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*.	§	

AMENDED ORDER

Pending before the court is a motion for partial summary judgment filed by defendant Solvay Pharmaceuticals, Inc. ("SPI" or "Solvay")[1] relating to Relators John King and Tammy Drummond's ("Relators") DrugDex theory. Dkt. 389. After considering the motion, response, reply, and applicable law, the court is of the opinion that the motion for partial summary judgment should be GRANTED.

I. BACKGROUND

This is a False Claims Act case relating to reimbursements from government programs such as Medicaid for prescriptions for three drugs—Aceon, AndroGel, and Luvox (collectively, the "Drugs at Issue")—that are manufactured and marketed by SPI or its affiliates.[2] Under the Medicaid statute, States must reimburse pharmacies for prescriptions for a drug if the drug is prescribed for a "medically accepted indication." 42 U.S.C. § 1396r-8(d)(1)(B)(I). A "medically accepted

[1] SPI is now known as AbbVie Products, LLC. Dkt. 388 at 1 n.1.

[2] All claims related to AndroGel have already been dismissed due to the False Claims Act public disclosure bar. Dkts. 386, 585. However, the court will continue to address AndroGel claims for the record.

indication" is defined as a "use for a covered drug which is approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described" by the Medicaid statute. 42 U.S.C. § 1396r-8(k)(6). DRUGDEX Information System ("DrugDex" or "Truven")[3] is one of these compendia. *See* 42 U.S.C. § 1396r-8(g)(1)(B)(i)(III).

The instant motion relates to Relators' allegations that SPI inappropriately influenced which uses for the Drugs at Issue were deemed medically accepted by influencing DrugDex entries (the "DrugDex Theory"). Dkt. 114. Relators allege in their complaint that SPI either "misled" DrugDex about certain medical studies and articles or "colluded with" DrugDex "so that the uses listed might be deemed eligible for reimbursement under various government health programs, especially Medicaid and Medicare." *Id.* ¶ 265. SPI contends that there is no evidence to support the allegation that SPI defrauded, colluded with, or otherwise improperly influenced DrugDex to obtain additional supportive listings for the Drugs at Issue. Dkt. 390. Relators argue that whether SPI defrauded, colluded with, or improperly influenced DrugDex is a question of fact for the jury to decide because SPI (1) suppressed negative research results regarding the drugs' effectiveness; (2) flooded the literature with positive but scientifically irrelevant small pilot studies by physicians it supported; and (3) ghostwrote many of the articles that appeared in DrugDex. Dkt. 428. SPI replies that the court should reject Relators' suppression theory because (a) Relators did not plead this theory and (b) Relators provide no evidence that SPI supported any study publication that inaccurately described the scope, methods, or conclusions of the study. Dkt. 459. As to the flooding the literature argument, SPI asserts that there is no evidence that SPI deceived DrugDex about the quality of any

[3] Truven Analytics is the company that produces the DrugDex compendia. Dkt. 388 at 1 n.2.

study and, regardless, the DrugDex clinicians exercised independent judgment. *Id.* With regard to ghostwriting, SPI argues that Relators have no evidence that its employees ghostwrote articles and, even if they did, it does not mean that DrugDex was the victim of fraud. *Id.*

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

In the live complaint, Relators contend, as part of their False Claims Act off-label promotion claim, that SPI

> fully understood that Medicaid and Medicare formularies do not encompass off-label uses for a drug without a supportive compendium listing. Accordingly, the company manufactured medical literature over which it maintained control in order to submit it to compendia and win access to Medicaid formulary coverage. . . . .
>
> In submitting DRUGDEX included uses for Luvox, Aceon, and AndroGel, despite their lack of support, either because Solvay misled DRUGDEX about the attributes of these authorities, or because DRUGDEX colluded with Solvay, so that the uses listed might be deemed eligible for reimbursement under the various

> government health programs, especially Medicaid and Medicare. Alternatively, the listings result from a combination of both deception and collusion. Solvay openly communicated with medical compendia about its drug entries. Upon information and belief, DRUGDEX learned about these inappropriate authorities through communications with Solvay, and Solvay chose not to disclose its financial ties to a study or author in submitting such authorities to DRUGDEX. . . .

Dkt. 154 ¶¶ 270–71.

A False Claims Act claim requires: "(1) a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that is presented to the Government." *United States ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 267 (5th Cir. 2010). To be "material," the false statement or fraudulent course of conduct must have "a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). In its motion to dismiss Relators' fourth amended complaint, SPI argued that Relators' off-label promotion claims should be dismissed because their complaint failed to plead materiality as to the False Claims Act violations based on off-label promotion. Dkt. 122 at 22, 26. In its order denying that motion to dismiss, the court found that Relators plausibly pled that the claims resulting from off-label promotion were material because the allegations about DrugDex, taken together with the alleged wooing of State Pharmacy and Therapeutic committee members, indicated a plausible influence as to which drugs were placed on state formularies. *See* Dkt. 153 at 64. SPI now moves for summary judgment with regard to this DrugDex theory, arguing that Relators have no evidence that (1) SPI made any misleading submissions to DrugDex; (2) SPI deceived DrugDex into listing support for off-label uses of Aceon, AndroGel, or Luvox; or (3) SPI and DrugDex colluded to expand the reimbursable uses of Aceon, AndroGel, or Luvox. Dkt. 388. SPI

also argues that Relators cannot survive summary judgment by asserting that they disagree with DrugDex's assessment of the medical literature. *Id.*

Relators assert that they do not need proof that SPI and DrugDex corresponded because the facts show that DrugDex invited undue influence and SPI took advantage of how easy it was to influence DrugDex by (1) establishing a relationship with DrugDex; (2) publishing smaller investigator-initiated studies and ghostwriting articles to impact DrugDex listings; (3) publishing paid journal supplements; and (4) suppressing the results of negative studies. Dkt. 428. Relators contend that SPI's suppression of study results altered the body of scientific research available for medical and public use, that the supplements subverted the scientific literature, and that suppressing the large studies while producing the small non-authoritative studies led DrugDex employees to turn to the low quality studies for inclusion in the compendia. *Id.* Because Relators do not have direct evidence of communications between SPI and DrugDex to support their DrugDex Theory, the court must determine if the circumstantial evidence is sufficient to raise an issue of material fact as to a violation of the False Claims Act.

A. SPI's Alleged Suppression of Study Results

Relators contend that SPI's fraud on DrugDex was perpetuated by both misrepresenting the results of studies and by omitting material facts. Dkt. 428. Specifically, Relators provide evidence that they claim indicates that SPI did not seek to publish results of negative studies for the use of Luvox to treat depression, alcoholism, panic disorder, anxiety, and eating disorders, yet it generated a plethora of small studies, which will be discussed *in seriatim* below. *Id.* Relators contend that DrugDex, faced with the absence of large studies (because SPI suppressed results) and the abundance of small studies, relied on small studies for supportive entries in DrugDex. *Id.*

1. SPI's Publishing Policy

SPI's Dr. RH[4] testified that he did not recall an instance where SPI sought publication of a negative study, but noted also that the "literature is not interested in negative studies very often." Dkt. 428, Ex. 6 at 94–95. He stated that SPI "always tried to get [its] studies published that [were] positive" as the investigators generally want those studies published. *Id.* at 115–16. He then clarified that he could "not recall any occasion that it did not come from the investigators that they wanted to publish," which the court interprets as meaning that the investigators, not SPI, determined if they wanted to publish study results. *Id.* at 116.

2. Luvox to Treat Depression

Relators contend that SPI or its affiliates conducted a large study on the use of Luvox to treat depression that had negative results that was not published, yet it funded and published lower quality work—with positive outcomes—that "eventually made it into DrugDex." Dkt. 428 at 22. According to Relators, this "distribution of lower quality studies while withholding higher-quality studies with negative results resulted in fraud on DrugDex." *Id.* The evidence provided by Relators in support of its assertion that SPI suppressed the results of the large study is testimony from Dr. RH in which he states (1) that he had no knowledge of SPI attempting to publish the results of a failed depression study; and (2) that when providing conclusions of this failed study to the FDA, SPI did not provide the efficacy section. Dkt. 428, Ex. 6 at 105, 272–74. In response to a question relating to why there was no efficacy data, Dr. RH responded: "It's just a matter of saving money on the report in the end. This is [the] minimum requirement the FDA has on us, so this is what we do." *Id.* at 273–74.

[4] The court has abbreviated the names of SPI employees in this order; the names of the specific employees have no bearing on the outcome.

3. Luvox to Treat Alcoholism

Dr. RH additionally testified that there were three studies relating to the use of Luvox to treat alcoholism and that he did not believe the outcomes were positive. Dkt. 428, Ex. 6 at 126. He did not recall if there were any publications out of SPI's research and development department or any smaller studies published relating to the use of Luvox for treating alcoholism. *Id.* Relators characterize this testimony as "suppressing" results to "mislead DrugDex editors." Dkt. 428. Relators point out that "[w]ithout the benefit of this failed study, DrugDex relied on a short (4 week) small study, Kranzler 1993, in which 18 of 26 patients treated with Luvox (70%) dropped out of treatment. . . . The study was sponsored by Solvay." *Id.*

4. Luvox to Treat Panic Disorders, Depression with Anxiety, and Eating Disorders

Next, Relators note that Luvox failed in SPI's "more rigorous panic disorder studies," and that SPI decided to pursue a publication strategy instead. *Id.* Similarly, Relators point out that SPI did not publish its registration studies indicating that Luvox did not effectively treat depression with anxiety, and DrugDex relied on a favorable Solvay-funded open-label study to support that use. *Id.* With regard to bulimia, Dr. RH testified that there were mixed results for using Luvox to treat bulimia and that SPI did not pursue the indication. Dkt. 428, Ex. 6 at 130. DrugDex ended up relying on "lesser studies on the use of Luvox for bulimia." Dkt. 428. One of the studies supporting the use was from a Solvay-funded supplement to the *Journal of Clinical Psychiatry*. *Id.*

5. Sufficiency of Evidence

This evidence, taken in the light most favorable to Relators, indicates that SPI's research and development department did not actively seek to publish studies with negative outcomes for off-label uses of Luvox. However, the evidence does not show that SPI actively *suppressed* the studies or in

any way discouraged investigators who desired to seek publication of their studies from doing so. Because there is no evidence of an affirmative misrepresentation, it appears that Relators are attempting to establish an issue of material fact as to fraud by omission.[5] The problem with this theory, even if one were to construe Relators' complaint liberally enough to determine that it is sufficiently pled, is that even fraud by omission requires the existence of a *duty* to disclose the facts. *See Berge Helene Ltd.*, 896 F. Supp. 2d at 618. Relators have pointed to no duty to publish negative results or even demonstrated that scientific journals would be inclined to publish such results.[6]

Relators argue that there is "'always a duty to correct one's own prior false or misleading statements,'" and that SPI's withholding of studies showing a lack of effectiveness while at the same time commissioning studies to show effectiveness created a duty to "correct the record." Dkt. 428 at 30 (quoting *Rimade Ltd. v. Hubbard Enters., Inc.*, 388 F.3d 138, 143 (5th Cir. 2004) (applying Texas law)). A "duty to disclose 'can arise by operation of law or by agreement of the parties,' or by 'some special relationship between the parties, such as a fiduciary or confidential relationship.'" *Rimade Ltd.*, 388 F.3d at 143 (quoting *Trs. of the N.W. Laundry & Dry Cleaners Health & Welfare Tr. Fund v. Burzynski*, 27 F.3d 153, 157 (5th Cir. 1994)). And, there is a duty to correct prior false statements "such that a speaker making a partial disclosure assumes a duty to tell the whole truth

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[5] Under Texas law, fraud by omission requires proof that "(1) the defendant failed to disclose facts to the plaintiff when the defendant had a duty to disclose such facts; (2) the facts were material; (3) the defendant knew of such facts; (4) the defendant knew that the plaintiff was ignorant of the facts and did not have an equal opportunity to discover the truth; (5) the defendant was deliberately silent and failed to disclose the facts with the intent to induce the plaintiff to take some action; (6) the plaintiff relied on the omission or concealment; and (7) the plaintiff suffered injury as a result of acting without knowledge of the undisclosed facts." *Berge Helene Ltd. v. GE Oil & Gas, Inc.*, 896 F. Supp. 2d 582, 618 (S.D. Tex. 2012).

[6] The testimony, in fact, indicates that the journals likely would not be interested in negative results. Dkt. 428, Ex. 6 at 94 ("The literature is not interested in negative studies very often . . . .").

even when the partial disclosure was not legally required." *Id.* Of course, this simple concept is incredibly more complicated when considered in light of studies about the efficacy of drugs to treat certain conditions. While clearly a large, double-blind, placebo-controlled study showing Luvox is not effective to treat a condition has more scientific credibility than a small, non-placebo controlled study showing it is effective, that does not mean that the reported *results* of the small study were false statements. If the larger study merely provides more reliable information about how efficacious a drug is for treating a condition overall, but the smaller study accurately reported the results as to the patients treated in that small study, then there is no actual misstatement or partial disclosure to correct.[7] Moreover, even if one were to construe the smaller study as being only partially true given the new information received from the larger study, it is unclear why Relators believe it is the drug company's burden to inform all drug compendia about the new study. Particularly in cases, as in this case, where there is no evidence that the drug company provided the smaller studies to DrugDex. There is, quite simply, no evidence that *SPI* made a partial disclosure to DrugDex that needed to be corrected.[8] Given this lack of evidence, Relators' suppression theory fails.

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[7] Relators do not allege that SPI represented to DrugDex that there were no negative studies.

[8] Relators urge the court to infer that SPI must have communicated the results of several small studies to DrugDex because there are SPI-sponsored Luvox depression studies cited in DrugDex that "do not appear to be publicly available in the United States." Dkt. 428 at 15–16. However, SPI has demonstrated that each of the articles was, in fact, available in the United States. *See* Dkt. 451, Ex. 1 (declaration of SPI's counsel indicating that she performed a search and determined that hard copies of each of the articles were available in multiple libraries throughout the United States); Ex. 2 (copy of 1988 Conti et al. article in *Current Therapeutic Research*, date stamped March 25, 1988); Ex. 3 (copy of 1987 Martin et al. article in *Pharmatherapeutica,* date stamped April 28, 1987); Ex. 4 (copy of 1988 Porro article in *Current Therapeutic Research*, date stamped April 27, 1988); Ex. 5 (copy of Siddiqui et al. article in *Current Medical Research*, date stamped February 24, 1988).

B. SPI's Alleged Manipulation of Published Results

Relators contend that there is evidence that SPI manipulated the results of studies that then became listed in DrugDex for an off-label use. Dkt. 428 at 27. This allegation also relates to Luvox. Relators assert that DrugDex relied on a single study to support a listing for the off-label use of Luvox for the treatment of post-traumatic stress disorder ("PTSD") and that it categorized Luvox as effective for off-label treatment of social anxiety disorder based on a single study. *Id.* at 27–29.

With regard to PTSD, Relators criticize DrugDex's reliance on a small study supported by SPI that is the only study in DrugDex supporting the rating of "possibly effective" for PTSD from 1997-2001. *Id.* at 28. Relators contend that DrugDex inaccurately portrays the study because (1) DrugDex relied on results SPI published by before the study was over; and (2) SPI suppressed the results of half of the study sample in that publication. *Id.* at 27. Relators argue that the "fact that this study was included in DrugDex, and was included with missing and undisclosed data points, is evidence of [SPI's] fraud on DrugDex." *Id.* at 29.

Relators have not provided any evidence that SPI suppressed the results of half of the study sample. At most, the evidence shows that there were originally eleven study participants, one of the original eleven participants dropped out of the study, and the study was extended to include ten to eleven more patients after the results were already published. *See* Dkt. 428, Ex. 21 (1996 publication describing a ten-week open-label study commencing after two weeks of screening with ten patients who completed the trial and one dropout); Ex. 57 (1999 publication strategy document indicating that the study was extended to include ten more patients), Ex. 58 (1997 study termination report showing that 21 patients completed the study and one patient dropped out).

As to social anxiety disorder, Relators argue that Luvox was categorized in 1999 as effective for the treatment of social anxiety disorder based on one study by an investigator funded by SPI, that SPI monitored and directed the investigator's progress, that SPI reviewed and revised the final manuscript, and that the results of the study were not accurately reported. *Id.*; *see* Dkt. 428, Ex. 99 (marked up copy of manuscript). Relators contend that there were only 68 patients and 19 discontinued treatment, but DrugDex does not show the discontinuations. *Id.; see* Dkt. 428, Ex. 68 at THA 000375 (reporting the results but not specifying the actual number of patients that discontinued treatment); Dkt. 428, Ex. 106 (letter from SPI to Stein indicating that as of October 10, 1996, there were 68 randomized patients "with 19 discontinued"). The evidence cited regarding 68 patients with 19 discontinuations is a letter from SPI to the lead investigator, Stein, in 1996 regarding "LUVOX in Social Phobia, Solvay Pharmaceuticals' Protocol # S1144001." *See* Dkt. 428, Ex. 106. The letter is about "patient enrollment," and it is not clear what the letter's author meant by "discontinued." *See* Dkt. 428, Ex. 106. By November 24, 1997, a study report from the same study protocol shows that there were a total of 92 patients enrolled with 86 evaluable. *See* Dkt. 428, Ex. 98. It explains that there were a "total of 105 patients . . . enrolled in the single-blind, placebo phase of the study with 92 patients being randomized. However, a total of 90 patients (86%) out of 105 received double-blind medication. Sixty-three of the randomized patients (68%) completed the study." *Id.* at 32. The Stein study on social phobia cited by DrugDex was published in 1999, and, according to the published article, there were 91 patients who started the study with six who did not return for at least one subsequent assessment. *See* Dkt. 459, Ex. 6 (Stein et al., Fluvoxamine Treatment of Social Phobia (Social Anxiety Disorder): A Double-Blind, Placebo-Controlled Study, 156 Am. J. of Psychiatry at 756 (May 1999)). The publication clearly notes that 25% of Luvox-

treated and 9.1% of placebo-treated patients discontinued the study due to adverse events. *Id.* at 758. The DrugDex entry also provides this discontinuation data. *See* Dkt. 428, Ex. 68 at THS 000375 ("Treatment was withdrawn due to adverse effects in 25% and 9.1% of patients treated with fluvoxamine and placebo, respectively."). It is unclear how the numbers in the 1996 letter relate to the numbers that are listed in the final study and DrugDex publication. Regardless, Relators fail to link the 1996 letter to a misrepresentation in the published study results or indicate how this could have led to false claims.

Relators also contend that SPI monitored and directed the investigator's progress and reviewed and revised the final manuscript for this 1999 social anxiety disorder study. *See* Dkt. 428. The evidence that SPI "directed" progress and revised the final manuscript is not probative. Relators provide two study reports with handwritten edits that are mostly nonsubstantive. Dkt. 428, Exs. 99, 109. They are both dated February 2, 2000, which is *after* the date the social anxiety study was published in the *American Journal of Psychiatry*. *See* Dkt. 428, Exs. 99, 109. The other evidence cited is (1) an August 13, 1996 Monthly Administrative Report that summarizes the status of the study; and (2) a May 29, 1997 document providing analysis results from the study. *See* Dkt. 428, Exs. 104, 105. Since this was an SPI-funded a study, a fact clearly noted on the face of the article publishing the results, it makes sense that SPI would be monitoring the study. Keeping track of the study and "directing" the study are not synonymous, and nothing in the cited exhibits would lead a reasonable finder of fact to conclude that SPI was directing the outcome of the study.

By 2000, DrugDex added another study to support the use of Luvox in social anxiety disorder, but Relators point out that the lead investigator in that study had received honorarium funds from SPI for speaking twice in 1997. *Id.* at 30 (citing Exs. 110–12). Relators did not provide the

published study upon which DrugDex relied, but it is clear from the DrugDex listing that there was more than one investigator listed. *See* Dkt. 428, Ex. 69 at THA 000626 (citing "DeVane et al, 1999"). The fact that one investigator in the study received funds from SPI for speaking two years before the study was published is not probative of whether SPI defrauded DrugDex into listing the study.

This evidence of alleged manipulation of study results is not sufficient to create an issue of material fact to survive summary judgment.

C. SPI's Alleged Use of Supplements to Subvert the Literature

Relators assert that SPI used studies published in non-peer-reviewed supplements to journals that were paid for by SPI to "subvert the literature" and ensure inclusion of sub-par studies in DrugDex. Dkt. 428 at 17, 30; *see* Dkt. 428, Ex. 8 at 155 (noting that the *Journal of Clinical Psychiatry* had such supplements). Relators contend that "DrugDex editors showed no understanding of how Solvay was manipulating them." Dkt. 428 at 20. Relators contend that these supplements were "bought and paid for advertisements parading as scientific literature." *Id.* at 31. Relators specifically complain about supplements supporting off-label uses of Luvox and Aceon. *Id.* at 18–19.

Relators provide the transcript of JR to support this aspect of their claim. JR was a product manager for Luvox. Dkt. 428, Ex. 8 at 254. He testified that drug companies would pay for supplements in journals, that the supplements were not peer reviewed, and that there was a practice whereby a third-party publisher or vendor would have staff people draft the original article. *Id.* at 155–56. JR noted that one copy of such supplements would be distributed to the SPI sales force for educational purposes only. *Id.* at 157. It appears that DrugDex would at times use these

supplements for off-label use listings, but the only SPI supplements relating to the Drugs at Issue that Relators link to DrugDex are two 1996 studies indicating that Aceon was "possibly effective" for treating secondary stroke due to results contained within a non-peer-reviewed supplement. Dkt. 428 at 20. SPI points out that the two 1996 supplements relied upon by DrugDex were published three years before SPI even acquired the license for Aceon. Dkt. 458 at 11 n.12. The mere facts that SPI paid for supplements at some point and that DrugDex would at times rely on the supplements has no bearing on this case without any evidence that DrugDex relied on SPI-funded supplements to support uses of the Drugs at Issue during the relevant timeframe.

D. Ghostwriting

Relators additionally contend that as part of SPI's publication strategy it commissioned smaller "investigator initiated" studies and then found "thought leaders" willing to lend their names to articles actually written by the writers who worked for SPI, known as ghostwriters. Dkt. 428 at 16. As evidence they cite to the deposition of Eric Hollander. *Id.* Hollander testified that he has "published articles where [he has] worked with medical writers who have been paid by a pharmaceutical company." *Id.* He noted, however, that in those instances he "contributed to the drafting of the manuscript." Dkt. 428, Ex. 35 at 234–35. When asked if he had any memory of working with medical writers for SPI regarding a journal article relating to obsessive-compulsive disorder, Hollander testified that he had "a memory of working in a sort [of] iterative fashion with a medical writer who was working for Solvay, and in that case, I did contribute to the thoughts and the writing of the manuscript." *Id.* at 235. He stated that it was a "back-and-forth process." *Id.* He later clarified that he did not recall working with any specific medical writers at SPI or have "any specific recall as it relates" to the specific article on obsessive-compulsive disorder. *Id.* at 237–38.

This testimony is not an admission that Hollander merely "lent his name" to an article wholly written by SPI's medical writers. Moreover, even if it were, Relators do not link Hollander's allegedly ghost-written article to any DrugDex entries. While the court understands Relators' theory that SPI had a strategy to publish articles on small studies with positive outcomes and even had its own staff members write the articles and that these non-authoritative studies ended up supporting off-label use in DrugDex and other compendia, at this stage Relators must have evidence specifically linking SPI's conduct to DrugDex entries relating to off-label use.[9] Innuendo related to small articles that may have been partially ghost-written but did not even end up in DrugDex is not sufficient.

E. DrugDex and SPI Communications

Relators note that neither DrugDex nor SPI admit to communicating with each other. Dkt. 428 at 35. However, they point to testimony that DrugDex admits to performing literature searches at times at the request of pharmaceutical companies to evaluate off-label indications. Relators urge the court to view this as a scintilla of evidence that DrugDex and SPI communicated with each other. *Id.* The court declines to make such an inference, which it finds is unreasonable. Relators had substantial time to conduct discovery and obtain proof that SPI and DrugDex communicated and that SPI somehow influenced DrugDex to include supportive listings for off-label uses of SPI drugs. There is no evidence in the record that is sufficient, even if taken together and viewed in the light most favorable to Relators, to allow a reasonable finder of fact to conclude that

[9] Relators attempt to convince the court that a jury must consider the DrugDex issue because whether a listing in DrugDex is "supportive" of a use is a question of fact. *See* Dkt. 428 at 32–33. However, since Relators have not provided any evidence sufficiently linking SPI's conduct to any of the *listings* in DrugDex, whether the listings support the use or not is inconsequential.

SPI colluded with DrugDex or defrauded it so that DrugDex would include supportive listings of the Drugs at Issue. Without evidence, there is no question of material fact.

IV. CONCLUSION

SPI's motion for summary judgment on Relators' theory that SPI defrauded or colluded with DrugDex to gain favorable listings in DrugDex is GRANTED. All claims based on this theory are DISMISSED WITH PREJUDICE.

Signed at Houston, Texas on December 14, 2015.

Gray H. Miller
United States District Judge