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.[6] 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];"
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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

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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, the parties' submissions and the Court's discussion of them has referred 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."

[5] Docket no. 1.

[6] Id. at 46-126.

> 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];"
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> 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];"[7] and
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> 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 Texas Medicaid False Claims Act (count 30).[8]

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.[9] 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.[10]

On March 18, 2015, the District Judge granted in part and denied in part defendants' joint pre-answer motion to dismiss.[11] 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

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

[8] Id. at 51-131.

[9] Docket no. 14.

[10] Docket no. 16.

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

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.[12]

Thereafter, as further reflected by the docket sheets,[13] the Court granted in part and denied in part relator's motion to file a second amended complaint[14] and granted in part and denied in part Atrium's motion for judgment on the pleading.[15] Specifically, the Court dismissed 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,

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[12] Id.

[13] The June 15, 2015 report of the undersigned includes a relatively detailed summary of the procedural history and a statement of the case (based on relator's allegations in the first amended complaint). Docket no. 90 at 2-9.

[14] The June 15, 2015 report stated:

> 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.

Id. at 41 (emphasis in original). The District Judge's July 30, 2015 order accepting the recommended ruling included a similar proviso and referred to the June 15 report. Docket no. 103 at 2.

[15] Docket no. 103 (order adopting in full the recommendations in the undersigned's June 15, 2015 report (docket no. 90)).

Mississippi, Colorado, Texas, Oklahoma, and New Mexico.[16] Following that order, plaintiffs' FCA claims for violations of the Anti-Kickback Statute and plaintiffs' state law claims remain pending for determination.[17]

On August 25, 2015, relator filed a motion for certification for interlocutory appeal of the part of the District Court's July 30, 2015 order that dismissed relator's fraud on the FDA claims.[18] Atrium opposes the request.[19]

III. ISSUES

Whether relator's motion for certification of an interlocutory appeal and stay pending disposition of the appeal should be granted or denied.

IV. STANDARD

Section 1292(b) of Title 28 of the United States Code states:

> When a district judge, in making in a civil action an order not otherwise appealable under this section, shall be of the opinion that such order involves a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from the order may materially advance the ultimate termination of the litigation, he shall so state in writing in such order. The Court of Appeals which would have jurisdiction of an appeal of such action may thereupon, in its discretion, permit an appeal to be taken from such order, if application is made to it within ten days after the entry of the order: Provided, however, That application for an appeal hereunder shall not stay proceedings in the district court unless the district judge or the Court of Appeals or a judge thereof shall so order.[20]

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[16] Id. at 2.

[17] Docket no. 90 at 41.

[18] Docket no. 106 at 1.

[19] Docket no. 110.

[20] 28 U.S.C. § 1292(b).

A party seeking an interlocutory appeal must show there is (a) a controlling question of law, (b) to which there is substantial ground for difference of opinion, and (c) an immediate appeal from the order may materially advance the ultimate termination of the litigation.

> While the Fifth Circuit has at different points applied broader and stricter standards for § 1292(b), the common principles are: (1) "the decision to permit such an appeal is firmly within the district court's discretion;" (2) "§1292(b) is not a vehicle to question the correctness of a district court's ruling or to obtain a second, more favorable opinion;" (3) the issue for appeal must involve a question of *law*—not fact;" (4) "the issue for appeal must involve a *controlling* question of law;" (5) "whether an interlocutory appeal will speed up the litigation;" and (6) "there must be substantial ground for difference of opinion over the controlling question of law for certification."[21]

V. DISCUSSION

Relator's motion for certification of an interlocutory appeal "requests that the Court certify for interlocutory appeal the part of the Court's order that dismisses Relator's fraud-on-the-FDA claims."[22] On July 30, 2015, the District Judge, in part, granted Atrium's motion for judgment on the pleadings "on Relator's claims of fraud on the FDA."[23] At issue in the July 30 ruling was relator's first amended complaint.[24] Relator's first amended complaint alleges, in pertinent part, "Atrium committed fraud on the FDA and fraudulently induced the FDA to

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[21] Lee v. Active Power, Inc., No. A-13-CA-797-SS, 2014 WL 4337860, at *1-*2 (W.D.Tex. Sept. 2, 2014) (emphasis in original) (quoting Ryan v. Flowserve Corp., 444 F. Supp.2d 718, 722-23 (N.D.Tex. 2006)).

[22] Docket no. 106 at 1.

[23] Docket no. 103 at 2.

[24] The District Judge's July 30 ruling also granted in part relator's motion to file a second amended complaint. Id. The Judge's July 30 ruling to dismiss the "fraud on the FDA" claim directly addressed relator's allegations in the first amended complaint. But, relator's then-proposed second amended complaint did not materially change relator's allegations relevant to the "fraud on the FDA" claim. See generally docket no. 104.

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."[25] Relator alleges "the FDA was fraudulently induced into approving the device for a purpose for which Atrium never intended it to be marketed or used."[26] Relator does not allege Atrium made a false or fraudulent claim for payment directly to the government or that Atrium engaged in any fraudulent conduct or made any false statement to the government agencies that administer reimbursements as part of a request for payment. As is apparent, no surgeon who inserted an iCAST stent or other health care provider is named as a defendant based on a false claim for payment submitted to the government.

In support of her motion for certification of interlocutory appeal,[27] relator presents three main arguments. First, relator argues the issue of whether her fraud on the FDA claims are

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[25] Docket no. 7 at 28, ¶ 67. See also docket no. 104 at 29, ¶ 70 (second amended complaint).

[26] Docket no. 7 at 47, ¶ 129. See also docket no. 104 at 55, ¶ 130.

[27] In her motion, relator variously describes the issue she seeks to appeal. Relator characterizes the question as "whether Relator has adequately pled fraudulent inducement and therefore made out a viable claim under the [FCA]," docket no. 106 at 2; "whether in a fraudulent inducement case under the FCA the misrepresentations must be made to the payor agency," id. at 3; "whether allegations regarding fraud on the FDA can constitute viable claims under the FCA," id.; "whether a fraud-on-the-FDA claim is cognizable under the FCA," id.. The Court does not agree with the various ways relator has framed the controlling question of law. Instead, the question should be framed according to the order from which relator's present motion seeks relief. Castellanos-Contreras v. Decatur Hotels, LLC, 622 F.3d 393, 399 (5th Cir. 2010). The controlling question of law is framed as: whether relator must plead a direct and immediate link between Atrium's alleged false statement or fraudulent conduct and any resulting claim for payment to satisfy the requirements of Rule 12(b)(6) and Rule 9(b) in support of an FCA claim based on a theory of fraud on the FDA. See docket no. 103 (adopting in full the recommendations in the undersigned's June 15, 2015 report (docket no. 90)).

viable under the FCA presents a controlling question of law.[28] Second, relator argues there is a substantial ground for difference of opinion as to whether her fraud on the FDA claims are viable.[29] Third, relator argues the determination whether her fraud on the FDA claims are viable would materially advance the ultimate termination of the litigation.[30]

A. Controlling Question of Law

Relator argues "whether Relator has adequately pled fraudulent inducement and therefore made out a viable claim under the [FCA] is a controlling question because it is dispositive of an entire set of Relator's claims."[31] Relator argues "[i]ssues that are dispositive are 'controlling.'"[32] Atrium disputes this contention, arguing relator "cannot establish a controlling question of law," that is, a question of law "the resolution of which could materially advance the ultimate termination of the litigation," because the appeal "seeks to expand and delay the present litigation," not simplify it.[33]

At the threshold, the parties agree that the Court's July 30, 2015 dismissal of relator's claim for violations of the FCA based on fraud on the FDA was based on the determination of "a purely legal issue."[34] "A question of law may be deemed 'controlling' if its resolution is quite

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[28] Docket no. 106 at 2-3.

[29] Id. at 3-6.

[30] Id. at 3.

[31] Id. at 2.

[32] Id. (citing Sokaogon Gaming Enter. Corp. v. Tushie-Montgomery Assocs., Inc., 86 F.3d 656, 658-59 (7th Cir. 1996)).

[33] Docket no. 110 at 1, 4.

[34] Docket no. 106 at 3; docket no. 110 at 4.

likely to affect the further course of the litigation, even if not certain to do so."[35]

On June 15, 2015, this Court recommended "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."[36] On July 30, 2015, the District Judge adopted the recommended ruling and dismissed relator's claim for violations of the FCA based on a theory of fraud on the FDA.[37] Because the Court's July 30 dismissal of relator's FCA claim based on a theory of fraud on the FDA "impact[s] whether or not plaintiff has a cause of action"[38] under the FCA based on a theory of fraud on the FDA and "the resolution of the issue on appeal could materially affect the outcome of the litigation,"[39] the Court's July 30, 2015 ruling decides a controlling question of law with respect to relator's FCA claim based on a theory of fraud on the FDA.

B. Substantial Ground for Difference of Opinion

Relator argues that substantial ground for difference of opinion exists as to whether her fraud on the FDA claims are viable because "district courts have come out differently on whether

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[35] Sokaogon Gaming Enter. Corp., 86 F.3d at 659.

[36] Docket no. 90 at 23.

[37] Docket no. 103.

[38] Stout v. Illinois Farmers Ins. Co., 882 F.Supp. 776, 778 (S.D. Ind. 1994).

[39] In re Cement Antitrust Litig., 673 F.2d 1020, 1026 (9th Cir. 1981), aff'd 459 U.S. 1190, 103 S.Ct. 1173 (1983).

a fraud-on-the-FDA claim is cognizable under the FCA."[40] Relator relies on two district court decisions in support of her contention there is a substantial ground for difference of opinion: Campie v. Gilead Sciences, Inc.[41] and Krahling v. Merck & Co..[42]

Relator argues that in Campie, the United States District Court for the Northern District of California "held that the relator could not make out a fraud-on-the-FDA claim since the 'false or fraudulent statement to [the] licensing or regulatory agency [was] disconnected from the request for payment.'"[43] Relator argues that Campie "is now on appeal before the Ninth Circuit."[44] But, the Campie appeal is a direct appeal, and is not being reviewed by the Ninth Circuit because the district court certified, and the Ninth Circuit accepted, an interlocutory appeal.[45] Further, and as discussed in the June 15, 2015 report and recommendation, the ruling in Campie is fully consistent with the ruling relator seeks to challenge in her interlocutory appeal.[46] Campie is not a contrary ruling and, therefore, does not constitute a substantial ground for difference of opinion.

Relator also argues that the United States District Court for the Eastern District of Pennsylvania's decision in Krahling is "[o]pposite to the holding in Campie" because in Krahling

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[40] Docket no. 106 at 3.

[41] No. C-11-0941 EMC, 2015 WL 106255 (N.D.Cal. Jan. 7, 2015).

[42] 44 F.Supp.3d 581 (E.D.Pa. 2014).

[43] Docket no. 106 at 3 (quoting Campie, 2015 WL 106255, at *9).

[44] Id. at 3.

[45] Id., exhibit 1.

[46] See docket no. 90 at 21-23 (analysis of Campie and Krahling).

the court held that "'withh[olding] pertinent information as to the safety and efficacy of a medication from the government'" is "'grounds for FCA liability.'"[47] But, as this Court explained in its report and recommendation of June 15, 2015, Krahling is distinguishable because in that case "defendants made claims for payment directly to the government," whereas relator "does not allege Atrium made a false or fraudulent claim for payment directly to the government."[48] Thus, the two cases on which relator relies to demonstrate a substantial ground for difference of opinion do not illustrate a difference of opinion.

Relator further argues that an FCA claim can survive "even where the misrepresentations were made to an entity different from the payor agency."[49] Relator argues that under the Fifth Circuit's decision in Longhi, there is "no requirement that the false statement be made in the claim for payment itself," and "even 'indirect or intangible actions' by a defendant can have the natural capacity or capability of influencing government action."[50] But Longhi is distinguishable for the same reason as Krahling—it concerns fraudulent statements made directly to a payor government entity.[51]

Relator similarly argues the Western District's decision in Bui stands for the proposition that the misrepresentation need not be made to the payor agency, because, as the Bui court held,

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[47] Docket no. 106 at 3-4 (quoting Krahling, 44 F.Supp.3d at 594).

[48] Docket no. 90 at 22.

[49] Docket no. 106 at 5 (citing Longhi v. Lithium Power Technologies, Inc., 575 F.3d 458 (5th Cir. 2009) and United States ex rel. Bui v. Vascular Solutions, Inc., No. 1:10-CV-883-SS, 2013 U.S.Dist. LEXIS 187974 (W.D.Tex. Mar. 7, 2013) (J. Sparks)).

[50] Docket no. 106 at 5 (citing Longhi, 575 F.3d at 467-68, 470)).

[51] Longhi, 575 F.3d at 463, 471-72.

false statements made to non-government physicians are actionable under the FCA.[52] In Bui, the defendant moved to dismiss relator's off-label promotion claims under Rule 12(b)(6) and Rule 9(b).[53] In Bui, the relator alleged the defendant "promoted, marketed, and sold its products to physicians" for "off-label use," "causing physicians and hospitals to submit claims to Medicare and TRICARE for off-label uses" and "such claims are 'false' under the FCA if the relevant federal program is not authorized to pay the claims."[54] The relator alleged the defendant's sales representatives misled physicians into believing its product was approved for perforator ablation, and suggested Medicare and TRICARE would cover such procedures, when in fact the product was not approved for such use.[55] Judge Sparks held the relator adequately pleaded a cause of action for fraud based on off-label promotion because the sales representatives' statements "set in motion a chain of events culminating in the submission of the claims at the heart of [the] case" and were material because they had the potential to influence the government's decisions.[56] By contrast, in Campie (which did not concern off-label marketing), the district court granted the defendant's motion to dismiss, declining to find a causal connection between the allegedly false statement and a request for payment "simply because [based on plaintiff's allegations] that false

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[52] Docket no. 106 at 5 (citing Bui, 2013 U.S.Dist. LEXIS at *5, *9).

[53] Bui, 2013 U.S. Dist. LEXIS 187974 at *5.

[54] Id. at *4-*5.

[55] Id. at *14-*15.

[56] Id. at *15, *18. In its June 15, 2015 report, this Court found Bui distinguishable for two reasons: first, "the Government intervened in Bui;" and second, "unlike the situation in Bui, relator does not allege that Atrium 'misled physicians into believing' the iCAST was 'FDA-approved' for vascular use." Docket no. 90 at 19-20, n.85.

or fraudulent statement to that licensing agency ultimately enabled the defendant to achieve eligibility for funding from the payor agency."[57]

Here, relator is not seeking certification of an interlocutory appeal on her off-label marketing claims.[58] Relator's FCA claim based on a theory of fraud on the FDA is distinguishable from the off-label promotion claim at issue in Bui and is consistent with the claim at issue in Campie. Therefore, this Court's reliance on Campie rather than Bui is correct. Bui is distinguishable from the circumstances of this case.[59] In sum, relator has not stated a substantial ground for difference of opinion in satisfaction of § 1292(b).

C. Material Advancement of the Ultimate Termination of the Litigation

Relator argues that the determination on whether relator has stated a claim for relief based on a fraud on the FDA theory would materially advance the ultimate termination of the litigation

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[57] Campie, 2015 WL 106255 at *9.

[58] See generally docket no. 106. On March 18, 2015, the District Judge dismissed relator's "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." Docket no. 68. Thereafter, on July 30, 2015, the District Judge dismissed relator's "FCA claims based on off-label marketing occurring on or after August 13, 2012 in Arkansas, Louisiana, Mississippi, Colorado, Texas, Oklahoma, and New Mexico." Docket no. 103.

[59] Relator's motion for certification devotes one sentence to Bui. See docket no. 106 at 5. The theory of the allegations of false claims and fraud at issue in Bui was, in sum, that "physicians were misled into believing the short kit was FDA-approved for treating perforator veins, possibly clouding their judgment as to reasonableness and medical necessity" and led to the submission "of false claims to Medicare and TRICARE." Bui, 2013 U.S. Dist. LEXIS 187974 at *12. In contrast, relator's theory is that, in sum, Atrium committed fraud on the FDA by fraudulently inducing the FDA to approve the iCAST as a Class II device but "never intended the iCAST to be used for this purpose." Docket no. 7 at 27, ¶68. Relator does not allege "fraud on the physicians," as in Bui, or that Atrium misled physicians into believing the iCAST was FDA-approved for vascular use prior to the physicians submitting claims for payment to the government, or explain how the allegations reviewed for sufficiency in Bui are comparable as a matter of law to relator's allegations of "fraud on the FDA."

because "Relator's fraud-on-the-FDA claim encompasses a large set of claims, while her allegations involving promotion of the iCAST for unapproved uses constitutes a subset of those claims," such that, if relator "were to prevail on the small subset of claims at trial," take a direct appeal, and the Fifth Circuit were to reverse this Court's July 30 ruling, then the parties would be required to reopen discovery and potentially have another trial.[60] In response, Atrium argues an interlocutory appeal would delay, not advance the disposition of this case because, in sum, the interlocutory appeal will not eliminate the need for a trial, simplify the trial, or eliminate issues to make the case less costly.[61]

After careful consideration, the Court must conclude that relator's request for permission for an interlocutory appeal fails to satisfy the third requirement for certification. Adding back the dismissed "fraud on the FDA" theory of liability not only will expand the issues to be addressed, but will add a complex issue, namely, whether the FDA would have cleared the iCAST stent absent Atrium's alleged misrepresentations. Relator suggests that having the Fifth Circuit address the legal question at issue now could "help move the case toward resolution through settlement,"[62] a potential resolution that could greatly minimize litigation costs. But, understandably, relator does not represent the case will settle if the July 30 ruling stands.

D. Conclusion

For the reasons discussed, relator seeks leave to file an interlocutory appeal of a controlling question of law, but relator has not demonstrated there is a substantial ground for

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[60] Docket no. 106 at 6.

[61] Docket no. 110 at 9.

[62] Docket no. 106 at 6.

difference of opinion or that an interlocutory appeal would materially advance the ultimate termination of the litigation. The ruling that relator seeks to challenge on appeal relied on Campie, a case the Court found to be well-reasoned and correctly decided. But, as noted in Campie, "[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 enabled the defendant to achieve eligibility for funding from the payor agency."[63] This is a novel question of law in the Fifth Circuit. Further, it appears that Campie is the only other published decision addressing an alleged fraud on the FDA theory similar to those made in this case and dismissed on July 30, 2015.

Given the novelty of the question of law at issue,[64] it may be appropriate for this Court to grant relator's motion to certify a narrow issue for interlocutory appeal to afford the Fifth Circuit the opportunity to decide if it wishes to grant an interlocutory appeal and review the legal

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[63] Campie, 2015 WL 106255, at *9.

[64] Mohawk Indus., Inc. v. Carpenter, 558 U.S. 100, 110-111, 130 S.Ct. 599, 607-608 (2009) ("The preconditions for § 1292(b) review . . . are most likely to be satisfied when a . . . ruling involves a new legal question or is of special consequence, and district courts should not hesitate to certify an interlocutory appeal in such cases."); E.E.O.C. v. Bass Pro Outdoor World, LLC, No. 4:11-CV-3425, 2014 WL 6453606, at *5 (S.D. Tex. Nov. 17, 2014) ("No court of appeals has yet squarely confronted the question, making it a 'novel . . . question of first impression' ripe for interlocutory appeal."). But see Ryan, 444 F. Supp. 2d at 723-724 (stating "courts have found substantial ground for difference of opinion . . . if novel and difficult questions of first impression are presented," "[b]ut simply because a court is the first to rule on a question or counsel disagrees on applicable precedent does not qualify the issue as one over which there is substantial disagreement.").

question at this time.[65] It appears Campie and this Court's July 30 ruling are the only courts to consider whether a relator states an FCA claim based on alleged false or fraudulent statements to the FDA when obtaining FDA approval for a medical device, disconnected from a request for payment. In the circumstances of this case, when the likely costs to the litigants are significantly greater if the Court's ruling on Atrium's motion for judgment on the pleadings—decided on a question of law, not fact—were to be reversed later, the Court concludes it is appropriate to submit the question to the Fifth Circuit. Specifically, the question to be certified is: whether relator must plead a direct and immediate link between Atrium's alleged false statement or fraudulent conduct and any resulting claim for payment to satisfy the requirements of Rule 12(b)(6) and Rule 9(b) in support of an FCA claim based on a theory of fraud on the FDA. Further, if relator's motion to certify is granted then this case should be stayed until the Fifth Circuit determines whether it will accept the interlocutory appeal or decides the interlocutory appeal, whichever is later.

VI. RECOMMENDATIONS

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

- relator's opposed motion for certification of an interlocutory appeal[66] be **GRANTED** so that the Fifth Circuit can have the opportunity to decide whether it wishes to review the novel legal question at issue, namely whether relator must plead a direct and immediate link between Atrium's alleged false statement or fraudulent conduct and any resulting claim for payment to support an FCA claim based on a theory of fraud on the FDA; and

- relator's opposed motion for stay of proceedings pending disposition of that

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[65] 28 U.S.C. § 1292(b) (Court of Appeals has discretion to accept interlocutory appeal).

[66] Docket no. 106.

> appeal[67] be **GRANTED**, and this case be **STAYED** through the date on which proceedings in the Fifth Circuit have been finally concluded (with the Court having the discretion to order the stay effective, nunc pro tunc, August 25, 2015, the date relator requested a stay).

If the District Judge accepts the recommended disposition, this case should be **STAYED and ADMINISTRATIVELY CLOSED** pending further order of the Court, and the parties should be directed to file joint or simultaneous advisories within **fourteen (14)** days of the conclusion of all proceedings in the Fifth Circuit.

VII. 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

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[67] Id.

and recommendations contained in this Report will bar the party from receiving a *de novo* determination by the District Court.[68] Additionally, a party's failure to file timely written objections to the proposed findings, conclusions and recommendations contained in this Report 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.[69]

SIGNED and **ENTERED** this 16th day of September, 2015.

Pamela A. Mathy

PAMELA A. MATHY
UNITED STATES MAGISTRATE JUDGE

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

[69] 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).