UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

UNITED STATES OF AMERICA *ex rel.* JOHN KING and TAMMY DRUMMOND, *et al.*, *Plaintiffs*,	§	
v.	§	CIVIL ACTION H-06-2662
SOLVAY S.A., *et al.*, *Defendants*.	§	

MEMORANDUM OPINION AND ORDER

Pending before the court is a motion for partial summary judgment filed by defendant Solvay Pharmaceuticals, Inc.[1] ("SPI") seeking summary judgment on Relators John King and Tammy Drummond's ("Relators") False Claims Act claims predicated on violations of the federal and Texas Anti-Kickback Statutes ("US AKS" and "TX AKS," respectively). Dkt. 398. Having considered the motion, response, reply, and the applicable law, the court is of the opinion that the motion should be GRANTED.

I. BACKGROUND

This is a qui tam case relating to claims paid by Medicare or other government health plans for prescriptions of three SPI drugs—AndroGel, Aceon, and Luvox (collectively, the "Drugs at Issue").[2] Relators contend that SPI violated the US AKS and TX AKS by providing "kickbacks to doctors in the form of 'honoraria,' consulting fees, gift certificates, dinners, trips, flowers, and many other forms." Dkt. 154 at 168, 245. Relators assert that SPI knew these kickbacks would induce

[1] Solvay Pharmaceuticals, Inc. is now known as AbbVie Products, Inc. Dkt. 399 at 1 n.1.

[2] The AndroGel claims have already been dismissed, but the court nevertheless addresses arguments relating to AndroGel out of an abundance of caution.

physicians to write prescriptions for off-label uses or prescriptions tainted by the kickbacks, which would in turn cause pharmacists to submit claims for fraudulent Medicaid and Medicare Part D reimbursement. *Id.* at 169. The kickbacks would therefore result in the filing of false claims in violation of the federal False Claims Act ("US FCA") and several state False Claims Acts, including the Texas False Claims Acts ("TX FCA"). *Id.* Relators allege that the false claims resulted in SPI making millions of dollars in sales of the Drugs at Issue that it otherwise would not have achieved and that the United States and individual states[3] have thus suffered substantial damages.[4] *Id.* at 169–70. Relators argue that SPI broke the law every time its sales force paid prescribers to induce them to write prescriptions for the Drugs at Issue. Dkt. 415 at 1.

Discovery is complete and SPI now moves for partial summary judgment on all of Relators' FCA claims that are based on violations of the US AKS and TX AKS. Dkt. 400. SPI contends that, based on Relators' discovery responses, Relators' allegations that SPI engaged in a scheme to violate the federal and state Anti-Kickback Statutes nationwide have been reduced to allegations that SPI paid kickbacks to forty-six Texas physicians. *Id.* And as to those forty-six physicians, SPI argues that Relators' discovery responses demonstrate that they cannot prove an AKS violation. *Id.* SPI asserts that, based on discovery responses and the court's rulings, Relators' AKS claims are limited to claims submitted to Texas Medicaid for prescriptions written by a few dozen physicians, and that SPI is entitled to summary judgment, as an initial matter, on all the alleged false claims arising from any other alleged kickbacks. *Id.* Additionally, SPI argues that the court should grant summary judgment on the allegations that false claims resulted from kickbacks paid to the forty-six Texas

[3] Medicaid is a joint federal and state healthcare program. *See* 42 U.S.C. § 1396a (2012).

[4] Relators assert additional claims not relevant to the instant motion.

physicians because (1) four physicians prescribed only AndroGel, and the court already granted summary judgment on all AndroGel-related claims; (2) the only evidence of false claims that Relators produced during discovery is inadmissible hearsay; and (3) Relators cannot show that the funds provided to the remaining forty-two physicians violated the AKS because (a) Relators cannot show that many of the alleged kickbacks were actually paid, (b) Relators have no evidence that SPI intended for physicians to prescribe these drugs to patients on government health programs, and (c) Relators have no evidence that any prescription or claim was the result of the payments or kickbacks. *Id.*

Relators allege that SPI remunerated thousands of physicians across the country in exchange for prescriptions and that they have identified hundreds of physicians in two states alone—Texas and New York—who received something of value from SPI in exchange for prescriptions. Dkt. 415 at 1. Relators contend that all of the grounds upon which SPI seeks summary judgment require the court to make credibility determinations that are not appropriate at the summary judgment stage. *Id.* Relators additionally assert that (1) the claims data is admissible because it was collected from government agencies; (2) whether the claims were caused by the kickbacks and whether SPI intended the payments to induce physicians to prescribe the Drugs at Issue are questions within the province of the trier of fact; and (3) whether the payments were inducements or served legitimate business purposes is essentially a question of whether the conduct fits within a safe harbor, and SPI has the burden to show that payments it made fit within the safe harbors.[5] *Id.* at 2–3. Relators contend that

[5] The statute specifically does not apply to certain types of payments, including "any payment practice specified by the Secretary in regulations promulgated pursuant to section 14(a) of the Medicare and Medicaid Patient and Program Protection Act of 1987." 42 U.S.C. § 1320a-7b(3)(E). A list of the safe harbors can be found at 42 C.F.R. § 1001.952 (2014). SPI contends that Relators' safe harbor argument is a red herring. Dkt. 446.

the evidence is overwhelming that SPI paid prescribers, in gifts, lavish events, cash, gift cards, speaking engagements, and services, for over a decade, and the jury could reasonably infer these payments were remuneration for purposes of the TX AKS and US AKS. *Id.* at 3.

II. LEGAL STANDARD

A court shall grant summary judgment when a "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(c). "[A] fact is genuinely in dispute only if a reasonable jury could return a verdict for the non-moving party." *Fordoche, Inc. v. Texaco, Inc.*, 463 F.3d 388, 392 (5th Cir. 2006). The moving party bears the initial burden of demonstrating the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323, 106 S. Ct. 2548 (1986). If the party meets its burden, the burden shifts to the non-moving party to set forth specific facts showing a genuine issue for trial. Fed. R. Civ. P. 56(e). The court must view the evidence in the light most favorable to the non-movant and draw all justifiable inferences in favor of the non-movant. *Envtl. Conservation Org. v. City of Dall., Tex.*, 529 F.3d 519, 524 (5th Cir. 2008).

III. ANALYSIS

The court will first discuss the US AKS and the TX AKS. It will then address SPI's contentions that Relators do not have admissible evidence that any claims were paid and that Relators' claims should be confined to the physicians for whom they have provided claims data during discovery. Then, the court will determine whether there is an issue of genuine fact as to causation and intent.

A. The Anti-Kickback Statutes

1. US AKS. Relators contend that a claim resulting from a violation of the US AKS is

a false claim for purposes of the US FCA. Dkt. 154 at 25. Under the applicable version of the US AKS, 42 U.S.C. § 1320a-7b(b), it is illegal for an individual to

> knowingly and willfully . . . [receive] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind . . . in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program.

42 U.S.C. § 1320a-7b(b)(1)(A). Likewise, it is illegal to

> knowingly and willfully [offer or pay] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person . . . to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program.

42 U.S.C. § 1320a-7b(b)(2)(A).

This statute prohibits practices in the healthcare industry that may be common in other business sectors. *Office of the Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers,* 68 Fed. Reg. 23,731, 23,734 (May 5, 2003). Liability under the statute "ultimately turns on a party's intent." *Id.* However, the Office of the Inspector General ("OIG") advises manufacturers to identify any practices that may present a potential for abuse, starting with identifying any remunerative relationship between the manufacturer and persons who are in a position to generate federal healthcare business, including physicians. *Id.* Then, the company should "determine whether any one purpose of the remuneration may be to induce or reward the referral or recommendation of business payable" by the government. *Id.* A "lawful purpose will not legitimize a payment that also has an unlawful purpose." *Id.*

2. TX AKS. In their live complaint, Relators assert that SPI is liable for kickbacks to Texas physicians under the Texas Medicaid Fraud Prevention Act ("TMFPA"), which makes it

unlawful for a person to "knowingly engage[] in conduct that constitutes a violation under Section 32.039(b)," the TX AKS. Tex. Hum. Res. Code Ann. § 36.002(13) (West 2015). This subsection was enacted in 2007 and became effective on September 1, 2007. Act of May 1, 2007, 80th Leg., R.S., Ch. 78, § 1, 2007 Tex. Gen. Laws 80 (codified at Tex. Hum. Res. Code Ann. § 36.002). It "applies only to conduct that occurs on or after the effective date of [the] Act." *Id.* § 2(a).

A person violates the current version of the TX AKS, if he or she

> (1-d) offers or pays, directly or indirectly, overtly or covertly any remuneration, including any kickback, bribe, or rebate, in cash or in kind to induce a person to refer an individual to another person for the furnishing of, or for arranging the furnishing of, any item or service for which payment may be made, in whole or in part, under the medical assistance program, provided that this subdivision does not prohibit the referral of a patient to another practitioner within a multispecialty group or university medical services research and development plan (practice plan) for medically necessary services; [or]
> (1-e) offers or pays, directly or indirectly, overtly or covertly any remuneration, including any kickback, bribe, or rebate, in cash or in kind to induce a person to purchase, lease, or order, or arrange for or recommend the purchase, lease, or order of, any good, facility, service, or item for which payment may be made, in whole or in part, under the medical assistance program[.]

Tex. Hum. Res. Code Ann. § 32.039 (West) (2015). SPI argues, citing legislative history, that liability can attach only to violations of the TX AKS that occurred before the TMFPA was amended to encompass violations of the TX AKS if they can prove violations of the US AKS. Dkt. 400 at 24. Relators do not address this argument, and the court therefore deems the argument unopposed. *See* S.D. Tex. L.R. 7.4 ("Failure to respond will be taken as a representation of no opposition."). The court will consider only the US AKS for allegations of pre-2007 violations. Since both the post-2007 TMFPA and the US AKS require intentional conduct on the part of the entity violating the

AKS for liability to attach, there is no relevant difference for the purposes of the issues addressed by the instant motion.

B. Authentication of Claims Data

SPI argues that Relators do not have any evidence upon which they can rely that claims were paid by any government program. Dkt. 399. During discovery, Relators produced data sets that they claim contain data of claims for the Drugs at Issue that were submitted to New York and Texas Medicaid. Dkt. 399 & Ex. 1. SPI asserts that Relators did not provide any information regarding the source, composition, or manipulation of the data. Dkt. 399. SPI specifically requested the names of persons who would authenticate the claims data in Interrogatory No. 10, and Relators objected to the request.[6]

In response to SPI's argument that Relators cannot rely on the evidence now, Relators explain where they received the data and how the spreadsheets were compiled. Dkt. 415. Relators assert that the Office of the Attorney General for the State of Texas ("OAG") obtained the data pursuant

[6] Relators objected to the interrogatory, stating that they "need not identify the person or persons who could testify at trial to support the authenticity of the Claims Data at this time," citing Federal Rule of Civil Procedure 26(a)(3)(B). Dkt. 399, Ex. 5 at 117 (interrogatory responses dated Dec. 1, 2014). Relators were required to disclose information about any witnesses that had discoverable information pursuant to Federal Rule of Civil Procedure 26(a)(1). The individuals who compiled the claims data—the data that is at the heart of Relators' case—certainly had discoverable information. Relators rely on Federal Rule of Civil Procedure 26(a)(3)(b) in their objection to SPI's Interrogatory No. 10, which sought information about the individuals who could authenticate the claims data. Rule 26(a)(3)(B) deals with the timing of pretrial disclosures. Under Rule 26(a)(3), parties must provide information about the evidence they will present at trial other than evidence solely used for impeachment, including providing information about witnesses the party may call if the need arises, 30 days before the trial. Fed. R. Civ. P. 26(a)(3). This requirement for pretrial disclosure of witnesses clearly states it is in "addition to the disclosures required by Rule 26(a)(1) and (2)," not in lieu of the requirement. Relators have had the spreadsheets containing the claims data for many years and presumably know how they obtained them. Thus, it is unclear how Relators believe this Rule supported their objection to timely disclosing the information.

to a State Action Request in 2006 and produced the data to Relators in raw form. *Id.* Relators provide a declaration of Kevin Raymond, the Litigation Section Chief of the Texas Health and Human Services Commission ("HHSC")—the state agency responsibly for administering the Medicaid program in Texas. Dkt. 415, Ex. 17. The Texas Medicaid Health Partnership ("TMHP") is a contractor for Texas HHSC. *Id.* According to Raymond, TMHP created and provided data extracts in response to a request to "run an ad hoc query involving several drugs identified according to NDC codes specified by the OAG." *Id.* The TMHP provided the data via CD-ROMs to the OAG representative on January 17, 2006. *Id.* Relators next provide a declaration from Anthony Maro of EvriChart, Inc. Dkt. 415, Ex. 18. Maro states that he received the raw data in 2006 and converted it into Excel spreadsheets for each drug. *Id.* The third declaration is from Karen Karban, who was a contract medical coder with Healthcare Contract Resources in 2006. Dkt. 415, Ex. 19. Karban states that she received the spreadsheets from Maro and used them to create separate spreadsheets for each of the drugs based on on-label and off-label diagnosis codes and descriptions. *Id.*

SPI objects to Relators' reliance on the declarations of Raymond, Maro, and Karban. Dkt. 446. SPI points out that Relators did not provide this information in response to its interrogatory, that discovery is over now, and that it is improper to use affidavits of undisclosed witnesses to create an issue of material fact. SPI additionally asserts that "a cursory review of the declarations and Karban's spreadsheets reveals that they are not simply data extracted from records of the Texas Medicaid pharmacy claims" as they "include far more information than a record of pharmacy claims would." Dkt. 446 at 8. SPI argues that the data must have been augmented in an undisclosed way and that perhaps Relators do not even understand the origins of the data. *Id.* at 9.

SPI urges the court to rule that neither the spreadsheets nor the surprise witness declarations are competent summary judgment evidence. *Id.* at 9.

Relators did not file a response to SPI's objection, which is contained in SPI's reply. While the court is admittedly concerned that the names of these witnesses were not disclosed during discovery, it need not rule on this objection at this time because even if Relators can rely on the claims data, summary judgment should be granted for other reasons.

C. Scope of Claims

SPI contends that it is entitled to summary judgment on the allegations that false claims resulted from kickbacks provided to all providers except the forty-six Texas Medicaid providers who are on the list that Relators provided to their damages expert.[7] Dkt. 399 at 12. SPI additionally argues that Relators' claims should be limited to certain physicians disclosed by Relators in response to Interrogatory No. 2. *Id.* Thirty of the physicians on the list provided to Relators' expert are also listed in the response to Interrogatory No. 2. *Id.* (comparing the lists). According to SPI, the remaining sixteen physicians appear only in the complaint. *Id.*

In Interrogatory No. 2, SPI requested that Relators identify the payments that they allege SPI made in violation of the US AKS and specify the claims that SPI caused to be submitted to a federal health care program as a result. Dkt. 399, Ex. 6 at 72. Relators responded by providing a list of 465 physicians who received remuneration from SPI. According to SPI, Relators provided a list of alleged false claims resulting from prescriptions written by forty-four of those physicians, and

[7] SPI notes that the list includes 47 names but that one of the people listed does not have prescribing privileges. Dkt. 400 at 8 n.5 (citing Relators' expert's report). Relators argue that the Texas claims data lists this person as a billing provider and a provider who performed the service. Dkt. 415 at 16 n.39. This one prescriber does not impact the outcome, so the court need not resolve whether the prescribing evidence associated with this prescriber is reliable.

Relators indicated that they would supplement Medicaid claims data for the remaining physicians. Dkt. 399 & Ex. 6. SPI asserts that Relators never supplemented their response. Dkt. 399.

Relators contend that their claims should not be limited to the physicians provided in discovery response or to their expert because they do not have to identify every physician who wrote a prescription that led to a false claim being submitted as a result of SPI's actions to prevail at summary judgment or trial. Dkt. 415. They refer instead to the "examples" that they have provided. *Id.* The cases Relators rely on for their argument that it is unnecessary to disclose or provide evidence of each claim or each prescriber at the summary judgment stage are *Grubbs v. Kanneganti*, *United States ex rel. Pogue v. Diabetes Treatment Centers of America*, and *United States ex rel. El-Amin v. George Washington*.

In *Grubbs*, the Fifth Circuit considered whether a district court appropriately dismissed a qui tam case pursuant to Federal Rule of Civil Procedure 9(b) and 12(b)(6). 565 F.3d 180, 183 (5th Cir. 2009). The qui tam relator alleged that the defendants engaged in a fraudulent billing scheme in which physicians billed for regular hospital visits with patients on weekends when the physicians actually met with patients only as needed. *Id.* at 184. Grubbs's complaint alleged at least one overt act of false billing for each physician. *Id.* at 185. The court noted that the pleading requirements cannot be more stringent than the requirement of proof at trial and explained that if

> at trial a *qui tam* plaintiff proves the existence of a billing scheme and offers particular and reliable indicia that false bills were actually submitted as a result of the scheme—such as dates that the services were fraudulently provided or recorded, by whom, and evidence of the department's standard billing procedure—a reasonable jury could infer that more likely than not the defendant presented a false bill to the government, this despite no evidence of the particular contents of the misrepresentation.

Id. at 189–90. The court went on to note that "the exact dollar amounts fraudulently billed will often surface through discovery and will in most cases be necessary to sufficiently prove actual damages above the Act's civil penalty, [but] [n]evertheless, a plaintiff does not necessarily need the exact dollar amounts, billing numbers, or dates to prove to a preponderance that fraudulent bills were actually submitted." *Id.* at 190.

In *Pogue*, the federal district court for the District of Columbia considered a motion for summary judgment in a case in which the qui tam relator alleged that physicians were receiving kickbacks for patient referrals to diabetes treatment centers in violation of the Anti-Kickback provision of the US FCA. 565 F. Supp. 2d 153, 155 (D.D.C. 2008). The defendant argued that the relators had no evidence that the claims were presented to the government. The court agreed that whether the defendant presented a false or fraudulent claim to the government was a central question. *Id.* at 160. It found, however, that the evidence that plaintiff provided was sufficient. *Id.* at 161. The relator provided a declaration from an official at the Centers for Medicare & Medicaid Services ("CMS"), who stated that he responded to the relator's subpoena by assembling claims data on a CD and providing it to the relator. *Id.* The court noted that the official could testify at trial to authenticate the data and that the data was therefore properly considered by the court. *Id.* (citing *United States v. Rogan*, 459 F. Supp. 2d 692, 727 n.17 (N.D. Ill.), *aff'd*, 517 F.3d 449 (7th Cir. 2008)).

The *Pogue* defendant also argued that even if the CD were allowed, the court should grant summary judgment with respect to the medical directors whose patients' Medicare claims were not on the CD. *Id.* The court found that it was "unnecessary for relators to produce evidence of every single claim submitted to the Government, provided relators [could] highlight sufficient evidence

of claim submission in general." *Id.* (citing *United States ex rel. El-Amin v. George Washington Univ.*, 522 F. Supp. 2d 135, 141–42 (D.D.C. 2007)). The court held that the determination as to whether there were claims submitted from referrals by medical directors whose patients were not on the CD was properly left to the jury. *Id.*

In *El-Amin*, the FCA relators alleged that false claims were submitted to Medicaid for anesthesia services. 522 F. Supp. 2d at 137. The defendants moved for partial summary judgment with respect to the submission of false claims for claims for which the relators did not possess Medicare claims forms. *Id.* The relators conceded that they were not in possession of a claim form for every claim at issue but asserted that they had compiled twenty boxes of direct evidence that the defendant billed Medicare, which was an adequate substitute for the actual Medicare claim forms. *Id.* The defendants argued that any evidence other than the actual claim forms could not be used at trial under the best evidence rule. *Id.* at 138. The court noted that under 31 U.S.C. § 3729(a), the relators were required to show that the defendant had submitted a claim to the government, but nothing in the language of the statute required the relators to possess the actual claim forms. *Id.* at 141. The court found that the evidence the relators possessed was sufficient to create a genuine issue as to whether the defendant submitted claims to Medicare. *Id.* at 143. However, in a later decision, the court dismissed the remaining claims because the relators had not provided any evidence that would be admissible at trial to prove that the defendant knowingly submitted a false claim. *United States ex rel. El-Amin v. George Washington Univ.*, 4 F. Supp. 3d 30, 39 (D.D.C. 2013).

These cases indicate that Relators do not need to have an actual claim form for each and every alleged false claim if they have other evidence of false claims. They do not indicate that Relators can wholesale survive summary judgment on their multi-state multi-year kickback scheme

theory with evidence relating to a confined list of physicians who allegedly received remuneration from the defendant in one state. While theoretically Relators could survive summary judgment with examples, the examples would have to be linked to remuneration from SPI, some evidence of intent that the renumeration would lead to claims, and claims for prescriptions written by these physicians that a reasonable juror could believe resulted from the unlawful remuneration. Additionally, to continue a claim on a national-level scheme, Relators would need to demonstrate that kickbacks were provided to physicians in different areas of the country as part of a nationwide scheme to increase prescriptions of the specific Drugs at Issue to patients who are on Medicaid or part of some other government prescription program. Here, the physicians listed who are linked to claims are confined to Texas, and discovery ended long ago.[8] Since Relators provide no examples outside of Texas, the multi-state claims must fail.

D. Causation

SPI asserts that Relators cannot demonstrate an issue of material fact as to whether the claims resulted from a kickback. Dkt. 399 at 19. It contends that in order to be a violation of the US FCA (and the pre-2007 TX FCA), a US AKS violation must be linked to a claim for payment, and Relators have no evidence that any of the Texas physicians for whom Relators provide claims data wrote a prescription for one of the Drugs at Issue *because of* a kickback. *Id.* at 21. Specifically, SPI points out that nine of the physicians were writing prescriptions for SPI drugs before the alleged kickbacks (Ex. 11 at Attach. J), and there was too much time between the alleged kickback and claim for one doctor (over two years). *Id.* at 22. Four additional doctors allegedly received kickbacks in

[8] There are physicians from Florida and New York listed as well, but Relators did not provide claims data for these physicians and never supplemented their responses.

the form of payments for giving presentations that resulted in claims over a year later, which SPI argues is not a sufficient temporal link. *Id.* For the remainder of the physicians, SPI contends that there is no evidence that the physicians were actually influenced. *Id.* at 23.

Relators argue that the court already found that there was a sufficient temporal link between the payments and the claims to survive SPI's motion to dismiss, and they provide several examples of physicians who received payments from SPI and then wrote prescriptions for the Drugs at Issue to Medicaid patients within months. Dkt. 415 at 17–19. Relators acknowledge that some of the physicians listed in their response to SPI's interrogatories prescribed small amounts of the Drugs at Issue prior to receiving kickbacks. *Id.* They argue, however, that SPI was making payments to these "dabblers" in an attempt to transform them into high prescribers. *Id.* Relators direct the court to a February 2003 business plan for the Southwest Region in which the SPI regional business director indicated that in order to position Aceon in the physician's mind for hypertensive patients, the sales representatives should use certain strategies "to pin-point the MDs that are . . . 'dabblers.'" Dkt. 415 & Ex. 48 at 73. Relators provide a specific example of a physician who wrote three Aceon prescriptions in 1999, received a $3000 honorarium in February 2000, and then wrote twenty-six Aceon prescriptions in 2000. Dkt. 415 at 19 (citing Exs. 21, 49).

SPI points out that prescription rates for Aceon increased from 1999 to 2000 because Aceon was launched in the fourth quarter of 1999. Dkt. 446 at 13. SPI asserts that Relators have not shown that the prescriptions written by physicians after receiving compensation for attending SPI educational programs were more likely the result of compensation than they were the result of the information presented, and it argues that the causation evidence is "wishful thinking" and not sufficient to create a triable issue. *Id.* at 14.

The court agrees that there are issues with causation as to many of the physicians on the list. However, there is enough evidence as to some of the physicians to survive summary judgment on the issue of whether the payments or other "kickbacks" caused physicians to write more prescriptions for the Drugs at Issue, ultimately leading to false claims being submitted for these drugs.

E. Intent

While there is some evidence that some claims were made because of the payments, that does not end the inquiry. A violation of the US AKS requires a knowing and willful provision of funds in return for prescriptions. SPI contends that Relators have no evidence that the programs in which the physicians received payments were crafted with the intent that the physicians receiving payments would write prescriptions for the Drugs at Issue. Dkt. 399. Relators contend that an FCA relator may establish the scienter element of her claim through circumstantial evidence, and since determining whether a business arrangement violates the US AKS is largely a question of intent, resolution of this issue is the province of the trier of fact. Dkt. 415. Relators assert that the motion can be granted only if there is *no evidence* of scienter. *Id.* They point out that SPI employees knew about the US AKS, and they argue that there is "ample evidence of purposeful conduct offering remuneration in exchange for prescriptions." *Id.*

The evidence Relators provide of scienter relates to the following SPI programs: (1) the "preceptorship" program; (2) the "Physician Profile Interview" program; (3) the "Case X-Change" program; (4) "ACT" and "REACT" programs; and (5) speaker programs. The preceptorship program involved SPI paying physicians to allow a sales representative to spend part or all of a day with a physician in his or her office. As evidence that this program was an intentional attempt to pay physicians to write prescriptions for the Drugs at Issue, Relators provide an email and attachment

relating to the AndroGel 2002 budget for SPI's South Central Region. Dkt. 415, Ex. 7. The budget indicates that preceptorships cost $250 per program, but it does not indicate that any funds were spent for the program or that any programs were scheduled. *See id.* at 41. The description of the program states:

> Preceptorships are a great way for new reps to learn a bit about the MD perspective and for seasoned reps to develop a more in-depth knowledge of hypogonadism. We typically pay $250 for a half-day preceptorship. You may choose to adjust this amount, but it should be "within reason." You may conduct as many or as few of these programs as you please.

Id. at 42. This evidence shows that conducting preceptorship programs was an option in the South Central Region. It does not show that SPI paid any physicians in that region to prescribe AndroGel.[9]

The other evidence cited relating to the preceptorship program is a Kansas City District Monthly Business Update from January 2002. Dkt. 415, Ex. 6 at 54. It indicates that a nephrologist, who appears to have no ties to Texas or New York, had begun to prescribe Aceon after a preceptorship. *Id.* While the Fifth Circuit "hesitate[s] to grant summary judgment when a case turns on a state of mind determination," and it "is possible for an FCA relator . . . to establish the scienter element of her claim through circumstantial evidence," there must be enough evidence of scienter to establish a genuine issue of fact for trial. *United States ex rel. Taylor-Vick v. Smith*, 513 F.3d 228, 231–32 (5th Cir. 2008). The evidence provided does not raise an issue of material fact that the

[9] There is one entry on Relators' discovery responses that links a $750 preceptorship in the Southwest Region in February 2000 to Medicaid claims for Luvox starting in May 2001. *See* Dkt. 399, Ex. 6 at 302. There is no evidence offered about intent as it relates to use of preceptorships to increase Luvox prescriptions. Moreover, even if there were, the temporal link for this physician is insufficient to infer causation. The physician received an honorarium and a payment for a preceptorship in February 2000 and the first Texas Medicaid claim is in May 2001. *See id.* The next Medicaid claim after that is not until August 2003. *See id.*

physicians who are linked to claims were part of a preceptorship program intended to produce prescriptions for the Drugs at Issue.

The next program Relators contend demonstrates SPI's scienter is the Physician Profile Interview program. Dkt. 415 at 13. Relators provide an exhibit that describes "physician profile interviews." Dkt. 415 Ex. 8. It instructs sales representatives to meet with physicians prior to the launch of Aceon "to obtain key information about [their] physicians' practice and treatment of hypertension," and it provides a timeframe during which the interviews should take place. *Id.* It advises the representatives to "[i]nform the physician that [SPI was] preparing to enter the Cardiovascular market" and was scheduling interviews "to better understand the needs of its customers." *Id.* The document specifically warns: "DO NOT MENTION THE PRODUCT OR THE PRODUCT CLASS . . . . THIS IS CRUCIAL." *Id.* (alteration in original). It states that the "physician should understand that the purpose of [the] interivew is to learn about his/her practice, enhance [the sale representative's] understanding of hypertension and the physician's/patients [sic.] needs." *Id.* The interviews were to last thirty minutes and SPI was providing a $100 consulting fee or honorarium in consideration of the physician's time. *Id.* After this description, the sales representatives were again warned: "To ensure the integrity of the program, no details will be given on ACEON or other Solvay products during the Expert Interview." *Id.*

This evidence is even less helpful than the scienter evidence on the Preceptorship program. Relators have pointed to no evidence that any of the physicians they have linked to claims data participated in a Physician Profile Interview. And, even if they did have such evidence, the sole document provided fails to show that SPI intended to use this program to pay physicians to write

prescriptions for the Drugs at Issue. It specifically warns the representatives to not even mention Aceon.

Relators next assert that SPI "even paid physicians to participate in [Continuing Medical Education ('CME')] programs, [SPI's] Case X-Change program consisted of [SPI] paying physicians $150 to submit a 'case study' illustrating the prevention of secondary stroke, clearly an effort to offer inducement to physicians in conjunction with promoting Aceon for stroke prevention." *Id.* Relators point the court to a form entitled "CME CaseXchange Newsletter Case Study Submission Form: Prevention of Secondary Stroke." Dkt. 154, Ex. 114 (ECF No. 111). The form indicates that somebody (presumably SPI) was collecting cases that illustrate the prevention of secondary stroke for a composite that would be published in a newsletter, and that physicians who submitted case studies would receive a $150 honorarium. *Id.* Relators also provide an email in which an SPI regional business director discusses "Case Exchange" programs. It states that "Case Exchanges are targeted towards 10–12 physicians who will become thought leaders and influencers on PROGRESS. Each attendee will receive a $150 honorarium along with CME - a double hit!"[10] Dkt. 415, Ex. 82. Relators then provide a document entitled "'Top-Prescribers' Case X-Change Contest" that outlines a contest for representatives in the SPI Southwest Region. It states that sales representatives "have the opportunity to invite [their] highest-decile physicians . . . to the Case X-Change occurring in [their] area and maximize this great opportunity to generate Aceon prescriptions and benefit from the peer influence that will occur." Dkt. 415, Ex. 9. This document emphasizes that it was critical for

[10] The PROGRESS trials were trials sponsored by SPI to determine Aceon's effectiveness in preventing secondary stroke. *See* Dkt. 154 at 60. According to Relators, the trials showed "that the incidence of secondary strokes in study subjects was lowered, but only once a rarely used diuretic, indapamide, was added to Aceon." *Id.*

representatives to invite the "*right physicians*" and that the program would reward representatives "for targeting the most important doctors for our continued success." *Id.* While this evidence is probative with regard to SPI's intent to use its Case Exchange or X-Change program to increase Aceon prescriptions, Relators have not pointed to any evidence indicating that any of the physicians who wrote Aceon prescriptions for which they provide claims data actually participated in the Case Exchange or X-Change program.

Relators next discuss the ACT and REACT programs. Dkt. 415 at 14. According to Relators, ACT stands for "Aceon Community Trial" and was a program in which SPI paid physicians to attend orientation sessions at luxury hotels, and after the orientation, physicians placed patients on Aceon, tracked them, and sent data to SPI to publish as a Phase IV study. *See id.* at 14 n.37 (citing the live complaint, but providing no evidence); *see* Dkt. 154 (live complaint), Ex. 123 (memorandum describing the ACT trial as a community-based investigation). Relators contend that ACT was "so successful at boosting Aceon prescriptions that [SPI] followed it up with REACT, which targeted physicians who had never prescribed Aceon." Dkt. 415 at 14 n.37 (again citing only the complaint). Relators provide a business plan from an Indianapolis district manager in which he indicates that his district would use physicians who participated in ACT to "drive RX" and proposes "6 doctors per territory for REACT." Dkt. 415, Ex. 10 at 80, 83. This business plan from Indianapolis in which one district manager indicates that ACT drove prescriptions and then makes a proposal for the number of physicians who should participate in REACT has no relevance, as the intent of this one manager has not been linked to the sales representatives that dealt with the physicians who are linked to claims data in this case. Relators also provide a document indicating that a district manager in Chicago had a goal to "[g]ain six patients per REACT physicians [sic.] per territory," Dkt. 415, Ex. 11 at 72, and

a business plan from a different district manager in Chicago who budgeted money to "be spent with doctors of REACT trials for preceptorships to increase return" and noted that increasing prescriptions from REACT doctors was an opportunity, Dkt. 415, Ex. 12 at 9–11. Again, these documents have not been linked to Texas or New York and thus do not establish an issue of material fact as to intent.

Finally, with regard to speaker programs, Relators assert that SPI paid for one physician's spouse to attend a golf outing, that SPI invited physicians and their families to watch a performance of the Nutcracker, and that one SPI speaker program included a Philadelphia Seventy-Sixers game. Dkt. 415 at 15 & Exs. 13–16. The physician going to the Seventy-Sixers game is not listed in the interrogatory response. *See* Dkt. 399, Ex. 6. The other two physicians are listed, but the response indicates that the claims data will be supplemented later. *See id.* Relators have provided no evidence indicating these physicians wrote prescriptions that resulted in claims paid by government payors. Thus, even if paying for these events is evidence of intent, it is not sufficient to lead a reasonable fact-finder to determine that SPI intended to pay physicians to write prescriptions and that these payments resulted in claims.

Most of the physicians for whom Relators provide claims data received payments for speaker programs, presentations, or Solvay Cities.[11] While a jury could possibly infer that these payments caused the physicians to prescribe the Drugs at Issue for payments that are close in time to the prescriptions, there has been no evidence presented that would allow a reasonable juror to conclude that SPI intended for the payments to the physicians linked to claims data to result in prescriptions for the Drugs at Issue. The only evidence of intent is not linked to claims paid by the government and is therefore not probative of an intent to induce physicians to write prescriptions for the Drugs at Issue

[11] According to Relators, Solvay Cities was a "regional dinner program." Dkt. 399, Ex. 6.

that would result in claims paid for the government. Thus, the evidence is insufficient to support a TX FCA or US FCA claim.

IV. CONCLUSION

SPI's motion for partial summary judgment on the TX FCA and US FCA claims predicated on violations of the TX AKS and US AKS is GRANTED. These claims are DISMISSED WITH PREJUDICE.

Signed at Houston, Texas on December 10, 2015.

Gray H. Miller
United States District Judge