IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

United States Court of Appeals
Fifth Circuit
FILED
September 12, 2017
Lyle W. Cayce
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No. 16-20259
c/w No. 16-20509

United States of America, State of Illinois, State of California, State of Florida, State of Tennessee, State of Texas, State of Massachusetts, State of Delaware, State of Nevada, State of Louisiana, State of Hawaii, District of Columbia, State of Virginia, State of Georgia, State of Indiana, State of Michigan, State of Montana, State of New Hampshire, State of New Jersey, State of New Mexico, State of New York, State of Oklahoma, State of Rhode Island, State of Wisconsin, ex rel, JOHN KING; TAMMY DRUMMOND,

Plaintiffs - Appellants

v.

SOLVAY PHARMACEUTICALS, INCORPORATED,

Defendant - Appellee

Appeals from the United States District Court
for the Southern District of Texas

Before HIGGINBOTHAM, SMITH, and HAYNES, Circuit Judges.

PER CURIAM:

John King and Tammy Drummond (collectively, "Relators") appeal the district court's grant of summary judgment to Solvay Pharmaceuticals, Inc., on their False Claims Act ("FCA") claims and a subsequent ruling that partly granted court costs to Solvay. For the reasons explained below, we AFFIRM.

I. Background

Relators are both former Solvay sales and marketing employees. They brought this FCA suit against Solvay claiming that Solvay induced false Medicaid claims through a nationwide off-label marketing and kickback scheme to promote three drugs: Luvox, Aceon, and AndroGel. *See* 31 U.S.C. § 3729(a)(1)(A)–(B). They allege that this scheme proximately caused physicians to prescribe these drugs for off-label uses to Medicaid patients, the cost of which was reimbursed by the federal government. Relators also claim they were retaliated against for their internal complaints about Solvay's off-label marketing. The district court granted summary judgment to Solvay on all of Relators' claims.

After final judgment, Solvay sought an award of $961,380.51 in taxable costs against Relators under 28 U.S.C. § 1920. Relators objected to almost all of those costs, claiming that Solvay was entitled to just $5,808.17. The district court awarded Solvay $232,809.92. Relators appealed both the final order granting summary judgment on all of Relators' claims and the order granting taxable costs to Solvay.

II. Standard of Review

"We review an order granting summary judgment *de novo*, applying the same standards as the district court." *Cooley v. Hous. Auth. of City of Slidell*, 747 F.3d 295, 297 (5th Cir. 2014). Summary judgment is appropriate when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). A disputed fact is material if it has the potential to "affect the outcome of the suit under the governing law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). "[W]e may affirm the district court's decision on any grounds supported by the record." *Phillips ex rel. Phillips v. Monroe Cty.*, 311 F.3d 369, 376 (5th Cir. 2002).

"The district court has broad discretion in taxing costs, and we will reverse only upon a clear showing of abuse of discretion." *Brazos Valley Coal. for Life, Inc. v. City of Bryan*, 421 F.3d 314, 327 (5th Cir. 2005) (quoting *Migis v. Pearle Vision*, 135 F.3d 1041, 1049 (5th Cir. 1998)).

III. Discussion

A. FCA Claims

The FCA imposes civil liability and treble damages on any person who, inter alia, "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" to the United States government; or "knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A)–(B); *see also United States ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 267 (5th Cir. 2010). An FCA claim consists of four elements: "(1) whether there was a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that caused the government to pay out money or to forfeit moneys due (i.e., that involved a claim)." *United States ex rel. Longhi v. United States*, 575 F.3d 458, 467 (5th Cir. 2009) (citation omitted).

Relators have developed several theories of FCA liability with varying degrees of connectivity between Solvay's off-label marketing of Luvox, Aceon, and AndroGel and the actual filing of false claims. Those theories are that (1) Solvay marketed the three relevant drugs for off-label uses causing physicians to prescribe them to Medicaid patients for those uses; (2) Solvay lobbied members of state pharmaceutical and therapeutic committees ("P&T committees") to list these three drugs on their preferred drug lists; (3) Solvay used misleading scientific literature to lobby the publisher of drug compendium DRUGDEX Information System ("DrugDex") to include the off-label uses of these drugs in the compendium; and (4) Solvay paid doctors

kickbacks to prescribe these drugs to Medicaid patients in violation of the anti-kickback statute ("AKS"), 42 U.S.C. § 1320a-7b(b)(2)(A).[1] Relators also brought an FCA retaliation claim challenging their terminations.

The district court disposed of all of Relators' claims through a series of partial summary judgment orders. Relators' AndroGel claims were dismissed on summary judgment for lack of jurisdiction under the FCA's public disclosure bar. For the remaining two drugs, Luvox and Aceon, the off-label marketing claims failed to survive summary judgment because Relators' evidence of Medicaid claims was inadmissible and, even if it were admissible, did not sufficiently demonstrate causation. Both the lobbying theories of liability relating to state P&T committees and DrugDex and the retaliation claims also failed to survive summary judgment due to insufficient causation evidence. Finally, the AKS claims did not survive summary judgment because there was insufficient evidence that Solvay intended the kickbacks to induce payments from Medicaid. The summary judgment orders in the district court involved additional issues, but Relators do not challenge the district court's judgment on those issues so we do not consider them.[2]

Because we conclude that Relators failed to produce sufficient evidence to survive summary judgment on any of their briefed claims, we affirm the district court's grant of summary judgment to Solvay.

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[1] "The AKS provides no private right of action; therefore, a private plaintiff may not sue a health care provider under the AKS alone." *United States ex rel. Ruscher v. Omnicare, Inc.*, 663 F. App'x 368, 371 n.2 (5th Cir. 2016) (per curiam) (quoting *United States ex rel. Nunnally v. W. Calcasieu Cameron Hosp.*, 519 F. App'x 890, 893 n.5 (5th Cir. 2013)). We now reiterate these holdings in a precedential, published opinion.

[2] Relators' Fifth Amended Complaint also includes counts under the false claims acts of numerous states. However, because the state false claims issues are not raised at all in the appellate briefing, we deem them waived. *See Williams v. Parker*, 843 F.3d 617, 622 n.14 (5th Cir. 2016) ("Failure to raise an issue on appeal is waiver.").

1. Public Disclosure Bar

The district court first determined that it lacked jurisdiction to consider any of Relators' AndroGel claims because they were subject to the FCA's public disclosure bar. The applicable version of the FCA's public disclosure bar, which has since changed, provides that "[n]o court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions . . . 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) (emphasis added).[3] The statute defines original source as "an individual who [1] has direct and independent knowledge of the information on which the allegations are based and [2] has voluntarily provided the information to the Government before filing an action under this section which is based on the information." *Id.* § 3730(e)(4)(B).

The district court determined that Relators' AndroGel claims were based on publicly disclosed allegations from a magazine article and that Relators' pre-suit disclosure made the day before filing suit could not satisfy the voluntary disclosure requirement of the original source exception. Specifically, the district court concluded that because Relators' pre-suit disclosure satisfied the *mandatory* disclosure requirement under § 3730(b)(2), it could not simultaneously satisfy the *voluntary* disclosure requirement under § 3730(e)(4). Relators appeal only the district court's determination that they are not original sources.

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[3] The section creating the public disclosure bar was amended in 2010, but the Supreme Court has held that the amendment is not retroactive. *Graham Cty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 283 n.1 (2010) (noting that section 10104(j)(2) of the Patient Protection and Affordable Care Act, Pub. L. 111–148, 124 Stat. 119, "replace[d] the prior version of 31 U.S.C. § 3730(e)(4) with new language" but "makes no mention of retroactivity"); *Abbott v. BP Expl. & Prod., Inc.*, 851 F.3d 384, 387 n.2 (5th Cir. 2017) (concluding that the 2010 amendment altered the jurisdictional nature of the public disclosure bar). Accordingly, all citations to this section refer to the applicable 2006 version of the public disclosure bar.

It is well established that the party invoking federal jurisdiction carries the burden of establishing that jurisdiction is proper. *United States ex rel. Jamison v. McKesson Corp.*, 649 F.3d 322, 327 (5th Cir. 2011). Thus, it was Relators' burden to show that they qualified under the original source exception; otherwise, the public disclosure bar "strips" the court of subject matter jurisdiction. *See United States ex rel. Fried v. W. Indep. Sch. Dist.*, 527 F.3d 439, 441–42 (5th Cir. 2008); *see also* § 3730(e)(4)(A) (stating that "[n]o court shall have jurisdiction" if the public disclosure bar applies). However, because "[a] challenge under the FCA jurisdictional bar is necessarily intertwined with the merits," we treat it as a motion for summary judgment. *Jamison*, 649 F.3d at 326 (quoting *United States ex rel. Reagan v. E. Tex. Med. Ctr. Reg'l Healthcare Sys.,* 384 F.3d 168, 173 (5th Cir. 2004)).

Assuming without deciding that a single pre-suit disclosure can satisfy both the pre-suit mandatory and voluntary disclosure requirements, Relators still failed to create a genuine issue of material fact as to whether their pre-suit disclosure to the government disclosed "the information on which the allegations are based." 31 U.S.C. § 3730(e)(4)(B). The Supreme Court has interpreted the phrase "information on which the allegations are based" as referring to the "information underlying the allegations of the relator's action." *Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 470–72 (2007) (abrogating *United States ex rel. Laird v. Lockheed Martin Eng'g & Sci. Servs. Co.*, 336 F.3d 346, 354–55 (5th Cir. 2003) (holding that a relator must have direct and independent knowledge of information on which the allegations in the *public disclosure* are based)). The Court further indicated that such information includes knowledge of conduct suggesting that false claims were made to the government. *See id.* at 475 (concluding that relator's knowledge fell short because he was not employed by the defendant during the relevant time period and thus could not have known about the predicate conduct and subsequent

false statements to the government). Indeed, without knowledge of conduct that—when placed in the context of all of the other relevant information—suggests that false claims were made to the government, Relators could not allege an FCA claim.[4] *See United States ex rel. Spicer v. Westbrook*, 751 F.3d 354, 364–65 (5th Cir. 2014) (stating that "the statute attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the claim for payment" (quoting *Longhi*, 575 F.3d at 467)); *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 188 (5th Cir. 2009) (stating that proof of a false claim against the government is the "*sine qua non*" of liability under the FCA). Accordingly, the Fourth Circuit has affirmed a finding that a relator was not entitled to original source status where, inter alia, his pre-suit disclosure never connected information about the alleged fraudulent conduct with the filing of a claim for reimbursement from the government. *United States ex rel. Vuyyuru v. Jadhav*, 555 F.3d 337, 353, 355 (4th Cir. 2009).

Here, Relators failed to present any evidence indicating that their pre-suit disclosure connected the knowledge of Solvay's conduct to false claims made to the government. Relators cite to a declaration of their attorney, Joel Androphy, and a PowerPoint presentation to support the details of their pre-suit disclosure.[5] However, the declaration simply refers to discussions

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[4] Requiring relators to have direct and independent knowledge of information that, when viewed in context, suggests the filing of false claims is also consistent with the FCA's dual goals of "preventing parasitic suits by opportunistic late-comers who add nothing to the exposure of fraud," *Reagan,* 384 F.3d at 174 (quoting *Laird*, 336 F.3d at 351), and "encourag[ing] those who are either *close observers* or *otherwise involved* in the fraudulent activity to come forward," *United States ex rel. Oliver v. Philip Morris USA Inc.*, 826 F.3d 466, 480 (D.C. Cir. 2016) (quoting *United States ex rel. Barth v. Ridgedale Elec., Inc.*, 44 F.3d 699, 703–04 (8th Cir. 1995)); *see also United States ex rel. Lam v. Tenet Healthcare Corp.*, 287 F. App'x 396, 400 (5th Cir. 2008) ("Congress's intent was to encourage qui tam suits brought by insiders, such as employees who come across information of fraud in the course of their employment." (quoting *Laird*, 336 F.3d at 355–56)).

[5] The parties dispute whether any of this evidence should be considered in making the FCA jurisdictional determination. However, we need not decide this issue because we

Relators had with the Food and Drug Administration ("FDA") about the off-label marketing and kickbacks associated with AndroGel, as well as Relators' terminations. But the declaration does not indicate that Relators connected this information with any false claims presented to the government. Moreover, the lack of detail about which off-label uses Solvay marketed or how it paid kickbacks to physicians is an additional defect that makes the declaration insufficient to support the voluntary disclosure necessary for the original source exception. *See Rockwell*, 549 U.S. at 473 (indicating that a relator must satisfy his original source status as to each theory of fraud in the complaint as amended); *Jamison*, 649 F.3d at 332 (holding that a relator was not an original source of the allegations in his complaint because the information on which the allegations were based described the fraud only generally).

Although the PowerPoint presentation provides additional details about the information disclosed to the FDA, the presentation does not suggest that any false claims were submitted to the government. It makes no mention of any FCA provisions, never suggests that the off-label marketing or the remuneration caused prescriptions to be reimbursed by the government, and never suggests any false certifications of compliance with the AKS. Instead, the information disclosed in the PowerPoint presentation suggests only Food, Drug and Cosmetic Act ("FDCA") and AKS violations, not FCA violations. For Relators to satisfy the FCA's voluntary pre-suit disclosure requirement of disclosing information underlying their *FCA action*, their disclosure must—at a minimum—connect direct and independent knowledge of information about Solvay's conduct to false claims submitted to the government, i.e., suggest an

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conclude that, even if all of the evidence is considered, Relators still failed to meet their summary judgment burden.

FCA violation.[6] Even assuming all of the information in the PowerPoint presentation regarding possible FDCA and AKS violations came from Relators' direct and independent knowledge, the presentation still fails to create a genuine issue of material fact as to its disclosure of information on which the FCA allegations are based because it is completely devoid of any indication connecting such information with false claims presented to the government.

Accordingly, because Relators' evidence of the information provided to the government in their voluntary pre-suit disclosure does not suggest any FCA violations, it is insufficient to support a finding that Relators disclosed to the government the information underlying their FCA allegations prior to filing suit. Consequently, Relators have failed to meet their summary judgment burden as to their status as original sources under § 3730(e)(4) of the FCA. Because the FCA public disclosure bar applies, the district court correctly determined that it lacked jurisdiction to consider Relators' AndroGel claims.

2. Alleged Off-Label Marketing to Physicians

The FDCA prohibits a drug from being introduced in interstate commerce unless the FDA approves the drug as safe and effective for each of the uses suggested on its labeling. 21 U.S.C. § 355(a), (d); *see also* 21 C.F.R. § 310.303(a) ("[A] new drug may not be approved for marketing unless it has been shown to be safe and effective for its intended use(s)."). The Medicaid Act empowers states to deny reimbursement for a drug if "the prescribed use is not

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[6] *Cf. United States ex rel. Rigsby v. State Farm Fire & Cas. Co.*, 794 F.3d 457, 462–63, 474 (5th Cir. 2015) (holding that direct and independent knowledge of information by claims adjusters of fraudulent claims adjusting practices connected to claims for government-backed flood insurance in the wake of Hurricane Katrina was sufficient to confer original source status), *aff'd on other grounds sub nom. State Farm Fire & Cas. Co. v. United States ex rel. Rigsby*, 137 S. Ct. 436 (2016); *Oliver*, 826 F.3d at 478 ("[I]n order to have 'direct' knowledge for purposes of the original source exception, a relator must have some first-hand knowledge that would lead him to believe that a fraud had been committed." (collecting cases)).

for a medically accepted indication." 42 U.S.C. § 1396r-8(d)(1)(B)(i).[7] A "medically accepted indication" is "any use for a covered outpatient drug which is approved under the [FDCA] or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described" elsewhere in the statute. 42 U.S.C. § 1396r-8(k)(6). That is to say, states may deny Medicaid reimbursement for drugs prescribed for off-label uses that are not otherwise listed in compendia described in the Medicaid statute.

Because off-label prescriptions may be ineligible for Medicaid reimbursement, submitting such claims for Medicaid reimbursement may result in FCA liability. *See United States ex rel. Booker v. Pfizer, Inc.*, 847 F.3d 52, 58 & n.7 (1st Cir. 2017). Accordingly, when, as here, an off-label marketing scheme is alleged to have violated the FCA, plaintiffs' summary judgment burden is to come forward with evidence sufficient to create a genuine issue of material fact that the off-label marketing scheme caused physicians to make off-label prescriptions that were submitted for Medicaid reimbursement.

Complicating matters is the fact that the FDA does not restrict physicians from prescribing an otherwise FDA-approved drug for an off-label use. *See* 21 U.S.C. § 396 ("Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship."). One commentator has observed that "[o]ff-label prescription of drugs is common,

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[7] The First Circuit has noted that "whether state Medicaid programs actually have the discretion to reimburse for off-label uses of a drug under the Medicaid statute 'is up for debate.'" *United States ex rel. Booker v. Pfizer, Inc.*, 847 F.3d 52, 58 n.7 (1st Cir. 2017) (quoting *United States ex rel. Banigan v. Organon USA Inc.*, 883 F. Supp.2d 277, 294 (D. Mass. 2012)). If state Medicaid programs do have the discretion to choose between granting or denying reimbursements for off-label prescriptions, Relators claims would fail because they have not presented evidence showing that any states in this case have chosen to deny reimbursements for off-label prescriptions. However, we need not decide this issue because we conclude that Relators' claims easily fail on other grounds.

with as many as forty percent of all prescriptions issued involving off-label use." Stephanie Greene, *False Claims Act Liability for Off-Label Promotion of Pharmaceutical Products*, 110 PENN ST. L. REV. 41, 46 (2005). Indeed, "in many cases, off-label drug prescription may represent the standard of care in the industry." *Id.*

Relators' remaining off-label marketing claims relate to the drugs Luvox and Aceon. Luvox received FDA approval in 1994 for use in treating obsessive compulsive disorder ("OCD"). Relators contend that Solvay marketed Luvox for a broader "spectrum" of disorders that they labeled the "OC Spectrum," a marketing approach the FDA rejected. Aceon was approved to treat hypertension in 1993. Relators assert that Solvay attempted to expand sales of Aceon by claiming that it would also improve arterial health, was particularly good for the kidneys of diabetic hypertensives, and reduced the risk of secondary strokes.

The main issue on appeal is the sufficiency of Realtors' evidence that this alleged off-label marketing caused the filing of false Medicaid reimbursement claims. Relators first argue that the district court ignored circumstantial evidence purportedly showing a nationwide off-label marketing scheme, execution of that scheme, and an impact on prescriptions to Medicaid patients. The expert report claiming to show that off-label marketing actually impacted Medicaid prescriptions, however, shows no such thing. The report concludes that, because economic studies show that pharmaceutical marketing is generally linked to increased pharmaceutical sales and Solvay uses marketing as a means of increasing sales, Solvay's off-label marketing scheme must have caused increased off-label prescriptions reimbursed through Medicaid. But this conclusion is speculative and therefore insufficient to preclude summary judgment. *Simmons v. Willcox*, 911 F.2d 1077, 1082 (5th Cir. 1990) ("[S]peculative allegations . . . are insufficient to create a genuine issue of

material fact precluding summary judgment."). At best, Relators' circumstantial evidence suggests only the potential for a causal link between Solvay's alleged off-label marketing and off-label prescriptions but says nothing about whether the marketing scheme *actually caused* off-label prescriptions to Medicaid patients. Without evidence indicating that off-label marketing actually caused off-label prescriptions to Medicaid patients resulting in false claims to the government, Relators' off-label marketing theory of FCA liability cannot survive summary judgment. *Cf. Grubbs*, 565 F.3d at 192 (holding that allegations of a fraudulent billing scheme were sufficient at the motion to dismiss stage to show that doctors' fraudulent records caused the hospital's billing system to present fraudulent claims where presenting such claims was the regular course of billing for the hospital); *see also Booker*, 847 F.3d at 58 (holding that circumstantial evidence could be used at the summary-judgment stage to prove causation, but "not that such proof could be used to demonstrate the *existence* of false claims.").

The only evidence Relators present that attempts to show the actual effect of the off-label marketing scheme alleged in this case is a set of call notes recorded by Solvay sales representatives about their telephone communications with physicians regarding Luvox and Aceon. Relators identify eight examples of causation, in which they connect a call note to an off-label prescription made to a specific Medicaid patient.[8] Even assuming all of the call notes are admissible, they still do not create a genuine issue of material fact as to causation. Most of the call notes do not even discuss the specific off-label use for which the relevant prescription was written. The few

[8] Relators have included only these eight examples in their appellate briefs and merely stated that they offered others below. Any argument with respect to the other examples is waived due to inadequate briefing. *See United States v. Martinez*, 263 F.3d 436, 438 (5th Cir. 2001).

that do merely show physicians explaining their practices and how they prescribe the drug, which provides no insight into whether Solvay marketed the off-label uses to them, let alone caused them to make off-label prescriptions. Relators also point to academic articles discussed in some of the calls, but there is no indication that those articles came to the physicians' attention because of Solvay. At bottom, the probative value of Relators' causation evidence is primarily based on conjecture and speculation and is therefore insufficient to create a genuine issue of material fact for trial. *See Little v. Liquid Air Corp.*, 37 F.3d 1069, 1079 (5th Cir. 1994) (en banc) (per curiam).[9]

3. Lobbying Activities

i. State P&T Committees

Several state Medicaid programs use P&T committees to decide whether to place certain drugs on state preferred drug lists, thereby authorizing prescriptions to Medicaid patients without pre-approval. These committees are made up of practicing physicians, pharmacists, and others with recognized expertise in prescribing, dispensing, and monitoring outpatient drugs, as well as in drug use review and medical quality assurance. Relators allege that Solvay violated the FCA by unduly influencing P&T committees to place Solvay's drugs on these preferred drug lists.

[9] The parties suggested at oral argument that Medicaid pays for claims without asking whether the drugs were prescribed for off-label uses or asking for what purpose the drugs were prescribed. If this is true, given that it is not uncommon for physicians to make off-label prescriptions, we think it unlikely that prescribing off-label is material to Medicaid's payment decisions under the FCA. *See Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2003–04 (2016) ("[I]f the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material."). Nevertheless, because Relators have failed to survive summary judgment on the issue of causation, we need not reach the issue of materiality in this case.

Assuming all of the relevant evidence is admissible for the three state committees Relators challenge (Alabama, Kentucky, and California), Relators have still failed to create a genuine issue of material fact as to causation. Relators' evidence shows Solvay's campaign to get its drugs added to these three state preferred drug lists and that those states ultimately added those drugs to their preferred drug lists. However, Relators lack evidence indicating that Solvay's campaign *caused* these results. The supposed "smoking gun" email not considered by the district court does not help Relators meet their burden. The most generous reading of that email shows that the Alabama P&T committee added Aceon to its preferred drug list because it determined that the *data* on Aceon's secondary prevention of strokes supported such a decision. But there is no evidence indicating that the Alabama P&T committee—made up of medical experts—was unduly influenced by Solvay's alleged lobbying campaign in making this determination.

Moreover, even assuming that the P&T committees were influenced by Solvay's campaign, Relators have not connected this theory of liability to the filing of any false claims. First, Relators failed to show that particular conduct they contend was "lobbying" of the P&T committees was improper under the particular states' rules and regulations governing the same. Second, even assuming it was improper, Relators failed to discuss how placement on the preferred drug lists caused *false* claims to be presented to Medicaid for reimbursement. The closest explanation provided is that "drugs requiring prior authorization are less likely to be prescribed." But Relators do not point to any record evidence indicating that false claims were actually filed *because* Solvay's drugs were placed on preferred drug lists. Again, Relators need more than speculation to meet their burden as to causation. Perhaps the state P&T committees were unduly influenced, but that does not absolve Relators from their burden of producing evidence indicating that this influence caused actual

false claims (as opposed to claims for approved uses) to be submitted for Medicaid reimbursement. *See Spicer*, 751 F.3d at 364–65 ("[T]he statute attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the claim for payment[.]" (quoting *Longhi*, 575 F.3d at 467)). Relators' evidence is insufficient to create a genuine issue of material fact on this matter.

ii. DrugDex

Relators argue that Solvay became subject to FCA liability by misleading one of the three leading drug compendia, DrugDex. Medicaid reimbursement is not just limited to FDA approved uses, but also includes medically accepted indications listed on Medicaid compendia, including DrugDex. *See* 42 U.S.C. § 1396r-8(d)(1)(B)(i), (g)(1)(B)(i)(III), (k)(6). Relators' theory of FCA liability is that Solvay "manufactured medical literature" and engaged in "deception and collusion" in an effort to have DrugDex list the off-label uses of Solvay's drugs so they "might be deemed eligible for reimbursement under the various government health programs, especially Medicaid and Medicare."

Relators first argue that Solvay suppressed negative studies about the efficacy of Luvox for off-label uses that Solvay had a duty to disclose. Relators also contend that Solvay paid for "smaller and lower quality studies" that would support off-label uses for Luvox, creating an "echo chamber" in which the majority of literature supporting off-label uses for Luvox was sponsored by Solvay. DrugDex ultimately rated over two-dozen conditions as medically accepted uses for Luvox, including off-label uses.

Relators again fail to create a genuine issue of material fact as to causation. The best evidence Relators point to shows that Solvay's Medical Affairs department would generally communicate with medical compendia publishers about Luvox entries and review DrugDex draft documents to verify their accuracy as to the name of the drug, trademarks, and similar items. But

Relators point to no evidence indicating that Solvay's failure to publish studies showing negative results while also paying for lower quality studies to support Luvox's off-label uses misled DrugDex's publisher and caused it to list Luvox on its compendium. There is no record evidence that Solvay communicated with DrugDex's publisher about these studies; in fact, the only evidence cited indicates that there was no communication about the studies. As Solvay suggests, DrugDex's publisher was able to review the studies and decide whether it was appropriate to rely on them. Because Relators failed to produce any evidence suggesting that Solvay's studies misled DrugDex's publisher and caused Luvox to be listed on DrugDex for off-label uses, which in turn resulted in false claims to the government, their DrugDex claim cannot survive summary judgment.

4. Anti-Kickback Statute

The AKS prohibits offering money or other things of value to entice another party to provide a good or service that would be paid for by a federal health care program. 42 U.S.C. § 1320a-7b(b)(2)(A). Relators allege that Solvay paid illegal kickbacks to physicians through various marketing programs.[10] They further allege that Solvay "knew these kickbacks would induce 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." Medicaid claims induced by kickbacks are false if "the provider certified compliance with the kickback statute in submitting a claim." *United States ex rel. Colquitt v. Abbott Labs.*, 858 F.3d 365, 371 (5th Cir. 2017).

Relators' evidence shows (1) physicians participating in Solvay programs in which they were compensated for consultations or presentations and

[10] Relators only appeal the AKS-based claims with respect to Texas Medicaid patients.

(2) subsequent prescriptions by those physicians of Solvay's drugs to Medicaid patients.[11] Nowhere, however, do Relators cite to evidence creating a genuine issue of material fact that such compensation, or any incidental benefits, caused those physicians to prescribe to Medicaid patients. There was nothing illegal about paying physicians for their participation in these types of programs and there is no evidence that participation was conditioned upon prescribing Solvay's drugs to Medicaid patients. Although it is not an unreasonable inference that Solvay intended these programs to boost prescriptions, it would be speculation to infer that compensation for professional services legally rendered actually caused the physicians to prescribe Solvay's drugs to Medicaid patients.[12] Accordingly, summary judgment was appropriate on Relators' AKS theory of liability.

5. Retaliation

Both Relators bring FCA retaliation claims against Solvay alleging they were terminated for filing internal complaints about Solvay's alleged off-label marketing scheme. The elements of an FCA retaliation claim are: (1) the employee "engaged in protected activity," (2) the "employer, or the entity with

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[11] As an initial matter, Solvay contends that Relators now rely on new evidence of intent that they did not rely on in the district court, and thus we should not consider any such evidence on appeal. We need not resolve this dispute, however, because, even if we consider all of the evidence, Relators have not presented sufficient evidence to survive summary judgment on their AKS theory of liability.

[12] Relators also failed to create a genuine issue of material fact as to the AKS's scienter requirement. Proving a violation of the AKS requires evidence that "the defendant willfully committed an act that violated the [AKS]." *United States v. St. Junius*, 739 F.3d 193, 210 (5th Cir. 2013). Because AKS liability is limited to prescriptions that were reimbursed by the government, not private parties, 42 U.S.C. § 1320a-7b(b)(2)(A), satisfying the scienter requirement of "willfully" requires evidence indicating that Solvay intended Medicaid to pay for these prescriptions, *see, e.g.*, *Ruscher*, 663 F. App'x at 374. Relators, however, do not cite to evidence creating a genuine issue of material fact that Solvay intended for those physicians to prescribe to Medicaid patients. As with causation, it would be speculation to infer that Solvay specifically intended such prescriptions to be reimbursed by Medicaid. *See, e.g.*, *id.* at 373 n.4 ("Relator's arguments amount to mere speculation and are therefore insufficient to create a genuine issue of material fact as to Omnicare's intent.").

which he has contracted or serves as an agent, knew about the protected activity," and (3) "retaliat[ion] . . . because of his protected activity." *United States ex rel. Bias v. Tangipahoa Par. Sch. Bd.*, 816 F.3d 315, 323 (5th Cir. 2016).

We "apply the *McDonnell Douglas* framework to the False Claims Act's anti-retaliation provision." *Diaz v. Kaplan Higher Educ., L.L.C.*, 820 F.3d 172, 175 n.3 (5th Cir. 2016); *see McDonnell Douglas Corp. v. Green*, 411 U.S. 792 (1973). Once an employee establishes a prima facie case, "the burden shifts to the employer to state a legitimate, non-retaliatory reason for its decision. After the employer states its reason, the burden shifts back to the employee to demonstrate that the employer's reason is actually a pretext for retaliation." *Diaz*, 820 F.3d at 176 (quoting *LeMaire v. La. Dep't of Transp. & Dev.*, 480 F.3d 383, 388–89 (5th Cir. 2007)). Here, Solvay stated that Relators were terminated for creating unapproved marketing materials, and Relators admit to violating Solvay's marketing policies.[13] The district court held that Relators failed to produce enough evidence of causation to create a genuine issue of material fact that Solvay's reasons for terminating them were pretextual.[14]

We agree with the district court that neither King nor Drummond has provided sufficient evidence of pretext to survive summary judgment. The FCA prohibits adverse employment action taken "because of" protected activity relating to an FCA suit. 31 U.S.C. § 3730(h)(1). Therefore, to survive summary

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[13] Ironically, given the allegations of improper marketing Relators make against Solvay, Solvay provided supporting evidence to the district court indicating that King was terminated for violating company policy by making unapproved alterations to promotional materials that jeopardized Solvay's relationship with another company, and that Drummond was terminated for violating company policy by working on an unapproved letter campaign and then attempting to solicit doctors to mail those letters out to patients.

[14] The district court also determined that only King survived summary judgment on the issue of protected activity. However, because we decide Relators' FCA retaliation claim on causation grounds, we do not reach the issue of protected activity.

judgment, Relators must point to evidence creating a genuine issue of material fact that their complaints were the but-for cause of their terminations. *See Gross v. FBL Financial Servs., Inc.*, 557 U.S. 167, 176 (2009) (holding that the language "because of" requires a "'but-for' cause of the employer's adverse decision" under ADEA retaliation claims); *see also Univ. of Tex. Sw. Med. Ctr. v. Nassar*, 133 S. Ct. 2517, 2528 (2013) ("Given the lack of any meaningful textual difference between the text in this statute and the one in *Gross,* the proper conclusion here, as in *Gross,* is that Title VII retaliation claims require proof that the desire to retaliate was the but-for cause of the challenged employment action."). Relators argue in their opening brief that their evidence allegedly showing temporal proximity between protected activities and their terminations, Relators' positive performance reviews, Solvay's disproportionate disciplinary response that departed from its procedures, and the disparate treatment of other employees is sufficient to survive summary judgment on causation.

As a threshold matter, Relators discussed only temporal proximity and job performance in the district court, and made a brief, unsupported reference to disproportionate discipline. Relators have not shown any extraordinary circumstances for omitting the additional arguments asserted on appeal. Therefore, Relators' causation arguments based on Solvay's alleged departure from disciplinary procedures and the disparate treatment of other employees are waived. *See Diaz*, 820 F.3d at 176–77 (declining to consider evidence of pretext for an FCA retaliation claim because relator failed to raise the argument in the district court and presented no extraordinary circumstances); *see also Skotak v. Tenneco Resins, Inc.*, 953 F.2d 909, 915 (5th Cir. 1992) ("Because the [nonmovant] failed to refer to [the evidence] in district court in their summary judgment response, the [evidence was] not properly before that court in deciding whether to grant the motion; therefore, [it] will not be

considered here.").[15] Similarly, a bare assertion to the district court that their termination was "disproportionate in light of the circumstances" without any record citation or discussion for support does not sufficiently raise that argument in the district court. *See Diaz*, 820 F.3d at 176–77; *Skotak*, 953 F.2d at 915.[16]

Relators are left with the temporal proximity of their terminations to their complaints and their positive performance reviews as evidence of causation. "[T]emporal proximity alone is insufficient to prove but for causation." *Strong v. Univ. Healthcare Sys., L.L.C.*, 482 F.3d 802, 808 (5th Cir. 2007). But "the combination of suspicious timing with other significant evidence of pretext, can be sufficient to survive summary judgment." *Shackelford v. Deloitte & Touche, LLP*, 190 F.3d 398, 409 (5th Cir. 1999).[17] This standard can be met when "the plaintiff had highly positive performance reviews up until the complaint was leveled against the company, and then suffered a sharp decline in treatment immediately after the protected conduct occurred." *Khalfani v. Balfour Beatty Communities, L.L.C.*, 595 F. App'x 363,

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[15] The district court rejected Relators' additional assertion that "both worked under consistently underenforced company policies." Because Relators only mention this argument in their reply brief, it is abandoned. *See Turner v. Kan. City S. Ry. Co.,* 675 F.3d 887, 892 n.3 (5th Cir. 2012) ("[T]his Court will not consider a claim raised for the first time in a reply brief.").

[16] Even if we consider Relators' evidence related to disproportionate disciplinary action, it fails to create a genuine issue of material fact as to whether their termination was a disproportionate response to Relators' infractions. The evidence Relators cite shows that termination was an appropriate disciplinary action for violating company policies. It is undisputed that Relators violated company policies. Moreover, Relators point to no evidence indicating that their infractions merited lesser punishment. Relators' bare assertions that these infractions were minor and therefore undeserving of termination do not suffice at the summary judgment stage.

[17] Although *Strong* and *Shackelford* are retaliation claims under Title VII, they inform our causation analysis here because such claims involve the same "but-for" causation requirement at issue in FCA retaliation claims. *See Nassar*, 133 S. Ct. at 2527–28.

366 (5th Cir. 2014) (per curiam).[18] In *Shackelford*, for example, the plaintiff survived summary judgment because, in addition to showing "tight temporal proximity" of being terminated within days of engaging in several protected activities, there was also evidence of unfounded performance concerns by the employer, warnings not to get involved in the protected activity, and disparate treatment in job reviews. *Shackelford*, 190 F.3d at 408–09.

Here, Relators' evidence of both being terminated at least three-and-a-half months after making their complaints and positive performance reviews prior to their terminations does not create a fact issue as to pretext. Relators admit that they violated Solvay's marketing policies and that employees may be terminated for marketing policy violations. Furthermore, they do not point to any causation evidence that is similar to the evidence described in *Shackelford*. *See id.* Relators point to no evidence that Solvay raised dubious performance problems as a reason for their terminations, mistreated them immediately after their protected activities, or knew of their policy violations prior to Relators' positive performance reviews.[19] Simply put, Relators have failed to show that a reasonable jury could conclude that their complaints were the but-for cause of their terminations.

B. Taxable Costs

A district court may award certain taxable costs to a prevailing party. *See* 28 U.S.C. § 1920; FED. R. CIV. P. 54(d)(1). "Taxable costs are limited to relatively minor, incidental expenses" amounting to "a fraction of the nontaxable expenses borne by litigants for attorneys, experts, consultants, and

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[18] Although *Khalfani* is not "controlling precedent," it "may be [cited as] persuasive authority." *Ballard v. Burton*, 444 F.3d 391, 401 n.7 (5th Cir. 2006) (citing 5TH CIR. R. 47.5.4).

[19] Moreover, as previously discussed, Relators waived any arguments of disproportionate discipline, disparate treatment, and departure from company procedures because they failed to make these arguments and identify supporting evidence before the district court.

investigators." *Taniguchi v. Kan Pac. Saipan, Ltd.*, 132 S. Ct. 1997, 2006 (2012). Taxable costs may include, among other things, "[f]ees for printed or electronically recorded transcripts necessarily obtained for use in the case" and "[f]ees for exemplification and the costs of making copies of any materials where the copies are necessarily obtained for use in the case." § 1920(2), (4).

Solvay sought taxable costs on both of these grounds, which the district court granted in part. Relators argue on appeal that Solvay failed to show that its costs were "necessarily obtained for use in the case." Relators also contend that the district court erred in overruling some of its specific objections to costs related to deposition transcripts, photocopying, and e-discovery.

1. Materials Necessarily Obtained for Use in the Case

Relators claim that a document is only "necessarily obtained for use in the case" if it "was actually used at trial or as a summary judgment exhibit." But we have interpreted "necessarily obtained for use in the case" to include documents "reasonably expected to be used for trial or trial preparation" at the time it was obtained. *United States ex rel. Long v. GSDMIdea City, L.L.C.*, 807 F.3d 125, 130 (5th Cir. 2015). "Whether a deposition or copy was necessarily obtained for use in the case is a factual determination within the district court's discretion, and 'we accord the district court great latitude in this determination.'" *Id.* (quoting *Fogleman v. ARAMCO (Arabian Am. Oil Co.)*, 920 F.2d 278, 285–86 (5th Cir. 1991)); *see also United States v. Kolesar*, 313 F.2d 835, 840 (5th Cir. 1963).

To be sure, a party seeking to recover costs must explain why those costs were necessary. *See Fogleman*, 920 F.2d at 286 ("While we certainly do not expect a prevailing party to identify every xerox copy made for use in the course of legal proceedings, we do require some demonstration that reproduction costs necessarily result from that litigation."). Here, Solvay submitted a declaration listing costs incurred during the case and explaining why the court should

allow it to recover those costs. The district court found that Solvay had shown the necessity of some of its claimed costs and allowed Solvay to recover only those costs.

Relators also claim that "[t]he vehicle for recovering the costs of complying with discovery obligations is a protective order under Rule 26(e)," and "section 1920 [and] Rule 54 . . . are not intended to govern the taxing of discovery costs." However, we have repeatedly said that "the authority of the trial court to assess 'necessary and reasonable' costs incurred during discovery 'can hardly be doubted.'" *Rundus v. City of Dallas*, 634 F.3d 309, 316 (5th Cir. 2011) (quoting *Harrington v. Texaco, Inc.*, 339 F.2d 814, 822 (5th Cir. 1964)). Discovery costs are recoverable under Rule 54 "if the party making the copies has a reasonable belief that the documents will be used 'during trial or for trial preparation.'" *Id.* (quoting *Fogleman*, 920 F.2d at 285).

After reviewing Solvay's declaration in support of its bill of costs, the district court exercised its considerable discretion and determined that Solvay adequately explained the necessity of its costs. Relators have failed to show that the district court abused its discretion in making this determination.

2. Additional Objections to Solvay's Costs

Relators objected to most of the costs billed for deposition transcripts, photocopying, and e-discovery. Relators now appeal the district court's decisions overruling some of these objections.

As to the costs for deposition transcripts, Relators contend that the district court should not have taxed any costs against them given the absence of itemized invoices. We disagree. Solvay's counsel explained why these deposition transcripts were necessary to Solvay's defense, and the district court found Solvay's justifications convincing and acted accordingly. In doing so, the district court did not abuse its discretion.

As to the photocopying costs, Relators claim that the district court should not have awarded any photocopying costs because Solvay failed to provide sufficient supporting documentation. The district court acknowledged that Solvay's invoices were not detailed but explained that, given nearly three million pages of copies Solvay produced for its defense in this case, it would have been impossible for Solvay to explain each page's usefulness. The district court also noted that Solvay had attested that the photocopying expenses were necessarily incurred, had reduced its request to only fifty percent of the costs actually incurred, and was not seeking costs for copies made by its employees. In light of these circumstances, the district court found that the costs were both necessary and reasonable.

We have previously affirmed awards for non-itemized photocopying expenses. *See, e.g.*, *Long*, 807 F.3d at 131; *United Teacher Assocs. Ins. Co. v Union Labor Life Ins. Co.*, 414 F.3d 558, 574–75 (5th Cir. 2005). District courts have great latitude in making these determinations, and the district court here did not abuse its discretion in exercising that latitude in determining reasonable photocopying costs in light of the circumstances of this complex case. *See Rundus*, 634 F.3d at 316.

As to the e-discovery costs, the district court disallowed the bulk of Solvay's request but did allow Solvay to recover for costs relating to (1) TIFF image conversion, (2) scanning, (3) formatting electronic documents, and (4) PDF conversion—per § 1920(4), which allows recovery for "exemplification" and "making copies" of case materials. The district court explained that it interprets § 1920(4) "narrowly" in this context but understands the statute to allow a prevailing party to recover the costs of complying with an opposing party's request to reformat electronic documents or scan hard copies of documents.

Relators contend that Solvay did not provide sufficient information to justify the necessity of these costs. To the contrary, Solvay explained their necessity in its declaration of costs. The district court carefully considered Relators' objections and did not abuse its discretion by overruling those objections.

Finally, Relators make a one sentence argument that "processing fees paid to third-party providers to digitize large quantities of print materials or to compile and convert electronic records"—that is, electronic formatting and TIFF image conversion costs—are not costs related to "making copies" within the meaning of § 1920(4). However, under similar circumstances, we have previously held that a district court does not abuse its discretion in allowing reimbursement of such costs. *See Long*, 807 F.3d at 131–32.

IV. Conclusion

For the foregoing reasons, the district court's grant of both summary judgment and taxable costs to Solvay is AFFIRMED.