UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

UNITED STATES OF AMERICA	§	
ex rel. JOHN KING and	§	
TAMMY DRUMMOND, *et al.*,	§	
	§	
*Plaintiff*s,	§	
	§	
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. ("SPI").[1] (Dkt. 358); and a motion to reconsider a motion to file a surreply filed by relators John King and Tammy Drummond ("Relators") (Dkt. 376). After considering the motions, related documents in the record, and the applicable law, the court is of the opinion that the motion for partial summary judgment (Dkt. 358) should be GRANTED IN PART AND DENIED IN PART, and the motion to reconsider (Dkt. 376) should be DENIED, but the alternative request to supplement the record contained within that motion should be GRANTED.

I. BACKGROUND

This is a False Claims Act and retaliation case in which Relators allege that SPI caused false claims to be made through various government programs, including Medicaid, for reimbursement for prescriptions of three drugs: AndroGel, Aceon, and Luvox. The current motions involve alleged false claims relating to SPI's or a related entity's marketing of AndroGel. Relators were employed

[1] Solvay Pharmaceuticals, Inc. is now known as AbbVie Products, LLC. Dkt. 359.

by SPI or a related entity as District Sales Managers. Dkt. 154. King allegedly worked on marketing materials for AndroGel while working for SPI or a related entity, voiced his dissatisfaction with SPI's marketing practices, and was suspended in April 2002. *Id.* Drummond allegedly questioned certain marketing tactics of SPI and raised questions about King's termination. *Id.* Her employment was terminated in September 2002. *Id.* Relators initially filed suit, under seal, on June 10, 2003, asserting claims on behalf of the United States, ten states, and the District of Columbia. Dkt. 1. The complaint has been amended five times, and the current version contains claims on behalf of the United States, 28 states or municipalities, and the District of Columbia. *See, e.g.*, Dkts. 54, 111, 114, 154. The second amended complaint was unsealed on December 7, 2009, and summons was served to SPI on January 12, 2010. Dkts. 53, 56.

SPI now moves for summary judgment on Relators' federal and state False Claims Act claims with regard to AndroGel, arguing that Relators' claims related to the marketing of AndroGel were disclosed to the public prior to the lawsuit and that the public disclosure bars contained in the federal and state False Claims Act statutes prohibit the claims. Dkt. 359. Specifically, SPI points out that an article in the *New Yorker* that was published in 2002 "reported at length allegations concerning AndroGel, SPI, off-label marketing of AndroGel for a wide variety of conditions, and payments to thought leaders and prescribing physicians." *Id.* SPI also provides various newspaper and magazine articles dating from 2000 that discuss AndroGel.

Relators argue that the public disclosure bar does not preclude their AndroGel related claims because (1) the majority of the news articles cited by SPI are the result of SPI's own press releases; (2) the articles do not highlight SPI's off-label promotion to physicians, which is at the core of the alleged fraud; (3) even if the articles could be considered public disclosures, Relators may still

pursue their claims because they are the original sources and they satisfied all pre-filing disclosure requirements. Dkt. 361.

II. MOTION TO RECONSIDER

On January 9, 2015, Relators filed a response to a motion SPI had filed requesting to extend the page limit for its reply to Relators' response to SPI's motion for summary judgment. Dkt. 369. In the response to the motion to extend the page limit, Relators stated that they were not opposed to the court extending SPI's page limit on the reply *if* the court would allow Relators to file a surreply. *Id.* The only justification given for the need to file a surreply was that the reply would be lengthy (thirteen pages). *See id.* The court did not deem this sufficient reason for a surreply and denied the request. Dkt. 371. On January 18, 2015, Relators filed a motion to reconsider the denial of the request to file a surreply, or, in the alternative, motion to supplement the summary judgment record. Dkt. 376. In this motion, Relators actually provide valid reasons for needing to file a surreply or at least supplement the record. *See id.* SPI argues that Relators have failed to provide an extraordinary circumstances justifying reconsideration or show that the court's decision was clearly erroneous or would work a manifest injustice. Dkt. 381. SPI also points to various evidentiary issues with the documents Relators wish to provide. *See id.*

The Federal Rules of Civil Procedure do not recognize a motion for reconsideration. *Edwards v. City of Hous.*, 78 F.3d 983, 995 (5th Cir. 1996). However, motions that challenge a prior judgment on the merits are treated as either a Rule 59(e) or Rule 60(b) motion. *Id.* "If the motion is served within [28] days of the rendition of judgment, the motion falls under Rule 59(e); if it is served after that time, it falls under Rule 60(b)." *Ford Motor Credit Co. v. Bright*, 34 F.3d 322, 324 (5th Cir. 1994). Here, the motion was filed within 28 days, so the court considers it pursuant to Rule

59(e). A "motion to alter or amend the judgment under Rule 59(e) 'must clearly establish either a manifest error of law or fact or must present newly discovered evidence' and "cannot be used to raise arguments which could, and should, have been made before the judgment issued.'" *Rosenzweig v. Azurix Corp.*, 332 F.3d 854, 864 (5th Cir. 2003) (quoting *Simon v. United States*, 891 F.2d 1154, 1159 (5th Cir. 1990)).

Relators have failed to meet their burden with respect to the court reconsidering its order denying Relators' motion to file a surreply, as there was no manifest error of law in the court's decision not to allow a surreply, and Relators have pointed to no new newly discovered evidence. However, the court will consider the supplemental materials as a supplement to the summary judgment record, to the extent the evidence is valid. Relators' motion to reconsider is DENIED, but the alternative request to supplement the summary judgment record is GRANTED.

III. Legal Standards

A. Motion for Summary Judgment

Summary judgment is proper if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); *see also Carrizales v. State Farm Lloyds*, 518 F.3d 343, 345 (5th Cir. 2008). The mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; there must be an absence of any genuine issue of material fact. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247–48, 106 S. Ct. 2505 (1986). An issue is "material" if its resolution could affect the outcome of the action. *Burrell v. Dr. Pepper/Seven Up Bottling Grp., Inc.*, 482 F.3d 408, 411 (5th Cir. 2007). "[A]nd 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 informing the court of all evidence demonstrating the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323, 106 S. Ct. 2548 (1986). Only when the moving party has discharged this initial burden does the burden shift to the non-moving party to demonstrate that there is a genuine issue of material fact. *Id.* at 322. If the moving party fails to meet this burden, then it is not entitled to a summary judgment, and no defense to the motion is required. *Id* . "For any matter on which the non-movant would bear the burden of proof at trial . . . , the movant may merely point to the absence of evidence and thereby shift to the non-movant the burden of demonstrating by competent summary judgment proof that there is an issue of material fact warranting trial." *Transamerica Ins. Co. v. Avenell* , 66 F.3d 715, 718–19 (5th Cir. 1995); *see also Celotex*, 477 U.S. at 323–25. To prevent summary judgment, "the non-moving party must come forward with 'specific facts showing that there is a genuine issue for trial.'" *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587, 106 S. Ct. 1348 (1986) (quoting Fed. R. Civ. P. 56(e)).

When considering a motion for summary judgment, 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 Dallas, Tex.*, 529 F.3d 519, 524 (5th Cir. 2008). The court must review all of the evidence in the record, but make no credibility determinations or weigh any evidence; disregard all evidence favorable to the moving party that the jury is not required to believe; and give credence to the evidence favoring the non-moving party as well as to the evidence supporting the moving party that is uncontradicted and unimpeached. *Moore v. Willis Ind. Sch.*

Dist., 233 F.3d 871, 874 (5th Cir. 2000). However, the non-movant cannot avoid summary judgment simply by presenting "conclusory allegations and denials, speculation, improbable inferences, unsubstantiated assertions, and legalistic argumentation." *TIG Ins. Co. v. Sedgwick James of Wash.*, 276 F.3d 754, 759 (5th Cir. 2002); *Little v. Liquid Air Corp.*, 37 F.3d 1069, 1075 (5th Cir. 1994) (en banc). By the same token, the moving party will not meet its burden of proof based on conclusory "bald assertions of ultimate facts." *Gossett v. Du-Ra-Kel Corp.*, 569 F.2d 869, 872 (5th Cir. 1978); *see also Galindo v. Precision Am. Corp.*, 754 F.2d 1212, 1221 (5th Cir. 1985).

B. False Claims Act Public Disclosure Bar

1. Federal False Claims Act

Under the applicable version of the federal False Claims Act, courts cannot exercise jurisdiction "over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, or in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information." 31 U.S.C. § 3730(e)(4)(A) (2006) (amended 2010) (previous text available in amendment notes).[2] This jurisdictional requirement may be distilled into "a three-part test, asking 1) whether there has been a 'public disclosure' of allegations or transactions, 2) whether the qui tam action is 'based upon' such publicly disclosed allegations, and 3) if so, whether the

[2] The statute was amended in 2010, but the U.S. Supreme Court has held that the amendment is not retroactive. *Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 283 n.1, 130 S. Ct. 1396 (2010). Under the current version, a court must "dismiss an action or claim . . . "if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed – . . . from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information." 31 U.S.C.A. § 3730(e)(4)(A).

relator is the 'original source' of the information." *Fed. Recovery Servs., Inc. v. United States*, 72 F.3d 447, 450 (5th Cir. 1995). The "jurisdictional nature of the original-source requirement is clear *ex visceribus verborum*" and "speaks to the power of a particular court" and the "substantive rights of the parties." *Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 468, 127 S. Ct. 1397 (2007) (citations and quotations omitted).

A disclosure is a "public disclosure" if it "alerted the government to the industry-wide nature of the fraud and enabled the government to readily identify wrongdoers through an investigation." *United States ex rel. Jamison v. McKesson Corp.*, 649 F.3d 322, 329 (5th Cir. 2011) (quoting *In re Natural Gas Royalties*, 562 F.3d 1032, 1039 (10th Cir. 2009)). The disclosures must provide enough specific details to "'set the government on the trail of the fraud' and ensure that the government will not 'need to comb through myriad transactions performed by various types of entities in search of potential fraud.'" *Id.* (quoting *In re Natural Gas Royalties*, 562 F.3d at 1042–43). Moreover, it must disclose both "the true state of the facts" and that "the defendants represented the facts to be something other than what they were." *United States ex rel. Reagan v. E. Tex. Med. Ctr. Reg'l Healthcare Sys.*, 384 F.3d 168, 174 (5th Cir. 2004) (citing *United States ex rel. Minn. Ass'n of Nurse Anesthetists v. Allina Health Sys. Corp.*, 276 F.3d 1032, 1048–49 (8th Cir. 2002)).

A qui tam action cannot be "based upon" publicly disclosed allegations. Courts look to the "original complaint to define the scope of [the relator's] action and to determine whether it was based on public disclosures of allegations or transactions." *Jamison*, 649 F.3d at 328 . This is because an amended complaint "cannot 'be used to create jurisdiction retroactively where it did not

previously exist.'"[3] *Id.* (quoting *Aetna Cas. & Sur. Co. v. Hillman*, 796 F.2d 770, 775 (5th Cir. 1986)). The "public disclosures need not name particular defendants so long as they 'alerted the government to the industry-wide nature of the fraud and enabled the government to readily identify wrongdoers through an investigation.'" *Id.* at 329 (quoting *In re Natural Gas Royalties*, 562 F.3d 1032, 1039 (10th Cir. 2009)).

If a court finds that the qui tam action was based upon publicly disclosed allegations, a court may still exercise jurisdiction if the relator is an "original source" of the information. An "original source" is "an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information." 31 U.S.C. § 3730(E)(4)(B) (2006) (amended 2010) (previous text available in amendment notes). The "information on which the allegations are based" component of the definition of "original source" refers to the relator's allegations, not the publicly disclosed allegations. *Rockwell Int'l Corp.*, 549 U.S. at 472–73. The term "'allegations' is not limited to the original complaint. It includes (at a minimum) the allegations in the original complaint *as amended*."[4] *Id.* at 473. The relator's "direct and independent

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[3] An amendment can, however, cause a court to lose jurisdiction of a False Claims Act claim. *See Jamison*, 649 F.3d at 328 (explaining *Rockwell*'s holding). Relators insist that considering the original complaint when analyzing whether the allegations are based on the public disclosure "ignores Supreme Court precedent and numerous authorities to the contrary." Dkt. 376-1. However, the Supreme Court precedent cited, *Rockwell*, was considering only the "original source" requirement, not whether the allegations were based upon a public disclosure. *See generally Rockwell*, 549 U.S. 457 (noting that it granted *certiorari* to consider whether the respondent was an "original source").

[4] If it were limited to the original complaint, a relator could plead a trivial theory for which he or she had some knowledge but then amend to include a different fraudulent scheme that was already in the public domain. *Rockwell Int'l Corp.*, 549 U.S. at 473. "[N]ew allegations regarding a fundamentally different fraudulent scheme require reevaluation of the court's jurisdiction." *Id.*

knowledge" must be "derived from the source without interruption or gained by the relator's own efforts rather than learned second-hand through the efforts of others" and must not be "derived from the public disclosure." *Reagan*, 384 F.3d at 177. The relator must also "'demonstrate that he or she has "voluntarily provided the information to the Government before filing" his or her qui tam action.'" *Id.* (quoting *United States ex rel. Laird v. Lockheed Martin Eng'g & Sci. Servs., Co.*, 336 F.3d 346, 352 (5th Cir. 2004) (quoting 31 U.S.C. § 3730(e)(4)(B))). Disclosure "to the United States Attorney, FBI, other suitable law enforcement office, or the agency or official responsible for the particular claim in question" qualifies as providing the information "to the Government." *Id.* at 175.

2. State False Claims Acts

SPI asserts that its motion applies equally to Relators' allegations under the state False Claims Act statutes because these statutes all contain a parallel public disclosure bar provision. Dkt. 359 at 5 n.4. Relators then cite to the allegedly parallel provisions in the False Claims Acts of California, Texas, and Virginia. *Id.* (citing Cal. Gov't Code § 12652(d)(3); Tex. Hum. Res. Code Ann. § 36.113(b); and Va. Code Ann. § 8.01-216.8). SPI does not provide statutory citations for any of the other states.

The California provision, as it existed at the time, indicated that a court would not have jurisdiction if an action was "based upon the public disclosure of allegations or transactions . . . by the news media, unless . . . the person bringing the action is the original source of the information." Cal. Gov't Code § 12652(d)(3) (amended 2012) (prior text in current statute notes). It defined "original source" as "an individual who has direct and independent knowledge of the information on which the allegations are based, who voluntarily provided the information to the state or political subdivision before filing an action based on that information, and whose information provided the

basis or catalyst for the investigation, hearing, audit, or report that led to the public disclosure . . . ." *Id.* The statute was amended in 2012, but there is no indication that the amendment was meant to apply retroactively. For the version of the statute at issue, California courts look to cases interpreting the federal False Claims Act for guidance in interpreting California's statute because it is patterned on the federal statutory scheme. *State ex rel. Grayson v. Pac. Bell Tel. Co.*, 48 Cal. Rptr. 3d 427, 430 n.3 (Cal App. 2006). Notwithstanding the fact that the definition of "original source" in the California statute states that an original source's information must have "led to the public disclosure," the Ninth Circuit held that there was no requirement that the individual informed the government prior to the "public disclosure" to qualify as an "original source." *United States v. Johnson Cntls., Inc.*, 457 F.3d 1009, 1022 (9th Cir. 2006). This court thus applies the California statute, as it existed during the relevant time period, in the same manner it applies the federal statute.

The Texas statute, as in existed at the relevant time, indicated that a person could not bring "an action . . . that is based on the public disclosure of allegations or transactions . . . [in] the news media, unless the person bringing the action is an original source of the information." An Act Relating to Unlawful Acts Against and Criminal Offenses Involving the Medicaid Program, ch. 572, sec. 4, 2013 Tex. Sess. Law Serv. Ch. 572 (S.B. 746).[5] "Original source" was somebody who had "direct and independent knowledge of the information on which the allegations are based and ha[d] voluntarily provided the information to the state before filing an action under this subchapter that is based on the information." *Id.* The Texas legislature expressly indicated that the changes made to the statute in 2013 were not retroactive. *Id.* This statute is substantially similar to the applicable

[5] The statute was amended on June 14, 2013. The court cites the redlined version of the bill, which includes the stricken language of the prior version of the statute.

version of the federal statute, with the exception of the information needing to be disclosed to the state rather than federal government. The court will thus apply the Texas statute in the same manner it applies the federal statute.

The Virginia statute, as it existed at the time, indicated that a court would not have jurisdiction over an action "based on the public disclosure of allegations or transactions . . . [in] the news media, unless . . . the person bringing the action is an original source of the information." Va. Code Ann. § 8.01-216.8 (amended 2011) (prior text in current statute notes). An "original source" is "an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Commonwealth before filing an action under this article that is based on the information." *Id.* Thus the Virginia statute, like the Texas statute, is substantially similar to the federal statute and will be applied in the same manner.

IV. LEGAL ANALYSIS

The court will first consider whether the public disclosure bar in the relevant version of the federal False Claims Act prohibits it from exercising jurisdiction over the federal False Claims Act claims relating to AndroGel. Then, it will consider SPI's motion for summary judgment with regard to the state False Claims Act statutes.

A. Was There a Public Disclosure?

According to SPI, the news media disclosed allegations that AndroGel was being promoted improperly multiple times before Relators filed suit in June 2003. Dkt. 359. SPI cites to articles that discuss AndroGel in the *Baltimore Sun*, *CBS HealthWatch*, *American Medical News*, *Newsday*, *Washington Post*, *Star-Ledger*, *Biotech Business*, *Denver Post*, *DG News*, *Los Angeles Times*,

Philadelphia Inquirer, *American Medical News*, and the *New Yorker*. *Id.* Relators contend that these articles cannot be considered public disclosures because (1) they are, for the most part, a result of a pre-launch press release campaign by SPI; and (2) the one article that was not the result of this campaign, the *New Yorker* article, does not contain information about the core of SPI's alleged off-label marketing fraud—that SPI's sales force promoted AndroGel off-label to prescribing physicians. Dkt. 361. Additionally, Relators contend that none of the articles discuss the kickbacks alleged in Relators' fifth amended complaint. *Id.*

The court must first consider whether these publications were sufficient to set the government on the trail of the fraud. The *New Yorker* article, entitled "Hormones for Men: Is Male Menopause a Question of Medicine or of Marketing?," discusses advertisements for male menopause that were paid for by Unimed, "a division of the Belgian conglomerate Solvay." Dkt. 359, Ex. 1. It notes that Unimed makes AndroGel. *Id.* The article discusses the possibility of the pharmaceutical industry "inventing" diseases, such as andropause or male menopause. *Id.* It highlights a doctor that took out an advertisement about testosterone deficiency and urged men who were experiencing a low sex drive or low energy to have their testosterone levels checked at his clinic. The advertisement and the tests were allegedly underwritten by a Unimed educational grant. *Id.* Once at this physician's clinic, men completed a questionnaire, again provided by Unimed, that has ten questions about things such as being sad or grumpy, having a decreased sex drive or decreased enjoyment in life, and having a decreased libido. *Id.* The physician prescribed AndroGel to treat men with these symptoms of "andropause" even when their total testosterone levels were normal.[6] *Id.*

[6] This physician admitted to using AndroGel preventatively "for middle-aged men whose testosterone levels were in the lower quarter of the normal range." *Id.*

The article points out that a physician may prescribe a drug for any clinical condition once it is approved by the FDA, but that the "FDA prohibits drug companies from advertising 'off label' uses," and "andropause" was not an approved use. *Id.* It also discusses an andropause conference convened by the Endocrine Society that was solely financed by a Unimed/Solvay grant. *Id.* Nine out of the thirteen panelists in the final group had "significant financial ties to Unimed/Solvay. *Id.* The panel ultimately recommended that patients over fifty should be screened with a questionnaire about andropause and, if they had symptoms and tests confirmed testosterone below a certain level, they would (with some caveats) benefit from testosterone treatment. *Id.* These recommendations disclosed the educational grant but not the financial ties that the majority of the panelists had to Unimed/Solvay. *Id.* The article then discusses scientific research indicating that testosterone levels actually vary widely among men, even very young men, and that the commercial tests to measure testosterone levels are often unreliable. *Id.* It also points out that there is "a lot of uncertainty about the effects of age-related lowering of testosterone," questions about testosterone's effectiveness for preventing bone fractures, and points to many "worrisome" side effects of testosterone treatment. *Id.*

This article alone, without considering the others, is enough to put the FDA on the trail of fraud.[7] The court will consider it a public disclosure.

[7] The court discusses only the *New Yorker* article in this order because the *New Yorker* article essentially covers all of the information contained in the other articles. *Compare* Dkt. 359 Ex. 1, *with* Dkt. 359, Exs. 2–15. The court is not persuaded by Relators' argument that the court cannot consider the other articles because they were part of SPI's public relations campaign. *See* Dkt. 361 (asserting this argument). There is no question that these articles were in the "news media," which is what the statute requires; who provided them to the news media is irrelevant.

B. Are the Allegations "Based Upon" the Public Disclosure?

The court must next compare the public disclosure to the allegations in the original complaint to determine if the allegations are based on the public disclosure. Relators argue that their allegations cannot be based on the *New Yorker* article or any of the other articles because these articles do not discuss kickbacks and off-label marketing. Dkt. 361. Relators contend, in fact, that none of the articles gets close to implying or expressing the idea that the behavior highlighted results in fraud on the Government. Dkt. 376-1.

The original complaint discusses "rampant fraud perpetrated against Medicaid and other federal programs, through aggressive off-label marketing and kickback schemes." Dkt. 1. It alleges that SPI "deliberately misinformed doctors about the improved indications of its drugs, trained doctors to misstate diagnoses so that payment would be approved for unapproved uses, and gave kickbacks to doctors in exchange for prescribing various drugs." *Id.* Paragraph 8 of the original complaint describes Relators' original allegations with regard to AndroGel. *Id.* It alleges that AndroGel was approved for the treatment of hypogonadism, but that Solvay marketed it for the treatment of depression and "repeatedly marketed Androgel to doctors by making the extraordinary claim that Androgel should be prescribed for males who had *normal testosterone levels.*" *Id.* Paragraph 9 indicates that SPI bribed physicians to use its drugs with speaker programs, honoraria, Dine-N-Dashes, Lunch-N-Learns, and other programs, to "lock in patient referrals." *Id.*

The *New Yorker* article indicates that Unimed/Solvay was promoting AndroGel, at least indirectly, for the treatment of andropause, which the article highlights was not an approved use. The physician highlighted in the article states that he prescribed the drug even to patients without low testosterone. And, the article hints at kickbacks by noting that the physicians on the Endocrine

Society has "financial ties" to Unimed/Solvay. While this does not perfectly mirror everything alleged in the original complaint, and it does not directly state that the highlighted activities could result in false claims, there are certainly enough similarities for the court to conclude that the allegations are based on the public disclosure. It is not necessary for the disclosure to connect all the dots or reach legal conclusions, it just has to set the government on the trail of fraud. Being on the trail of fraud is not the same as highlighting exactly how the alleged wrongdoing resulted in defrauding the government.

C. Were Relators the Original Source?

Relators argue that even if there were a public disclosure, they may still pursue their AndroGel related claims because they are original sources. Dkt. 361. The assert that they had direct and independent knowledge of AndroGel's marketing and fulfilled the pre-filing disclosure requirements. *Id.*

SPI argues, however, that Relators failed to fulfill their pre-filing disclosure requirements and that the original source exception therefore cannot apply. Dkt. 359. They point out that King and Drummond both testified during depositions that they were unaware of or could not remember making any written disclosure to any governmental entity prior to filing the lawsuit. *Id.* SPI concedes that Relators executed and submitted the mandatory disclosure statement required at the time they filed suit, but argues that this disclosure does not fulfill the pre-filing voluntary disclosure requirement. *Id.* Finally, SPI asserts that Relators cannot satisfy the direct and independent knowledge prong because the original complaint does not contain any details about the promotion of AndroGel for the wide-ranging off-label uses detailed in later complaints, or the kickbacks related to AndroGel promotion discussed in later complaints, yet Relators no longer worked at SPI after

filing the original complaint and thus had no way of supplementing their direct and independent knowledge to flesh out these allegations. *Id.* SPI contends that Relators instead based subsequent allegations on documents produced in response to civil investigations in Texas and Virginia long after the suit was filed. *Id.* SPI argues that Relators "cannot claim that they are 'original source[s] if they base their claims on "information that did not even exist at the time of their termination."'" *Id.* (quoting *United States ex rel. Fitzgerald v. Novation, LLC*, No. 3:03-CV-1589-N, 2008 WL 9334966, at *4 (N.D. Tex. Sept. 17, 2008)).

Relators assert that they both had access to company strategy, messaging, and sales techniques as well as a number of documents supporting their claims against SPI as district managers. Dkt. 361 at 16. They supervised and enforced SPI's drug promotion policies and were privy to the plans of other managers. *Id.* Relators claim that their independent and direct knowledge is demonstrated by both their deposition testimony and the documents they preserved from their employment at SPI. Relators then cite testimony in which King stated that, during his time at SPI, SPI was "very committed" to andropause and believed you should treat the symptoms regardless of testosterone levels shown in blood work. Dkt. 361, Ex. 8 at 426–27, 531. Drummond also testified that during her time at SPI, her sales representatives advised doctors to treat the symptoms of andropause regardless of test results. Dkt. 361, Ex. 52 at 406. Relators point to various deposition testimony and documents that were in the possession of Relators when they left SPI that support off-label claims related to HIV, Depression, and Erectile Dysfunction, and that relate to the kickback claims in the current version of the complaint. Dkt. 361. As far as SPI's contention that the fifth amended complaint contains allegations relating to events that occurred *after* Relators left SPI and thus about which they could have no independent knowledge, Relators argue that they had "several

boxes full of marketing material when they filed suit," and the fact that they did not rely on these documents until later iterations of the complaint is of no consequence. *Id.* Moreover, they assert that the relator is not required to have knowledge of every element or detail of his or her complaint, only the essential elements of the claim.[8] *Id.*

With regard to disclosing the allegations to the government prior to filing the lawsuit, Relators contend that, notwithstanding their failure to recall events that happened over ten years ago during their depositions, Relators had conversations with FDA representatives prior to filing suit. Dkt. 361 (citing Ex. 3 (King Decl. (Dec. 22, 2014)). However, the evidence to which Relators cite—two declarations and an email—is insufficient to meet their summary judgment burden. First, Relators cite a declaration by King dated December 22, 2014. Dkt. 361, Ex. 3. This declaration does not discuss King having meetings with the FDA. *See id.* Next, Relators cite an email from King to Drummond dated September 22, 2002. Dkt. 361, Ex. 4. This email indicates, construed in a light most favorable to Relators, that King had some type of email from an individual named Michael Cummins in the criminal division of some agency. In the email, King states: "Tammy [Drummond]: Lookie, lookie. Note this boys [sic.] title. Not going to respond today. Want to talk to Nolan first. Criminal Division.....? It fits." *Id.* The email says nothing about actually meeting with the government or disclosing the allegations. At best, it indicates that King was thinking about talking with Cummins about something after he talked to a person named Nolan. Finally, Relators cite the

[8] Relators also contend that they are original sources "if they have 'direct and independent knowledge of the information on which the allegations [*constituting the public disclosure*] are based.'" Dkt. 361 (quoting 31 U.S.C. § 3730(e)(4)(B) (2006) (alteration added by Relators) (emphasis added). This is an incorrect statement of the law, as the U.S. Supreme Court has clarified that the "allegations" referred to in the original source requirement are the relators' allegations, not the allegations in the disclosure. *See Rockwell Int'l Corp.*, 549 U.S. at 472–73.

declaration of their lawyer, Joel M. Androphy, to support their contention that they disclosed the information to the FDA on June 9, 2003. Androphy provides details of a ten-hour meeting in which Drummond and King met with FDA representatives on June 9, 2003, and disclosed information about off-label marketing of Aceon, Luvox, and AndroGel and kickbacks. Dkt. 361, Ex. 1 ¶¶ 4–5. Androphy notes that they used a PowerPoint presentation that was "transmitted to the Government" on July 17, 2003. *Id.* ¶ 6. Adrophy also states that he discussed the case with an assistant U.S. Attorney in Philadelphia "[p]rior to filing suit." *Id.* ¶ 7. The evidence provided by Relators with regard to disclosure prior to suit can be boiled down to (1) King thinking about talking to someone in the "Criminal Division" in September 2002; and (2) Relators and their counsel meeting with the FDA on June 9, 2003. The lawsuit was filed on June 10, 2003. Dkt. 1.

SPI raises various evidentiary issues with the Androphy declaration and the PowerPoint presentation. The court, however, need not address these evidentiary issues because the evidence, regardless, is not sufficient to meet Relators' burden of showing that they voluntarily disclosed the allegations to the government prior to filing suit. This disclosure the day before filing suit cannot be considered the voluntary disclosure that the then-current version of section 3730(e)(4)(B) contemplated. Section 3730(b)(2) *requires* relators to serve a copy of the complaint and a written disclosure of "substantially all material evidence and information the person possesses" on the Government. 31 U.S.C. § 3730(b)(2). Section 3730(e)(4)(B) contemplates a *voluntary* provision of the information. "It is . . . clear from the statute that compliance with the disclosure requirements of § 3730 (b)(2) at the time of filing does not satisfy the pre-filing disclosure requirement of § 3730(e)(4)." *United States ex rel. King v. Hilcrest Health Ctr., Inc.*, 264 F.3d 1271, 1280 (10th Cir. 2001). "'More must be done to qualify as an original source than to file the action. The

government must be voluntarily notified beforehand.'" *Id.* (quoting *United States v. Bank of Farmington*, 166 F.3d 853, 866 (7th Cir. 1999), *overruled on other grounds in Glaser v. Wound Care Consultants, Inc.*, 570 F.3d 907, 910 (7th Cir. 2009)); *see also United States ex rel Beauchamp v. Academi Training Ctr., Inc.*, 933 F. Supp. 2d 825, 846 (E.D. Va. 2013) (finding that disclosures the relators sent to the Government approximately two weeks prior to filing suit, which were accompanied with a note that the relators planned to file suit, were not the voluntary disclosures required for the original source exception to the public disclosure bar to apply); *United States ex rel. Ackley v. Int'l Bus. Machs. Corp.*, 76 F. Supp. 2d 654, 668 (D. Md. 1999) (stating that "the point at which the pre-filing disclosure has to be made is, at a minimum, one sufficiently in advance of the time of filing to permit the Government to commence its analysis of the proposed litigation," determining that "[t]hirty days would seem reasonable in nearly every case," and noting that it is "elementary" that "just a few moments, hours or days before will not do"). Thus, the meeting with the FDA and PowerPoint provided do not fulfill the voluntary disclosure requirement of the original source exception. The other evidence of voluntary disclosure is essentially useless. Relators thus have not met their burden of raising an issue of material fact that they voluntarily disclosed the information to the government as required for the original source exception in the federal False Claims Act to apply. There is no need for the court to reach Relators' contention that they had independent and direct knowledge of the essential elements of the complaints.

D. States

SPI moves for summary judgment on all of the state False Claims Act claims related to AndroGel. However, SPI has met its initial burden with regard to only Texas, Virginia, and California. SPI must point to the absence of evidence for each claim it challenges in order to shift

the burden to Relators, and SPI has only done so with regard to these three states.[9] With regard to California, Texas, and Virginia, Relators contend that they cannot document transmission of pre-filing disclosures for these states (or a number of other states), but that each of these states "conducted robust investigations into the case." Dkt. 361. These states, however, all required a pre-filing disclosure, and Relators must provide an issue of material fact that this disclosure was accomplished *by Relators prior to filing suit* in order to survive summary judgment. They have failed to do so. Accordingly, SPI's motion for summary judgment with regard to Relators' AndroGel-related claims under the Texas, California, and Virginia False Claims Acts is GRANTED. SPI's motion for summary judgment under the False Claims Acts of the other states is DENIED.

[9] The court does not deem SPI's footnote indicating that the "analysis . . . applies equally to Relators' state [False Claims Act ("FCA")] causes of action because each state FCA statute at issue contains a parallel provision to the federal one," and citation to only three of those statutes, as sufficient to shift the burden with regard to the states for which SPI did not provide a statutory citation. While SPI's burden as movant is low, it must at least provide the appropriate legal arguments and citations. It is not the court's burden to find the relevant statutes and determine whether they are indeed parallel to the federal statute.

V. CONCLUSION

Relators' motion to reconsider (Dkt. 376) is DENIED, but the alternative request to supplement the summary judgment record is GRANTED. SPI's motion for summary judgment on Relators' AndroGel related claims due to the public disclosure bar with regard to the federal False Claims Act, and the Texas, Virginia, and California False Claims Acts, is GRANTED. Relators' federal and Texas, Virginia, and California False Claims Act claims related to AndroGel are DISMISSED WITH PREJUDICE. Relator's motion for summary judgment with regard to the False Claims Act of the remaining states is DENIED.

Signed at Houston, Texas on March 3, 2015.

Gray H. Miller
United States District Judge