UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

UNITED STATES OF AMERICA *ex rel.* KEVIN N. COLQUITT,	§	
Plaintiff,	§	
v.	§	No. 3:06-CV-1769-M
ABBOTT LABS., *et al.*,	§	
Defendants.	§	

MEMORANDUM OPINION AND ORDER

Before the Court are a Motion for Partial Summary Judgment [Docket Entry #440], filed by Relator Kevin N. Colquitt ("Relator"), and a Motion for Summary Judgment [Docket Entry #443], filed by Defendants Abbott Laboratories and Abbott Vascular Solutions, Inc. (together, "Abbott" or "Defendants"). For the reasons stated, both motions are DENIED.

I.

This is a *qui tam* action brought by Relator, a former employee of Guidant Corporation ("Guidant") and Guidant's successor-in-interest Abbott, for alleged violations of the False Claims Act, 31 U.S.C. §§ 3729, *et seq.* ("FCA"), in connection with claims for reimbursement of vascular stenting procedures involving Guidant- and Abbott-brand biliary stents submitted to Medicare between February 23, 2004 and June 21, 2006. *See* Mem. Opinions [Docket Entry ## 160, 313, & 434]. Because this case has been the subject of several prior opinions, *see id.*, the Court limits its discussion to the select legal and factual issues upon which the motions for summary judgment turn.

II.

As a preliminary matter, Relator has filed a Motion to Strike [Docket Entry # 459] and a Supplemental Motion to Strike [Docket Entry #495]. By his motions to strike, Relator seeks to exclude six categories of evidence relied upon by Defendants in their summary judgment motion and response, including: (1) undisclosed fact witnesses; (2) inadmissible hearsay evidence from fact witnesses through proposed expert testimony and reports; (3) opinion evidence from physicians solely designated as fact witnesses; (4) inadmissible expert testimony relying on the opinions of the physician fact witnesses; (5) evidence not timely disclosed in fact discovery; and (6) inadmissible hearsay evidence.[1] Relator's supplemental motion is further directed to striking an email exchange between Dr. Gary Dorfman and Dr. Katherine Krol, which occurred during the course of Dr. Krol's engagement as an expert in this case. Relator seeks to strike the email exchange and Krol's reliance on it because the document is (1) inadmissible hearsay, and (2) Dr. Dorfman is an undisclosed fact witness. The Court has not relied on any of this allegedly objectionable evidence in making its determination on the pending summary judgment motions. Accordingly, Relator's Motion to Strike and Supplemental Motion to Strike are DENIED as moot.

Relator also has filed a Motion to Exclude the testimony of Dr. Krol. [Docket Entry #488]. Dr. Krol, an interventional radiologist, has offered opinions on: (1) the correct Medicare codes for placement of biliary stents in the peripheral vasculature; (2) the propriety of Medicare reimbursement for use of biliary stents in peripheral vascular procedures; and (3) the appropriateness of off-label biliary stent use during the early to mid-2000s. Relator objects to,

[1] Relator identifies the objectionable evidence as Def. App. 3-18, 78-101, 113-31, 174-88, 198-261, 266-72, 361-591, 1236-41, 1269-1271, 1280-85, 1297-98, 1312, 1398-1478, 1498, 1505, 1514, 1530-34, 1709-10, 1711-13, 1734-36, 2033-40, 2041-52, 2053-69, 2099-2101, 2102-09, 2107-09, and 2818-21.

and moves to exclude, these opinions on grounds of reliability and relevancy. First, Relator argues Dr. Krol's opinions that Medicare contractors knew of and agreed to reimburse providers for peripheral vascular stenting procedures using unapproved biliary stents are not reliable because they are based on inadmissible hearsay from other physicians. Relator also contends that Dr. Krol's Medicare coverage and coding opinions are unreliable because they are based on alleged informal conversations with CMS, local contractors, and FDA, not official policy statements from a relevant agency. Further, Relator contends that Dr. Krol's role as an advocate prevents her from offering objective testimony and that Dr. Krol's lay witness testimony should be excluded because she was not timely disclosed as a fact witness. Notwithstanding these objections, Relator frequently cites to Dr. Krol's testimony in support of his own summary judgment motion. The Court determines that it can resolve the pending motions without relying on Dr. Krol's expert opinions. Accordingly, it will not consider Dr. Krol's opinions as evidence on summary judgment. The Court reserves Relator's *Daubert* challenges for determination either at trial or at a pretrial hearing for that purpose. *See Nielsen v. Alcon, Inc*., 2011 WL 4529762 at *5 (N.D. Tex. Sept. 2, 2011), *rec. adopted*, 2011 WL 4529674 (N.D. Tex. Sept. 30, 2011) (recognizing that a trial setting normally provides the best environment for resolving *Daubert* challenges).

III.

Summary judgment is warranted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56. A dispute as to a material fact is genuine, if the evidence is sufficient to permit a reasonable factfinder to return a verdict for the nonmoving party. *Crowe v. Henry*, 115 F.3d 294, 296 (5th Cir. 1997). A fact is material if its resolution could affect the outcome of the

action. *Weeks Marine, Inc. v. Fireman's Fund Ins. Co*., 340 F.3d 233, 235 (5th Cir. 2003). The substantive law determines which facts are material. *See Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 247 (1986).

A party seeking summary judgment who does not have the burden of proof at trial, like Defendants here, need only point to the absence of admissible evidence to support the nonmovant's claim. *See Duffy v. Leading Edge Prods., Inc*., 44 F.3d 308, 312 (5th Cir. 1995). Once the movant meets its initial burden, the burden shifts to the nonmoving party to produce evidence or designate specific facts in the record showing the existence of a genuine issue for trial. *See Fordoche, Inc. v. Texaco, Inc*., 463 F.3d 388, 392 (5th Cir. 2006). By contrast, a movant who bears the burden of proof at trial, such as Relator, must establish "beyond peradventure *all* of the essential elements of the claim or defense to warrant judgment in his favor." *Fontenot v. Upjohn Co*., 780 F.2d 1190, 1194 (5th Cir. 1986) (emphasis in original). The "beyond peradventure" standard is a "heavy" burden. *See Carolina Cas. Ins. Co. v. Sowell*, 603 F. Supp. 2d 914, 923–24 (N.D. Tex. 2009).

IV.

The FCA imposes liability on any person who (1) "knowingly presents, or causes to be presented, to the United States Government a false or fraudulent claim for payment or approval" or (2) "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government." 31 U.S.C. §§ 3729(a)(1)(A), (B). In this case, Relator proceeds on two theories of liability, asserting both a "false presentment" claim and a "false statement" claim. Relator's false presentment claim is based on his argument that Defendants' biliary stents were not eligible for Medicare reimbursement. His

false statement claim is related to the use of billing codes that allegedly misrepresented the nature of the stent used in the procedure for which reimbursement was sought.

Defendants move for summary judgment on three grounds: (1) Relator cannot establish the existence of any false claims; (2) Relator cannot establish Defendants' scienter; and (3) Relator cannot show that Defendants caused any provider to submit claims for reimbursement for vascular procedures using biliary stents. Relator also moves for partial summary judgment with respect to three elements of his FCA claim—falsity, materiality, and scienter—and argues that the case should proceed to trial on the issues of causation and damages.

a.

The threshold question in this case is whether claims for Medicare reimbursement of vascular stenting procedures involving Defendants' biliary stents constitute false claims under the FCA. Relator initially contends that the claims at issue are false because they are categorically ineligible for Medicare coverage. According to Relator, Medicare only pays claims for items and services that qualify as "reasonable and necessary," and an item or service must be affirmatively determined by the Food and Drug Administration ("FDA") to be safe and effective in order to qualify as reasonable and necessary. Relator argues that the FDA had not determined the safety and effectiveness of Defendants' biliary stents for use in the vascular system, and therefore the stents were not eligible for Medicare coverage. Because Medicare claims for expenses that are not covered and are ineligible for payment are false, as a matter of law, Relator asserts that he is entitled to summary judgment affirmatively establishing the primary element of his FCA claim. Defendants dispute Relator's assertions and argue that the claims at issue were eligible for reimbursement, and, in fact, properly reimbursed by the private insurance companies that were charged with the task of processing Medicare claims.

The Center for Medicare and Medicaid Services ("CMS") oversees the Medicare program at a national level, but it does not process individual claims submitted by health care providers for reimbursement. Instead, CMS contracts with private insurance companies to act as its agents in reviewing and processing Medicare claims. *See* Rel. App. at 497, ¶ 10. CMS has the authority to make Medicare coverage eligibility determinations for medical devices on a nationwide basis. When it makes a rule regarding the scope of coverage for a particular device, CMS issues a National Coverage Decision ("NCD"). *See* 42 C.F.R. § 405.1060(a)(1) ("An NCD is a determination . . . of whether a particular item or service is covered nationally under Medicare."). An NCD is binding on all private Medicare contractors. *Id.*, § 405.1060(a)(4), (b)(1). The private contractors are also bound by the terms of the Medicare statute in making reimbursement decisions. Among other things, the statute provides that "no payment may be made . . . for any expenses incurred for items . . . [which] are not reasonable and necessary for the diagnosis of illness or injury. . . ." 42 U.S.C. § 1395y(a)(1)(A). The private Medicare contractors determine which items are reasonable and necessary for purposes of coverage under the statute. *See* Rel. App. at 500, ¶ 15. If there is no NCD in place, Medicare contractors can issue Local Coverage Determinations ("LCDs") that address the reimbursement eligibility of certain procedures. *Id.*, ¶ 16. LCDs are binding only in the local areas for which the particular contractor has authority. 42 U.S.C. § 1395ff(f)(2)(B).

In this case, it is undisputed that there was no NCD in effect between 2004 and 2006 that addressed whether claims for vascular stenting procedures using biliary stents were covered by Medicare and eligible for reimbursement. *See* Rel. App. 505. Despite the lack of a nationwide rule, Relator argues that Defendants' stents are categorically ineligible for Medicare coverage because they cannot satisfy the statute's reasonable and necessary requirement. Medicare

contractors look to the Medicare Program Integrity Manual ("MPIM"), promulgated by the Secretary of Health and Human Services, for guidance in applying the "reasonable and necessary" standard. *See* Rel. App. 414-51. The MPIM directs that a device will be considered "reasonable and necessary" if the contractor determines that the item is "safe and effective," "not experimental or investigational," and "appropriate" in terms of accepted medical practice and the patient's medical need. *Id.* at 424. Relator contends that the FDA's determinations of safety and effectiveness are "dispositive" for purposes of determining whether a product satisfies the Medicare statute's reasonable and necessary requirement. In this case, the FDA determined that Defendants' biliary stents "had not been established" to be safe and effective when used in the vascular system, and even required the stents to carry a label to that effect. *See* Rel. App. at 1503-1150. Therefore, Relator argues, Defendants' biliary stents were ineligible for Medicare coverage on a nationwide basis.

Relator's argument oversimplifies the eligibility question. An FDA determination regarding the safety and effectiveness of a device is not a substitute for CMS review of whether the device is eligible for coverage. CMS and its contractors determine when a device is reasonable and necessary, and thus eligible for coverage, under the Medicare statute. *See* 68 Fed. Reg. 55,634 (Sept. 26, 2003). The FDA conducts premarket review of products under different statutory standards. *Id.* A device may be approved or cleared by the FDA and still not be eligible for Medicare coverage. *See id.* Further, lack of FDA approval or clearance for a specific use does not categorically disqualify a device from Medicare coverage. *See id.* Medicare reimbursement for off-label uses is permissible in some instances. *United States ex rel. Modglin v. DJO Global Inc.*, 48 F. Supp. 3d 1362, 1392 (C.D. Cal. 2014); *see also United States ex rel. Bennett v. Medtronic, Inc.*, 747 F.Supp.2d 745, 754 (S.D. Tex. 2010) (observing

that Medicare does not impose an absolute ban on coverage for off-label use of drugs and devices); *United States ex rel. Nowak v. Medtronic, Inc.*, 806 F.Supp.2d 310, 347 (D. Mass. 2011) (same); *Strom ex rel. United States v. Scios, Inc.*, 676 F.Supp.2d 884, 886 (N.D. Cal. 2009) (same). Relator has not established "beyond peradventure" that all claims for Medicare reimbursement of vascular stenting procedures involving Defendants' biliary stents are false claims under the FCA.

In the absence of an NCD governing the vascular stenting procedures at issue in this case, local Medicare contractors had discretion to make coverage determinations regarding the procedures. *See* Rel. App. at 505, ¶ 29. Between 2004 and 2006, local contractors with responsibility for roughly half of the United States issued at least fifty different LCDs addressing non-coronary vascular stenting. *See* Rel. App. at 1501-2293. These LCDs expressly recognized that coverage was allowable for procedures involving the off-label use of a stenting device in various circumstances. To determine whether procedures using Defendants' biliary stents were covered requires a fact-intensive analysis of the specific terms of each LCD. For example, New Jersey's Part B Medicare carrier had an LCD in place until January 3, 2005 that limited coverage to stents "used for the FDA-approved indication." Given this limitation, Defendants concede that Medicare claims for vascular procedures using their biliary stents were not eligible for reimbursement. *See* Def. MSJ Br. at 30; Rel. App. at 537, ¶ 47. Therefore, a claim submitted to New Jersey's Part B Medicare carrier while this LCD was in effect would constitute a false claim. Defendants are not entitled to summary judgment on Relator's FCA claims that involve requests for Medicare reimbursement governed by the New Jersey plan. This analysis must be repeated for each LCD pursuant to which claims for reimbursement were

processed. The parties have not attempted to perform such an analysis at this juncture in the litigation, and the Court declines to do so *sua sponte*. *See Franklin*, 2003 WL 22048255, at *3.

Relator contends that he can establish falsity as a matter of law without any LCD-specific analysis because all of the LCDs "uniformly required the use of an FDA approved vascular stent," and Defendants' stents were neither "vascular stents" nor "FDA approved." The Court rejects this attempt to circumvent the necessary analysis. The LCDs do not "uniformly require" any particular element; instead, the LCDs require different combinations of distinct conditions. The Court further observes that several of the LCDs use the term "vascular stent" in a manner that does not necessarily preclude coverage of "biliary stents." The LCDs in effect in Region X, an area that covers several northwestern states, describe the devices that may be used in covered procedures as follows:

> A stent is defined as a tubular-shaped device used to provide post dilitation support for narrowed or obstructed structures (e.g., vessels, biliary tract, and esophagus) to induce or maintain patency in an anatomic site. *Vascular stents are used to maintain patency in arteries and veins usually at the site of stenotic lesions*. Vascular stents are typically made of metallic interlocking threads that compress to fit near the tip of a catheter. They are deployed with the used of radiological guidance into a vessel with either self-expanding capabilities or with the use of a balloon catheter. Once deployed, the device remains in the vessel to provide support and patency of the narrowed vessel.

Def. App. at 2442; *see also id.* at 2451, 2460, 2469, 2478. Thus, at least some of the applicable LCDs define "vascular stents" with respect to their function, or use in the arteries or veins. Such a definition does not automatically prohibit a "biliary stent" from functioning as a vascular stent.

Relator argues that Defendants' stents are ineligible for coverage because a "majority" of the LCDs provide that "[c]overage for above indications for non-coronary vascular stents

depends on the use of an *FDA approved* stent" and "[s]tent placement is covered by Medicare only when an *FDA approved* stent is … used." Rel. App. at 1942 (emphasis added); *see also id.*, at 1501-2076. The Court has previously determined that this language creates a plausible basis to infer that the LCDs containing this limitation only provide coverage for off-label uses of Class III vascular stents that have received approval through the premarket approval process. *United States ex rel. Colquitt v. Abbott Labs.*, 864 F. Supp. 2d 499, 531 (N.D. Tex. 2012) ("*Colquitt I*"). However, this inference, without more, is insufficient to satisfy Relator's burden on his motion for summary judgment.

Relator points to testimony by Defendants' experts to support his interpretation of the LCDs, but the experts' testimony is neither entirely clear nor unequivocal. Relator also ignores Dr. William Mangold's expert report—that he included in the summary judgment record—which explains that Medicare contractors use the term "FDA approved" to refer to devices merely "cleared" through the FDA's 510(k) process, like Defendants' biliary stents. The summary judgment record establishes that a genuine dispute exists as to whether LCDs that limit coverage to procedures involving "FDA approved" devices encompasses Defendants' biliary stents.[2]

Local contractors with responsibility for the rest of the United States did not issue LCDs for non-coronary vascular stenting. Relator asserts that "[i]n the absence of locally approved coverage, off-label uses are considered not reasonable and necessary." Relator's sole support for this assertion is the "Krubsack letter" and Dr. Krol's testimony explaining the letter, which

[2] In addition to conditioning coverage on the use of an "FDA approved" stent, a number of the LCDs also require that the use of the stent be "supported by the peer medical literature" or that the use "represent current standard practice in the medical community." Expert testimony is required to determine the import of the peer medical literature and the standard practice in the medical community. The expert testimony on these subjects is in conflict, and much of the testimony has been challenged on *Daubert* and other grounds. The Court is not now taking any position on the admissibility of the expert testimony.

he objected to and moved to strike. The Court has determined not to consider this evidence for purposes of the summary judgment motions. Without this or any other evidence, Relator cannot satisfy his summary judgment burden.

b.

Next, Relator argues that claims to Medicare involving Defendants' biliary stents were false because the claims were assigned billing codes that misrepresented the nature of the stent used in the procedure. Claims are submitted to Medicare using a 5-digit billing code based on the Current Procedural Terminology Manual ("CPT code"), promulgated by the American Medical Association. Each CPT code corresponds to a specific medical service, and the amount Medicare pays for a service is based on the CPT code. CPT codes 37205 and 37206 correspond to the placement of an *intravascular* stent in a non-coronary vessel. Defendants allegedly instructed their customers and health care providers to use CPT codes 37205 and 37206 to bill Medicare for vascular stent procedures using *biliary* stents, rather than a code for an unlisted procedure, like CPT code 37799 for "unlisted procedure, vascular surgery," or a code with a GZ modifier, which would convey additional information about a claim where non-covered items were used.

In support of his argument, Relator points to testimony by Defendants' coding experts that concede CPT code 37205 does not inform the Medicare contractor that an FDA cleared biliary stent may have been used in the intravascular stenting procedure—or provide any information whatsoever regarding the nature of the stent involved. *See* Rel. App. at 3692. Defendants respond that their experts also testify that CPT codes 37205 and 37206 were unquestionably the correct codes for health care providers to use when submitting claims to Medicare for reimbursement of vascular stenting procedures using their biliary stents. See Def.

App. at 1670, 1675-81. Medicare reimbursement procedures and coding requirements are proper subjects of expert testimony. *United States v. White*, 492 F.3d 380, 403-04 (6th Cir. 2007). Here, the expert testimony regarding the propriety of using CPT codes 37205 and 37206 on claims involving Defendants' stents is in conflict and raises a genuine dispute of material fact that makes summary judgment inappropriate.

c.

Relator also moves for summary judgment on the issue of materiality with respect to his false statement claims. Liability under the FCA requires that the falsity be material to the claim. In the Fifth Circuit, "a false statement is material if it has a 'natural tendency to influence, or [is] capable of influencing, the decision of the decision-making body to which it was addressed.'" *United States ex rel. Longhi v. United States*, 575 F.3d 458, 468 (5th Cir. 2009) (quoting *Neder v. United States*, 527 U.S. 1, 16 (1999)).

According to Relator, the CPT codes are material because a "clean" 37205 or 37206 code, without a GZ modifier, resulted in automatic payment. Defendant does not dispute this assertion, but points out that Relator's own expert testified that use of a GZ modifier or even the 37799 code would not necessarily result in claim denial. Def. App. 2705-06. Relator has not established materiality "beyond peradventure," and his motion for summary judgment as to this element is denied.

d.

Both parties move for summary judgment on scienter. The scienter requirement comes from the FCA's requirement that the person to be held liable must have acted "knowingly." For purposes of the FCA, the term "knowingly" means that a person (1) has actual knowledge of the truth or falsity of the information; (2) acts in deliberate ignorance of the truth or falsity of the

information; or (3) acts in reckless disregard of the truth or falsity of the information. 31 U.S.C. § 3729(b). No proof of specific intent to defraud is required. *Id.* The state of knowledge is usually a factual inquiry. However, summary judgment may be granted where there is no evidence of the requisite scienter. *United States ex rel. Taylor-Vick v. Smith*, 513 F.3d 228, 231 (5th Cir. 2008).

Defendants argue that Medicare coverage of biliary stents was "arcane and confusing" and that, as a matter of law, they did not have scienter because they objectively and reasonably believed that Medicare properly reimbursed vascular stenting procedures using biliary stents between 2004 and 2006. Defendants have produced evidence that they believed such procedures were reimbursable and that their belief was reasonable because it was shared by numerous providers, medical societies, and Medicare contractors. Relator, on the other hand, has pointed to evidence, which if believed, indicates Defendants had a far-reaching scheme to unlawfully benefit from an off-label use of their products and never had a good faith belief that their stents were eligible for Medicare reimbursement. Circumstantial evidence can support a scienter inference. *Fin. Acquisition Partners LP v. Blackwell*, 440 F.3d 278, 287 (5th Cir. 2006).

Relator also has adduced evidence that Defendants avoided making any inquiries that would confirm whether claims for vascular procedures using its stents were eligible for reimbursement. Rel. App. 3043, 3063, 3067, 3040-50. The evaluation of this evidence, including the testimony of Guidant's Director of Reimbursement Linda Dickes, requires credibility determinations. Whether Defendants objectively and reasonably believed that Medicare could properly reimburse vascular stenting procedures using biliary stents is a genuinely disputed fact question that is not appropriate for summary judgment.

e.

Finally, Defendants move for summary judgment on causation. The FCA does not define the phrase "cause to be presented," *see* 31 U.S.C. § 3729, *et seq.*, and the Fifth Circuit has not delineated a specific causation standard applicable to FCA claims. The Court thus finds it appropriate to apply common-law tort concepts of proximate causation to determine whether there is a sufficient nexus between the Defendants' conduct and the ultimate presentation of the allegedly false claim. This approach is consistent with that of well-reasoned decisions by other courts. *See, e.g., United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 714-15 (10th Cir. 2006); *Franklin*, 2003 WL 22048255, at *5. Accordingly, Defendants' conduct may be found to have caused the submission of a claim for Medicare reimbursement if the conduct was (1) a substantial factor in inducing providers to submit claims for reimbursement, and (2) if the submission of claims for reimbursement was reasonably foreseeable or anticipated as a natural consequence of Defendants' conduct. *Franklin*, 2003 WL 22048255, at *5.

The Court determines that Relator has identified enough evidence to raise a genuine fact dispute as to whether Defendants' conduct was a substantial factor in causing the presentment of Medicare claims for reimbursement. In particular, Relator has produced evidence that Defendants employed a multitude of sales representatives to market and sell biliary stents to cardiologists, vascular surgeons, and interventional radiologists performing vascular procedures, *see, e.g.*, Rel. App. at 5514, 5536, and that, in connection with their sales efforts, Defendants offered training and advice on Medicare reimbursement procedures, *see id.* at 3906-07. Relator's evidence also raises at least the inference that Defendants' customers heeded the sales representatives' advice and submitted claims to Medicare for reimbursement of procedures

using Defendants' stents. Relator has produced a November 2001 email from Jim Neupert, Guidant's Vice President of Marketing, that a health care provider used a Medicare coding guide provided by a Guidant employee in connection with a successful claim for reimbursement. Rel. App. at 3873-74. Although the Neupert email is outside the relevant time period for this action, it is undisputed that Defendants engaged in similar marketing activities—and that Defendants' customers continued to submit claims for Medicare reimbursement—between February 23, 2004 and June 21, 2006.

Defendants dispute whether any provider ever used or relied on information or advice provided by Guidant or Abbott in connection with the submission of reimbursement claims to Medicare. Among other things, Defendants note that numerous independent sources instructed health care providers on the proper submission of claims to Medicare for reimbursement of vascular procedures using biliary stents. *See, e.g.*, Def. App. at 1676-79. They further note that Relator's own expert, Wendy Britton Knau, testified at her deposition that she has no knowledge of any person who relied on Defendants' coding guidelines during the period at issue to determine how to code a procedure where a biliary stent was used in the peripheral vasculature. *See* Def. App. at 196. The evidence, viewed as a whole, raises a fact question on the substantial factor element, and the Court will leave to the jury the task of making credibility determinations and weighing conflicting evidence.[3]

The summary judgment evidence is also sufficient to raise a genuine fact dispute as to whether it was reasonably foreseeable that Defendants' conduct would lead to the submission of

[3] Defendants identify other evidence in support of their contention that providers did not use their coding guidelines to decide how to code the procedures at issue in this case, including testimony by several doctors who coded claims as part of their practice. *See, e.g.*, Def. App. 100, 1237, 1242, 1270-71, 1330, 1451. However, Relator has objected to this evidence and moved to strike it from the summary judgment record, and the Court does not rely on it to support its determination of the pending motions.

false claims for reimbursement. Viewing the evidence in the light most favorable to Relator, as the Court must do in considering Defendants' summary judgment motion, a jury could find that a reasonably foreseeable result of Defendants' efforts to market and sell biliary stents to health care professionals for use in vascular procedures would be the submission of Medicare claims for reimbursement of those procedures. Defendants' efforts specifically included training and advice on Medicare reimbursement.

To the extent Defendants contend there is no fact question on causation because there is no evidence that they completed, or otherwise controlled the content of a claim for Medicare reimbursement, the lack of such evidence is not necessarily fatal to Relator's claim. The law does not require direct involvement in the submission process to establish liability. Rather, the law merely demands more than mere passive acquiescence in the presentation of the claim and "some sort of affirmative act" that causes or assists the presentation of a false claim. *See Sikkenga*, 472 F.3d 715; *see also United States v. Mackby*, 261 F.3d 821, 824–26, 828 (9th Cir. 2001) (affirming FCA liability of owner/managing director of physical-therapy clinic who instructed the clinic's billing company to use an improper code on Medicare reimbursement claim forms; stating, "[A] person need not be the one who actually submitted the claim forms in order to be liable"). The evidence here is sufficient to raise a genuine dispute as to whether Defendants engaged in an affirmative act that caused the presentation of a false claim. Accordingly, Defendants' motion for summary judgment on the issue of causation is denied.

V.

For the reasons stated, Relator's Motion to Strike [Docket Entry # 459] and Supplemental Motion to Strike [Docket Entry #495] are DENIED as moot.

Defendants' Motion for Summary Judgment [Docket Entry #443] and Relator's Motion for Partial Summary Judgment [Docket Entry #440] are DENIED.

SO ORDERED.

Dated: January 7, 2016.

BARBARA M. G. LYNN
UNITED STATES DISTRICT JUDGE
NORTHERN DISTRICT OF TEXAS