former employees of Merck & Co. alleging the company "billed the [Center for Disease Control] for purchase of its mumps vaccines when Defendant knew of the vaccine's diminished efficacy," and "Defendant falsified, abandoned, and manipulated testing data that should have been shared with the government in order to fraudulently mislead the government into purchasing the mumps vaccine."[94] Specifically, Krahling alleged "Defendants submitted test results to the government that contained falsifications, or omissions, of relevant testing data" which was "reflected in their labeling, their submissions for approvals, and their requests for payment for purchase of the medications."[95] Contrary to relator's argument, the Court finds Krahling distinguishable. In Krahling, defendants made claims for payment directly to the government for purchase of the mumps vaccine.[96] Here, relator does not allege Atrium made a false or fraudulent claim for payment directly to the government. Liability under the FCA attaches to the claim for payment, not to underlying fraudulent activity.[97]

Also, contrary to relator's argument, the Court does not find the decision in Campie to be distinguishable. Relator's first amended complaint alleges, in pertinent part, "the FDA was fraudulently induced into approving the device for a purpose for which Atrium never intended it

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[93] Id. at *9.

[94] Krahling, 44 F.Supp.3d at 588.

[95] Id. at 591.

[96] Id. at 593-94.

[97] Parikh, 587 F. App'x at 128-29; Grubbs, 565 F.3d at 188.

to be marketed or used."[98] Specifically, the first amended complaint alleges:

> Atrium committed fraud on the FDA and fraudulently induced the FDA to approve the iCAST device by representing that its intended use was a product with substantial equivalence to a product used to treat tracheobronchial strictures when, in fact, Atrium never intended the iCAST to be used for this purpose. The FDA, believing Atrium's representations, approved the iCAST device pursuant to the 510(k) procedure.[99]

Here, as in Campie, "the FDA was not the payor agency and was not directly involved in the reimbursement process."[100] Relator has failed to allege that Atrium engaged in any fraudulent conduct or made any false statement to CMS or TRICARE—the government agencies that administer reimbursements—as part of a request for payment.[101] "There must be a direct and immediate link between a false statement or fraudulent conduct and the resulting request for payment; payment must be conditioned on the falsity."[102] Accordingly, because relator has not pleaded any direct or immediate link between Atrium's alleged false statement or fraudulent conduct and any resulting claim for payment, Atrium's motion for judgment on relator's claim of fraud on the FDA should be **granted**, and plaintiff's claim for violations of the FCA based on a theory of fraud on the FDA **dismissed**.

Finally, to the extent Atrium argues relator's state law claims are preempted, Atrium's entire argument for preemption is contained in one conclusory footnote containing one case

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[98] Docket no. 7 at 47, ¶ 129.

[99] Docket no. 7 at 28, ¶ 67.

[100] Campie, No. C-11-0941 EMC, 2015 WL 106255, at *8.

[101] Id.

[102] Campie, No. C-11-0941 EMC, 2015 WL 106255, at *9.

citation, without further analysis. Accordingly, without any further analysis, to the extent Atrium moves for judgment on the pleadings on plaintiffs' state law claims, Atrium's motion should be **denied**.

C. Off-Label Marketing

1. summary of arguments

Atrium moves for judgment on the pleadings, arguing plaintiffs' off-label marketing claims "are precluded by the public disclosure bar."[103] Specifically, Atrium argues "iCAST's approval via the FDA's 510(k) process for tracheobronchial strictures was publicly disclosed," and "iCAST was advertised in *Endovascular Today*."[104] Atrium argues relator "cannot qualify as an original source because (1) she was no longer employed by Atrium as of the date the LCD became effective and (2) she did not work in any of the seven states covered by the LCD (nor does her Complaint contain any allegations arising out of those states)."[105]

In response, relator argues "relator's marketing allegations are not precluded by the public disclosure bar."[106] Specifically, relator asserts "mention of the placement of an ad in one journal does not plead public disclosure of the essential elements of an allegation of off-label

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[103] Docket no. 74 at 7.

[104] Id. at 9.

[105] Id. at 10. The LCD at issue, LCD L32641, became effective on August 13, 2012, and covered seven states: Arkansas, Louisiana, Mississippi, Colorado, Texas, Oklahoma, and New Mexico. See docket no. 58 at 52-53.

[106] Docket no. 77 at 9. In her response, relator attempts to "fully incorporate herein by reference" the arguments made in her motion for leave to file a second amended complaint. Id. at 12. The Court declines to consider arguments made in an unrelated motion. See infra at 32, section D.

marketing."[107] Relator argues she "is an original source of the off-label marketing allegations" because "her allegations are of *nationwide* conduct, and therefore do involve the seven states covered by the LCD," and "although Sullivan left Atrium's employ in 2012, the complaint shows that she still has 'independent' knowledge of the critical . . . elements of the allegations in the case."[108]

In reply, Atrium argues "the public disclosure of the essential elements is sufficient to bar all later off-label marketing claims, even if the advertisements stopped."[109] Atrium argues relator "lacks relevant knowledge to be an original source."[110] Specifically, Atrium argues relator "does not make any relevant allegations supporting any direct and independent knowledge of relevant off-label marketing of the iCAST in Arkansas, Louisiana, Mississippi, Colorado, Texas, Oklahoma, and New Mexico."[111]

2. analysis

As an initial matter, the District Judge adopted the recommendations in the undersigned's December 31, 2014 report, including granting defendants' motion to dismiss plaintiffs' FCA claims to the extent plaintiffs' first amended complaint alleged an FCA claim based on off-label marketing occurring in any state other than Arkansas, Louisiana, Mississippi, Colorado, Texas,

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[107] Id. at 14.

[108] Id. at 15, 17-18 (citing United States ex rel. Galmines v. Novartis Pharmaceutical Corp., No. 06-3213, 2015 WL 851837 (E.D. Pa. Feb. 27, 2015)).

[109] Docket no. 83 at 9.

[110] Id.

[111] Id. at 10.

Oklahoma, and New Mexico, and on or before August 13, 2012.[112] As stated in the December 31, 2014 report, "[r]elator does not state a claim based on off-label marketing outside of the seven states."[113] Therefore, plaintiffs' off-label marketing claims are limited to those occurring on or after August 13, 2012, in Arkansas, Louisiana, Mississippi, Colorado, Texas, Oklahoma, and New Mexico.

Relator's employment with Atrium terminated on July 30, 2012, prior to the August 13, 2012 effective date of the LCD.[114] Further, relator was employed as a sales representative in North Carolina, not one of the seven states covered by the LCD. Although relator argues her allegations are applicable nationwide, the factual allegations in the first amended complaint concern off-label marketing in North Carolina prior to August 13, 2012. Atrium argues relator is not an original source, and the public disclosure bar precludes any FCA claims on or after August 13, 2012 in the seven states.

Under the applicable version of the federal False Claims Act,[115] a court must "dismiss an

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[112] Docket nos. 58, 68.

[113] Docket no. 58 at 53.

[114] The Court takes judicial notice of the end date of relator's employment with Atrium. See Sullivan v. Atrium Med. Corp., et al, No. 13-CV-813 (E.D. N.C. Nov. 21, 2013) (docket no. 1 at 8, ¶ 48). See also docket no. 77 at 12 (relator concedes "the current allegations . . . are limited to one region and a period when Sullivan no longer worked at Atrium . . . .").

[115] Because the adopted December 31, 2014 report limited relator's off-label marketing claims to those in the specifically alleged LCD, which took effect on August 13, 2012, the 2010 amendments to the FCA are applicable to relator's off-label marketing claims, including the 2010 version of the public disclosure bar, and the 2010 version of the original source exception to the public disclosure bar. See docket nos. 58, 68. The 2010 amendment "recharacterizes the public disclosure bar as a ground for dismissal—effectively, an affirmative defense—rather than a jurisdictional bar." United States ex rel. Harman v. Trinity Indus., Inc., Case No. 2:12-CV-00089-JRG, 2014 WL 47258, at *3 (E.D.Tex. Jan. 6, 2014). Therefore, because the application

action or claim . . . if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed— . . . [(i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party; (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or (iii)] from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information."[116] An "original source" is defined as:

> an individual who either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.[117]

As stated in this Court's December 31, 2014 report, to determine whether the public disclosure bar applies, courts have used a three-part test, asking:

> 1) whether there has been a 'public disclosure' of allegations or transactions, 2) whether the qui tam action is 'based upon' such publicly disclosed allegations, and 3) if so, whether the relator is the 'original source' of the information.[118]

"Courts generally have concluded that the phrase 'allegations or transactions' refers to both: (1) the allegation of fraud itself, or (2) the material facts that underlie the allegation of fraud[,]" and "[i]f either the allegation of fraud or the material facts that underlie it are in the public

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of the public disclosure bar is no longer jurisdictional in nature, the Court is limited to the pleadings at issue in determining its application as an affirmative defense. See id.

[116] U.S. ex rel. King v. Solvay S.A., No. CIV.A. H-06-2662, 2015 WL 925612, at *10 (S.D. Tex. Mar. 3, 2015) (quoting 31 U.S.C. § 3730(e)(4)(A)).

[117] 31 U.S.C. § 3730(e)(4)(B).

[118] Fed. Recovery Servs., Inc. v. United States, 72 F.3d 447, 450 (5th Cir. 1995). A court "need not follow the three steps rigidly." United States ex rel. Jamison, 649 F.3d at 327.

domain, the [public disclosure] bar will generally apply."[119]

Some courts have applied an algebraic template in the "allegation of fraud" analysis first used by the United States Court of Appeals for the District of Columbia Circuit in United States ex rel. Springfield Terminal Railway Co.:

> [I]f X + Y = Z, Z represents an *allegation* of fraud and X and Y represent its essential elements. In order to disclose the fraudulent *transaction* publicly, the combination of X and Y must be revealed, from which readers or listeners may infer Z, *i.e.*, the conclusion that fraud has been committed. The language employed in § 3730(e)(4)(A) suggests that Congress sought to prohibit *qui tam* actions *only* when either the allegation of fraud [Z] or the critical elements of the fraudulent transaction themselves [X and Y] were in the public domain.[120]

Plaintiff's fraud claims "require[] recognition of two elements: a misrepresented state of facts and a true state of facts."[121] Here, the "misrepresented state of facts"—defendants' representation to the FDA the iCAST stent "was similar to other devices used to treat tracheobronchial strictures and that it was intended to be used that way"[122]—appears to have been made publicly in defendants' application for FDA approval through the 510(k) process. Further, the first amended complaint alleges that in 2007, "Atrium placed advertisements for the iCAST in *Endovascular*

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[119] United States ex rel. Ward v. Commercial Metals Co., No. C-05-56, 2007 WL 1390612, at *4 (S.D.Tex. May 9, 2007) (citing United States ex rel. Springfield Terminal Ry. Co. v. Quinn, 14 F.3d 645, 654 (D.C.Cir. 1994)).

[120] 14 F.3d at 654 (original emphasis). See, e.g., United States ex rel. Simms v. Austin Radiological Assoc., No. A-10-CV-914-AWA, 2013 WL 6837715, at *4 (W.D.Tex. Dec. 23, 2013) (J. Austin); United States ex rel. Colquitt, 864 F.Supp.2d at 519; United States ex rel. Heath v. Dallas/Fort Worth Int'l Airport Bd., No. Civ.A.3:99-CV-0100-M, 2004 WL 1197483, at *4 (N.D.Tex. May 28, 2004); United States ex rel. Johnson v. Shell Oil Co., 33 F.Supp.2d 528, 533 (E.D.Tex. 1999).

[121] Id. at 655. See also United States ex rel. Reagan 384 F.3d at 174-75.

[122] First amended complaint at 7.

Today, clearly in an effort to appeal to surgeons doing endovascular stenting, not to surgeons who would do tracheobronchial stenting."[123]

In Colquitt, the Northern District of Texas considered a motion to dismiss relator's qui tam action, and found that similar advertisements constituted public disclosure. Specifically, the court stated "[a] person who picks up a copy of *Endovascular Today* has just as much access to the advertisements as the edited content . . .[and] [t]hus, the advertisements that are described in the [third amended complaint] are 'from the news media,' within the meaning of the FCA's public disclosure bar."[124] Further, the court found that a 510(k) summary, which is "prepared and submitted by device manufacturers as part of the 510(k) clearance process," constitutes a federal administrative report within the meaning of the FCA's public disclosure bar.[125] The court stated:

> The advertisements, combined with the 510(k) summaries, disclose the critical elements of the allegations of off-label promotion: (1) that the Defendants advertised stents for vascular use, and (2) that those stents were approved only for biliary use. Therefore, the advertisements disclose transactions raising the inference that the Defendants promoted the stents identified in the ads for off-label use in the vascular system.[126]

Here, as in Colquitt, substantially the same allegations or transactions as alleged in the first amended complaint were publicly disclosed in a federal report (the 510(k) summary) and in the news media (*Endovascular Today*). Moreover, as in Colquitt, the presence of an advertisement for a tracheobronchial stent in an endovascular publication gives rise to an inference that Atrium

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[123] Docket no. 7 at 9.

[124] Colquitt, 864 F.supp.2d at 519.

[125] Id. at 517-518.

[126] Id. at 523.

promoted the iCAST (approved for tracheobronchial use) for off-label use in the vascular system. Thus, unless relator qualifies as an original source, the public disclosure bar precludes relator's off-label marketing claims.

Under the amended version of the FCA, there are two methods for qualifying as an original source. To qualify under the first method, relator must have "voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based" prior to the public disclosure under 31 U.S.C. § 3730(e)(4)(a).[127] Under the first method, relator does not qualify as an original source to prevent the application of the public disclosure bar. Relator does not allege she voluntarily disclosed the information on which her claims are based prior to either the 510(k) approval process or the 2007 advertisement in *Endovascular Today*. Therefore, to qualify as an original source, relator must satisfy the second method; meaning relator must have pleaded she had (1) "knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions," and (2) "voluntarily provided the information to the Government before filing an action under this section."[128] Regarding the second element, relator argues she "provided to the United States Attorney and the Attorneys General of all of the States named in the caption and the District of Columbia a full disclosure of substantially all material facts prior to filing the instant motion."[129] Regarding the first element—that relator has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions—relator has alleged that she was trained to and did promote the iCAST for off-label

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[127] 31 U.S.C. § 3730(e)(4)(B).

[128] 31 U.S.C. § 3730(e)(4)(B).

[129] Docket no. 77 at 18, n.5 (citing docket no. 7 at 5).

use in the vascular system in her territory during the period of her employment with Atrium (North Carolina from 2007-2012).[130] But, relator has not pleaded any allegations of off-label marketing on or after August 13, 2012 in Arkansas, Louisiana, Mississippi, Colorado, Texas, Oklahoma, and New Mexico.[131] Therefore, relator is not an original source because relator has not stated a claim for off-label marketing for the LCD at issue.

In opposition to Atrium's motion, relator cites to United States ex rel. Galmines v. Novartis Pharmaceuticals Corporation.[132] In Galmines, the Eastern District of Pennsylvania considered relator's motion for leave to file a fourth amended complaint; specifically whether the proposed amendment was futile because Novartis argued Galmines was not "an original source of the publicly disclosed allegations."[133] Specifically, the court considered whether "Galmines was an original source of the allegations that Novartis continued to unlawfully market Elidel after the filing of the original complaint."[134] The court stated "a relator's allegations need not be strictly limited to the information to which she has direct and independent knowledge, provided that the relator has direct and independent knowledge of the critical elements of the alleged fraudulent scheme."[135] Further, in Galmines, the court acknowledged "when determining the

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[130] Docket no. 7 at 8-20. Relator "was employed by Atrium as a territory business manager for the Raleigh, North Carolina territory between 2007 and 2012." Id. at 5.

[131] See id. at 8-20 (allegations of training and promotion directed towards North Carolina prior to the termination of relator's employment with Atrium).

[132] Id. at 16 (citing Galmines, No. 06-3213, 2015 WL 851837 (E.D. Pa. Feb. 27, 2015)).

[133] Galmines, No. 06-3213, 2015 WL 851837, at *1.

[134] Id. at *3.

[135] Id.

extent to which an original source can allege and seek discovery for additional aspects of the same underlying scheme, the limiting principle is the sufficiency of the allegations and the evidence."[136] Here, and as acknowledged in Galmines, the first amended complaint includes only bald assertions that the off-label marketing scheme continued after relator's termination, and only provides particularity as to false claims dating on or after August 13, 2012, in Arkansas, Louisiana, Mississippi, Colorado, Texas, Oklahoma, and New Mexico.

Finally, although relator argues "Atrium's theory" that relator's off-label marketing allegations are precluded by the public disclosure bar "is unsupported by public disclosure jurisprudence in the Fifth Circuit," relator does not cite to any Fifth Circuit case law or case law from federal courts within the Fifth Circuit to support her conclusion.[137] Accordingly, Atrium's motion for judgment on relator's claim of off-label marketing should be **granted**, and plaintiff's claim for violations of the FCA based on off-label marketing **dismissed**.

D. Amendment of Complaint

Rule 15(a)(1) of the Federal Rules of Civil Procedure provides, in sum, that a "party may amend its pleading once as a matter of course within" 21 days after serving it or, "if the pleading is one to which a responsive pleading is required, within 21 days after service of a responsive

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[136] Id. at *6 (citing United States ex rel. Duxbury v. Ortho Biotech Products, LP, 719 F. 3d 31, 39 (1st Cir. 2013) (stating "[t]he district court was not required to expand the scope of discovery based upon the amended complaint's bald assertions that the purported kickback scheme continued after Duxbury's termination or that it was 'nationwide' in scope."); United States ex rel. Rose v. Pfizer, Inc., 253 F.R.D. 11, 17 (D. Mass. 2008) (holding that where an original source of a fraudulent scheme had only provided particularity as to false claims in Indiana, the Court will permit discovery only relating to the sales and marketing region that includes Indiana.)).

[137] Docket no. 77 at 10.

pleading or 21 days after service of a Rule 12(b), (e), or (f), motion, whichever is earlier."[138] Rule 15(a)(2) addresses all other amendments.[139] Although Rule 15(a)(2) provides that leave shall be freely given "when justice so requires,"[140] leave is not automatic.[141] Whether to grant leave "lies within the sound discretion of the district court."[142] "In exercising its discretion, the Court may consider such factors as undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party, and futility of the amendment."[143]

Here, relator's motion for leave to file a second amended complaint was filed on May 26, 2015, after relator had already amended once, "as of course." Thus, the Court must evaluate whether "justice so requires" a further amendment at this time.

Notwithstanding the purported "early stage" of this two-year old case, as characterized by

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[138] FED. R. CIV. P. 15(a)(1)(A), (B). The Advisory Committee Notes state that the 21-day periods are not cumulative. For example, "if a responsive pleading is served after one of the designated motions is served, there is no new 21-day period." Advisory Committee Notes on FED. R. CIV. P. 15 (2009 Amendments).

[139] Rule 15(a)(2) provides:

> In all other cases, a party may amend its pleading only with the opposing party's written consent or the court's leave. The court should freely give leave when justice so requires.

FED. R. CIV. P. 15(a)(2).

[140] FED. R. CIV. P. 15(a)(2).

[141] In re Southmark Corp., 88 F.3d 311, 314 (5th Cir. 1996), cert. denied, 519 U.S. 1057, 117 S.Ct. 686 (1997). See Bakner, 2000 WL 33348191, at * 14 (citing Geiserman v. McDonald, 893 F.32d 787, 790 (5th Cir. 1990)).

[142] Bakner, 2000 WL 33348191, at * 14 (citing Louisiana v. Litton Mortg. Co., 50 F.3d 1298, 1302-03 (5th Cir. 1995)).

[143] Id. (citing Foman v. Davis, 371 U.S. 178, 182, 83 S.Ct. 227, 230 (1962). Southmark Corp., 88 F.3d 314-15).

relator, Atrium has a very strong argument the amendment should not be permitted. Atrium has presented evidence to show **relator affirmatively represented** to Atrium approximately two months ago relator would not seek to file a second amended complaint and defendants began computer-assisted discovery procedures based on **agreed-upon** search terms selected in reference to the first amended complaint. Specifically, on April 3, 2015, Atrium sent relator a letter that confirmed "Relator would not be seeking leave to file a second amended complaint" and asked relator to promptly notify defendants if the letter "misstates our agreement in any way."[144] There is no evidence relator notified Atrium the April 3 letter was not a correct statement of relator's position. Rather, relator's motion to amend explains that, "[a]s stated in Defendant's motion [for judgment on the pleadings], undersigned counsel did not plan to further amend her pleading as of her conversation with defense counsel on April 1, 2015."[145] Relator's reply brief in support of her leave to amend further argues "Atrium has known all along that the Relator could move to amend the complaint, even if she decided not to do so immediately following the Court's March 18 order," because the deadline for filing motions to amend has not yet expired.[146] But, relator fails to explain why Atrium should have known relator would file a motion for leave to file a second amended complaint when relator specifically represented she "would not be seeking leave to file a second amended complaint."[147] The disclaimer stated in the

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[144] Docket no. 84, exhibit 1 at 2.

[145] Docket no. 78 at 3.

[146] Docket no. 86 at 7.

[147] In a footnote in her response to Atrium's motion for judgment on the pleadings, relator argues that in the April 1 conference call that preceded the April 3 confirmatory letter, relator only "indicated she was not inclined to move to amend the complaint *at the time*." Docket no. 77

April 3 letter contains no limitation as to time period or contingencies, such as Atrium not seeking judgment on the pleadings directed to the first amended complaint. The fact remains that it was only after Atrium filed its motion for judgment on the pleadings—a motion to which the Court has devoted time and attention—that relator decided to seek to amend and respond to the motion for judgment on the pleadings.

Apparently to minimize the prejudicial timing of her May 26 motion to amend, relator argues her prior submissions show she "repeatedly sought" leave to amend.[148] But, the record is clear that relator did not file a motion to file a second amended complaint, tendering a copy of her second amended complaint, until May 26, 2015. The Local Court Rules require a party seeking to amend a pleading to tender a copy of the proposed amended pleading as an attachment to the motion.[149] Relator cites no authority to show any of her prior "repeated[] attempts" to amend were proper motions to amend attaching a proposed amended complaint. In any event,

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at 2 n.1 (emphasis in original). Relator further explains she made that decision "mainly because Atrium had not challenged her fraud-on-the-FDA theory, and Relator did not want to allow another motion to dismiss by amending her complaint." Id. Even if those explanations are accepted, they seem to address why relator waited until Atrium had filed a motion for judgment on the pleadings but do not explain why she did not respond to the April 3 letter by providing the invited clarification. As a result, although relator was on notice of the defects in her first amended complaint since December 31, 2014, by waiting until Atrium had filed a motion for judgment on the pleadings before amending, in part, to respond to issues identified in the December 31, 2014 report, relator caused Atrium to expend time and fees preparing a motion for judgment on the pleadings at this time directed to the first amended complaint when Atrium might have been better served by waiting to direct such a motion to the second amended complaint.

[148] Docket no. 86 at 5.

[149] Local Court Rule CV-7(b) ("When a motion for leave to file a pleading, motion, or other submission is required, an executed copy of the proposed pleading, motion, or other submission shall be filed as an exhibit to the motion for leave.").

each of the prior "repeated[]" attempts to amend identified by relator—her November 20, 2014 response to defendants' motion to dismiss, and January 14, 2015 objections to the December 31, 2014 report—occurred *before* April 1, 2015, and do not explain why Atrium is not entitled to hold relator to her express representation she would not file a motion to file a second amended complaint. After careful analysis, there is some evidence showing "bad faith" in relator seeking leave to file a second amended complaint on May 26.

Nevertheless, considering the merits of the motion to amend, to the extent the proposed second amended complaint purports to provide further allegations establishing relator as an original source for the period of time before and after her employment with Atrium, relator has not demonstrated portions of her motion to file the proposed second amended complaint are not futile. Specifically, although relator adds allegations of LCDs and National Coverage Determinations (NCDs) to plead a national scheme of off-label marketing, with effective dates before, during, and after her employment with Atrium, relator does not include any allegations to establish she has "knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions" upon which her claims are based for the entire time period alleged.[150]

With regards to several LCDs that terminated prior to relator's employment with Atrium, relator has not stated a claim for relief. Specifically, LCDs L10163 (eff. 1999-2005), L14464 (eff. 1999-2005), L16138 (eff. 2004-2004), L10552 (eff. 1999-2005), L10909 (eff. 1999-2004), L7714 (eff. 2001-2006), L11140 (eff. 2000-2005), L7486 (eff. 2001-2006), L11092 (eff. 1999-2004), L10855 (eff. 2003-2004), L3578 (eff. 2000-2005), L4072 (eff. 1994-2004), L16152 (eff.

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[150] 31 U.S.C. § 3730(e)(4)(B)(2). See docket no. 78, proposed second amended complaint at 36-37.

2004-2004), L4519 (eff. 2000-2005), L8044 (eff. 1998-2004), and L10684 (eff. 1999-2005), were all "retired" (no longer effective) prior to the start of relator's employment with Atrium, and relator has not pleaded with particularity any allegations to establish a claim for relief for a time period prior to her employment with Atrium.[151]

The Court notes that the proposed second amended complaint asserts that LCD L32641, which relator's first amended complaint alleged only covered the seven states of Arkansas, Louisiana, Mississippi, Colorado, Texas, Oklahoma, and New Mexico, is now alleged to additionally cover District of Columbia, Delaware, Maryland, New Jersey, and Pennsylvania.[152] Regarding LCD L32641, which became effective on August 13, 2012, to the extent the proposed second amended complaint purports to provide further allegations establishing relator as an original source for the period of time after her employment terminated and in the states covered by that LCD (to include Arkansas, Colorado, District of Columbia, Delaware, Louisiana, Maryland, Mississippi, New Jersey, New Mexico, Oklahoma, Pennsylvania, and Texas), relator's proposed amendments are insufficient to establish her as an original source after July 31, 2012, and in any of the states at issue in that LCD.[153]

Regarding allegations of off-label marketing post-dating her employment with Atrium, relator's proposed second amended complaint alleges, in sum and in part: (1) in 2013, she

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[151] See docket no. 78, exhibit B, proposed amended complaint at 36-37, 54-55 (covering Alaska, American Samoa, Arizona, Guam, Hawaii, Nevada, Oregon, Washington, Northern Mariana Islands, Arkansas, Colorado, Illinois, Indiana, Iowa, Kentucky, Michigan, Minnesota, New Jersey, New York, Oklahoma, Pennsylvania, Wisconsin, and Wyoming).

[152] Docket no. 7 at 29; docket no. 78, exhibit B, proposed second amended complaint at 36-37.

[153] See docket no. 78, exhibit B, proposed second amended complaint at 36-37, 55-56.

attended an endovascular symposium in New York at which Atrium had a booth advertising "the 'Atrium Avanta 12' (the European name of the iCAST);" (2) in April 2014, she attended an Easter party at which Dr. Leila Mureebe commented she had seen an Atrium booth at a vascular symposium in Las Vegas in October 2013; and (3) in January 2014, relator "provided the details of Atrium's displays promoting unapproved uses of the iCAST at several symposia" after her termination to the government.[154] Relator provides no authority to show the added allegations are not conclusory. Relator provides no authority to show the added allegations are sufficient to establish her as an original source on or after August 13, 2012, or in any of the states covered by LCD L32641. Relator has not provided argument or authority to show that, through the additional allegations in the proposed second amended complaint, she has knowledge that is independent of, and materially adds to, the publicly disclosed allegations or transactions. Further, in response, Atrium asserts, in relevant part, the Advanta 12 was (1) advertised at an international endovascular symposium in New York, and (2) is approved for vascular use in Europe.[155] In the absence of such allegations, relator does not qualify as an original source to preclude the application of the public disclosure bar. Accordingly, to the extent the proposed second amended complaint attempts to add off-label marketing allegations pre- and post-dating relator's employment, relator has not met her burden under Rule 15 to show the proposed second amended complaint is not futile.

Assuming the District Judge will not deny relator's motion to amend based on "bad

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[154] Docket no. 77 at 18-19; docket no. 78, exhibit B, proposed second amended complaint at 54-55.

[155] Docket no. 83 at 9, n.3.

faith," this report cautiously recommends the Court **grant in part** relator's motion to file a second amended complaint. In a case from the Southern District of Texas, Judge Lee Rosenthal considered a qui tam action alleging a medical device manufacturer violated the FCA by engaging in off-label marketing of a surgical ablation device to treat atrial fibrillation and providing kickbacks to physicians, thereby causing physicians and hospitals to submit false claims to Medicare.[156] Judge Rosenthal granted Medtronic's motion to dismiss, in pertinent part, for failing to allege that Medtronic caused physicians or hospitals to submit false claims for reimbursement to the government, but permitted relators to amend the complaint.[157] Specifically, Judge Rosenthal stated "relators have only amended once . . . before the filing of Medtronic's motion to dismiss," and "Medtronic does not argue that the relators' complaint is frivolous."[158] Further, in Campie, the court stated it could not "say at this early stage that any amendment would be futile," and therefore, relators would be afforded an opportunity to amend "consistent with the analysis," but "[s]hould Relators seek to file an amended complaint, the Court expect[ed] the Relators to organize and streamline the current 747 paragraph, 190 page complaint in light of the" court's analysis.[159]

As discussed, to the extent that relator's second amended complaint "add[s] details that show she is an original source of the illegal marketing allegations post-termination,"[160] the

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[156] United States ex rel. Bennett v. Medtronic, Inc., 747 F.Supp.2d 745 (S.D. Tex. 2010).

[157] Id. at 785.

[158] Id.

[159] Campie, No. C-11-941-EMC, 2015 WL 106255, at *15.

[160] Docket no. 86 at 8.

allegations are not sufficient to withstand the arguments set out in Atrium's motion for judgment on the pleadings such that the motion for leave to amend to add the allegations should be **denied** as futile. Further, to the extent relator's second amended complaint adds allegations establishing relator as an original source for the period of time before her employment with Atrium, relator has not pleaded with particularity any allegations to establish a claim for relief for a time period prior to her employment with Atrium such that the motion for leave to amend to add the allegations should be **denied** as futile. Relator has emphasized she "is not seeking to amend to add new theories, new counts, or new causes of action,"[161] but has sought to amend (in pertinent part) "in direct response to Atrium's motion for judgment on the pleadings."[162] Thus, that the sufficiency of relator's proposed second amended complaint is assessed in reference to the arguments in the motion for judgment on the pleadings is not a surprise to relator. To the extent relator's second amended complaint "include[s] all relevant and applicable LCDs and National Coverage Determinations ("NCDs")" and alleges "that Atrium's conduct was nationwide in scope and continues from 2004 to the present,"[163] based on the instruction of Judge Rosenthal in Bennett, relator's motion to amend should be **granted**. Finally, to be clear, although relator states she drafted the second amended complaint to conform to Judge Garcia's March 18, 2015 rulings, to the extent any inconsistencies may remain, the allegations and claims in the second

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[161] Id. More specifically, relator identifies three reasons for the amendment: to conform to the Court's March 18, 2015 order, "to add in the LCDs . . . [to] . . . expand[] the regional scope of a theory already in the case," and "to add details that show she is an original source of the illegal marketing allegations." Id.

[162] Id.

[163] Docket no. 78 at 7.

amended complaint remain subject to Judge Garcia's rulings on the sufficiency of allegations.

E. Conclusion

In sum, Atrium's motion for judgment on the pleadings should be **granted in part** and **denied in part**. Specifically, plaintiffs' FCA claims based on a theory of fraud on the FDA and plaintiffs' FCA claims based on off-label marketing occurring on or after August 13, 2012 in Arkansas, Louisiana, Mississippi, Colorado, Texas, Oklahoma, and New Mexico should be **dismissed**. If the District Judge accepts the recommendations in this report, plaintiffs' FCA claims for violations of the Anti-Kickback Statute and plaintiffs' state law claims will remain pending for determination.

Further, relator's motion for leave to file a second amended complaint should be **granted in part** and **denied in part** as discussed in the preceding section of this report, which provides, in sum, despite concerns about bad faith, relator's motion for leave to file a second amended complaint should be granted to permit relator to add allegations as to LCDs and NCDs, Atrium's conduct was nationwide, and continued from 2004 to the present. To be clear, to the extent the proposed second amended complaint adds allegations that may contradict the District's Judge's March 18, 2015 order addressing the December 31, 2014 report (and the order to be entered addressing this report), those portions of the proposed second amended complaint are (and will be) a legal nullity.

VII. RECOMMENDATIONS

Upon consideration thereof, it is **recommended** that

- relator's motion for leave to file a second amended complaint[164] be **GRANTED**

[164] Docket no. 78.

in part and **DENIED in part** as specified in this report; and

- Atrium's motion for judgment on the pleadings[165] be **GRANTED in part and DENIED in part** as specified in this report.

VIII. INSTRUCTIONS FOR SERVICE AND NOTICE OF RIGHT TO OBJECT/APPEAL

The United States District Clerk shall serve a copy of this Report and Recommendation on all parties by either: (1) electronic transmittal to all parties represented by an attorney registered as a Filing User with the Clerk of Court pursuant to the Court's Procedural Rules for Electronic Filing in Civil and Criminal Cases; or (2) by certified mail, return receipt requested, to any party not represented by an attorney registered as a Filing User.

As provided in 28 U.S.C. § 636(b)(1) and FED. R. CIV. P. 72(b), any party who desires to object to this Report must **file** with the District Clerk and **serve** on all parties and the Magistrate Judge written Objections to the Report and Recommendation within **14 days** after being served with a copy, unless this time period is modified by the District Court. A party filing Objections must specifically identify those findings, conclusions or recommendations to which objections are being made and the basis for such objections; the District Court need not consider frivolous, conclusive or general objections.

A party's failure to file timely written objections to the proposed findings, conclusions and recommendations contained in this Report will bar the party from receiving a *de novo* determination by the District Court.[166] Additionally, a party's failure to file timely written objections to the proposed findings, conclusions and recommendations contained in this Report

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[165] Docket no. 74.

[166] See Thomas v. Arn, 474 U.S. 140, 150, 106 S.Ct. 466, 472 (1985).

will bar the aggrieved party, except upon grounds of plain error, from attacking on appeal the unobjected-to proposed factual findings and legal conclusions accepted by the District Court.[167]

SIGNED and **ENTERED** this 15th day of June, 2015.

Pamela A. Mathy

PAMELA A. MATHY
UNITED STATES MAGISTRATE JUDGE

[167] Acuna v. Brown & Root Inc., 200 F.3d 335, 340 (5th Cir. 2000); Douglass v. United Serv. Auto. Ass'n., 79 F.3d 1415, 1428 (5th Cir.1996).