IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

United States Court of Appeals
Fifth Circuit
FILED
May 31, 2017
Lyle W. Cayce
Clerk

No. 16-10814

United States of America, ex rel; KEVIN N. COLQUITT, Individually,

Plaintiff - Appellant

v.

ABBOTT LABORATORIES, Individually and as Successor- in- Interest to Guidant Corporation; ABBOTT VASCULAR SOLUTIONS, INCORPORATED, formerly known as Guidant Endovascular Solutions, Incorporated,

Defendants - Appellees

Appeal from the United States District Court
for the Northern District of Texas

Before STEWART, Chief Judge, and HIGGINBOTHAM and COSTA, Circuit Judges.

GREGG COSTA, Circuit Judge:

Relator Kevin Colquitt lost the *qui tam* war against his former employer Abbott Laboratories in three battles. He pursued three False Claims Act theories based on claims submitted to Medicare by medical providers engaged in the "off-label" use of Abbott's medical stents. A false inducement claim and a claim predicated on false certification of compliance with the Anti-Kickback Statute failed on a motion to dismiss. A false presentment claim was limited at summary judgment to periods when Colquitt worked for Abbott. The jury

found against Colquitt on what was left of his false presentment claim. Colquitt argues that the motion to dismiss and motion for partial summary judgment should not have been granted. He also contends that erroneous evidentiary rulings and mistakes in instructing the jury tainted its verdict. Finding no reversible error, we affirm.

I.

Colquitt was a salesman for Guidant Corporation. He sold stents, which are little metal or plastic tubes that doctors insert inside the body's natural tubes, like veins, arteries, or bile ducts, to shore them up. These stents had been approved by the FDA to go into bile ducts, but Guidant was helping and encouraging doctors to use them in blood vessels. Two months before Colquitt left his job, Guidant was bought by Abbott Laboratories, which had a similar practice of promoting biliary stents for vascular use. Colquitt, who learned about the False Claims Act as a night law student, brought this *qui tam* action against Abbott because he thought that Guidant and Abbott had defrauded Medicare by seeking FDA approval for biliary stents but then encouraging and bribing providers to use them in vascular procedures for which the providers billed Medicare.

Colquitt's theories of fraud start with applications Guidant and Abbott made to the FDA to sell their stents. They applied under a fast track procedure for new medical devices that are substantially equivalent to devices already on the market. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 (1996). To do so, they submitted premarket notifications (usually called "510(k) notifications") to the FDA in which they labeled their new products as biliary, rather than vascular, stents. For some time, doctors had been using biliary stents, like the new models Abbott and Guidant wanted to release, in vascular procedures. Indeed, the only stents approved for vascular use were considered outmoded and applying biliary stents in vascular work was standard medical practice.

Had the companies submitted their stents for FDA approval as vascular stents, they would have been subject to the much more rigorous and lengthy "premarket approval" process, which requires companies to prove their devices' safety and efficacy through clinical studies. *See Riegel v. Medtronic, Inc.*, 451 F.3d 104, 109 (2d Cir. 2006). Using stents approved for biliary use in vascular procedures is considered "off-label" use.

Colquitt helped Guidant and later Abbott sell these biliary stents for off-label use to doctors performing vascular procedures, and they taught him the tricks of the trade. He learned how they advertised the stents in journals aimed at vein doctors; he learned about training seminars, discounts, dinners, and other company freebies for doctors. They also tutored him on Medicare billing, and he saw how the companies advised doctors and hospitals on which Medicare codes to use when they performed vascular repairs with the biliary stents.

Colquitt filed a *qui tam* suit against Abbott, and the government declined to intervene. He alleged that Abbott and Guidant had violated the False Claims Act in three ways:

(1) fraudulent inducement through misrepresentations in obtaining FDA clearance for the stents;

(2) violation of the federal Anti-Kickback Statute, rendering healthcare providers' claims certifying compliance with anti-kickback statutes false; and

(3) false presentment through promotions that caused hospitals to present Medicare claims that he contends were not eligible for payment because off-label use was not safe.

Abbott filed a combined motion to dismiss for failure to state a claim and for lack of subject matter jurisdiction due to public disclosure of the alleged

fraudulent scheme.[1] The court granted the motion to dismiss for failure to state a claim as to the Anti-Kickback allegations. It granted the motion to dismiss for want of jurisdiction as to the fraudulent inducement claim, holding that Colquitt's information had been publicly disclosed and that he was not an original source of that information. Colquitt's third theory—false presentment through encouraging doctors to present fraudulent claims to Medicare—survived this motion.

Abbott later filed a motion for partial summary judgment seeking to limit this remaining claim to periods when Colquitt was actually employed by Abbott and restrict it to Guidant's conduct, rather than Abbott's independent conduct outside its role as Guidant's successor in interest. Abbott argued that this limited timeframe was the only period when Colquitt could be an original source for this claim. The district court agreed.

Colquitt's evidence at trial centered on the many ways that Guidant promoted its stents for off-label use. Abbott's presentation was aimed at an open secret theory: it emphasized that everyone involved—the FDA, Medicare, doctors and hospitals—knew that using biliary stents in vascular work was standard practice and commonly reimbursed by Medicare. It offered testimony from physicians and a former Medicare officer. The jury returned a verdict against Colquitt who unsuccessfully sought a new trial before bringing this appeal.

II.

The district court dismissed Colquitt's Anti-Kickback allegations on the ground that he had failed to satisfy the heightened pleading requirements for

[1] At the time, the public disclosure bar was jurisdictional. 31 U.S.C. § 3730(e)(4)(A) (2006). Congress amended the statute in 2010 so that this is no longer the case. *See Abbott v. BP Exploration & Prod., Inc.*, 851 F.3d 384, 387 n.2 (5th Cir. 2017) (31 U.S.C. § 3730(e)(4)(A) .

fraud claims. *See* FED. R. CIV. P. 9(b). The Anti-Kickback Statute makes it a crime to pay someone to "refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2)(A). If a provider has violated the statute, then claims he or she submits to Medicare may be false claims when the provider certified compliance with the kickback statute in submitting a claim. *See United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902 (5th Cir. 1997).

As the False Claims Act is about fraud, claims asserted under it must comply with Rule 9(b)'s heightened pleading standard. *Id.* at 903. "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." FED R. CIV. P. 9(b). This requires, at a minimum, that a plaintiff plead the "who, what, when, where, and how" of the alleged fraud. *Williams v. WMX Tech., Inc.*, 112 F.3d 175, 179 (5th Cir. 1997).

In dismissing Abbott's kickback allegations, the district court faulted Colquitt for not describing "any details of the actual claims made by the physicians or hospitals that allegedly received kickbacks." It found that although Colquitt had identified some specific hospitals and doctors that allegedly received kickbacks, he did not plead that any of these hospitals or doctors signed up to be Medicare providers or submitted certified claims for reimbursement for procedures using Abbott's stents.

This may have been too rigid an application of Rule 9(b). The general rule is that a plaintiff must plead details such as the time and place of the false representations. *United States ex rel. Rafizadeh v. Cont'l Common, Inc.*, 553 F.3d 869, 873 (5th Cir. 2008). But *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180 (5th Cir. 2009), sounded a note of caution about its application in *qui tam* suits: "[T]he 'time, place, contents, and identity' standard is not a

straitjacket for Rule 9(b). Rather, the rule is context specific and flexible and must remain so to achieve the remedial purpose of the False Claim Act." *Id.* at 190. The details of particular claims submitted to the government may only be attainable for relators through discovery, which a dismissal on the pleadings forestalls altogether. *See id.* at 191 ("While Rule 9(b) stands as a hurdle preventing discovery when a complaint fails to sufficiently define its claims, it does not do away with discovery altogether by allowing access to discovery only when the complaint already contains all the information necessary to succeed at trial."). *Grubbs* thus concluded that "a relator's complaint, if it cannot allege the details of an actually submitted false claim, may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Id.*

A strong inference that the named hospitals submitted claims to Medicare for vascular procedures using biliary stents could likely be drawn from Colquitt's allegations. Nearly every hospital in America participates in Medicare and would most likely have billed Medicare had they performed procedures using Abbott's stents on a person over age 65. The complaint makes extensive allegations about that off-label use being common. And Colquitt alleged that the claims carried a certification of compliance with the Anti-Kickback Statute.[2]

But Colquitt's allegations fail at the first part of the *Grubbs* standard: it does not allege the details of the scheme with sufficient particularity. It devotes a single, vague paragraph to the alleged kickback scheme, mentioning

[2] Colquitt invokes *Universal Health Services., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016), and its holding that an implied certification of compliance is sufficient for FCA liability. 136 S. Ct. at 2001. We do not, however, find his anti-kickback allegations insufficient based on an absence of certification.

defendants' programs that provide "significant volume discounts and rebates to hospitals that could not be attained based solely on biliary use, but required substantial vascular use of the stents in order to receive the discount or rebate." That, along with reference to "vascular specialists" who received dinners, training, and fellowships, is the extent of the details alleged about the scheme. No specifics about the discounts and rebates are provided. We are not told that a particular hospital (including the only two that are identified in the complaint, Valley Hospital Medical Center and Shady Grove Adventist Hospital) ever achieved these unspecified thresholds through off-label use of the stents. No particulars are alleged to show that the unidentified doctors who received the ill-defined benefits caused the hospital to use Abbott stents. In short, the complaint never links the alleged carrots to the purchase and use of the stents at either of the hospitals. Unlike details about the Medicare claims that ended up being submitted, much of this information would be known to a relator with original information about an unlawful kickback scheme. Rule 9(b) was not satisfied.

III.

Colquitt's false inducement claim—that Medicare paying claims for stents used in vascular procedures was tainted by Abbott's making false statements about their intended use when obtaining FDA approval—was dismissed based on the public disclosure bar. That bar applies "whenever *qui tam* relators bring a suit based on publically available information." *United States ex rel. Jamison v. McKesson Corp.*, 649 F.3d 322, 327 (5th Cir. 2011). There is an exception if the relator is an original source of the information. 31 U.S.C. § 3730(e)(4)(A). Together, the public disclosure bar and its original source exception calibrate the incentives for individuals to bring *qui tam* suits under the False Claims Act. When the facts showing fraud are veiled, relators who discover them should receive a reward for bringing claims. Even when

the facts are publicly disclosed, a relator who is an original source may still bring something of value to the table and thus deserves to benefit. In other cases, the government—for whom the public disclosure bar is not an impediment to suit—either has notice of the wrongdoing or gains nothing from a relator with indirect knowledge of the same facts. Allowing private individuals to sue in those situations would provide an unnecessary windfall. *United States ex rel. Branch Consultants v. Allstate Ins. Co.*, 560 F.3d 371, 376 (5th Cir. 2009) (discussing repeated attempts by Congress to balance competing goals of encouraging whistleblowers while discouraging parasitic lawsuits); *United States ex rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645, 649–51 (D.C. Cir. 1994) (narrating the history of False Claims Act litigation that led to the passage of the public disclosure bar as an attempt to balance the competing interests of encouraging whistleblowing while preventing "parasitic" suits).

We apply a three-part test to determine whether this bar applies. It asks "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 relator is the 'original source' of the information." *Fed. Recovery Servs., Inc. v. United States*, 72 F.3d 447, 450 (5th Cir. 1995).

Although Abbott invoked the public disclosure bar through a motion to dismiss, the district court correctly decided it as a motion for summary judgment and considered evidence outside of the pleadings. *See Jamison*, 649 F.3d at 326 (explaining that public disclosure question is intertwined with the merits and so properly treated as motion for summary judgment when brought under a motion to dismiss). Following this procedure, it is Abbott's burden to "first point to documents plausibly containing allegations or transactions on which [the realtor's] complaint is based." *Id.* at 327. To survive summary

judgment, the relator must then produce evidence "to show that there is a genuine issue of material fact as to whether this action was based on those disclosures" or that he is an original source for the allegations in his compliant. *Id.*

Abbott has argued, and the district court agreed, that the 510(k) summaries issued by the FDA in connection with its approval of the stents demonstrated on their face that the information supporting Colquitt's claim was publically available. As evidence that FDA approval had been sought in bad faith, Colquitt pointed in his complaint to the fact that "more than 99 percent of Defendants' devices are too large or too small to fit the biliary tree." This information is in the public 510(k) summaries, which must include the devices' physical properties such as size. *See* 21 C.F.R. § 807.92(a)(4).

The district court saw that Colquitt hoisted himself with his own petard. His complaint relies on the dimensions of the stents to show that the 510(k) notifications submitted to the FDA were fraudulent. As the allegations recognize, the 510(k) summaries contained this information about the stents' dimensions. These public papers were all that one would have needed to discover the purported fraud—Abbott must have intended the stents for vascular use, contrary to its representations in its 510(k) notices, because the stents could not fit in the biliary tree but would fit arteries and veins. As one court has put it, "[i]n order to disclose the fraudulent *transaction* publicly, the combination of X and Y must be revealed, from which readers or listeners may infer Z, *i.e.*, the conclusion that fraud has been committed." *Springfield Terminal*, 14 F.3d at 654. In this case, X is the fact that Abbott presented the devices to the FDA as biliary stents, Y is the fact that most of the stents would not fit in bile ducts but would visit in the vascular tree, and Z is the conclusion that Abbott misstated the intended use of the stents. *See Little v. Shell Exploration & Prod. Co.*, 690 F.3d 282, 293 (5th Cir. 2012) ("A guiding query

is whether 'one could have produced the substance of the complaint merely by synthesizing the public disclosures' description' of a scheme." (quoting *United States ex rel. Jamison v. McKesson Corp.*, 649 F.3d 322, 331 (5th Cir. 2011)).

Colquitt asserts that only some of the 510(k) summaries disclosed the sizing information for the stents. This argument ignores *Federal Recovery Services Inc. v. United States*, 72 F.3d 447 (5th Cir. 1995). That relator insisted, like Colquitt, that "its investigation unearthed additional instances of fraudulent conduct." 72 F.3d at 451. But contributing more of the same does not change the public character of a relator's allegations: Colquitt "cannot avoid the jurisdictional bar simply by adding other claims that are substantively identical to those previously disclosed." *Id.*

Colquitt emphasized at oral argument that the 510(k) summaries did not say anything about catheter length—another giveaway as to the true purpose of the stents. Citing his complaint, he asserts that his "allegations regarding sizing as evidence of Defendants' true intended use in peripheral vascular procedures includes catheter length as a critical component." It is true that the complaint says that biliary catheters should be less than 50 centimeters or greater than 170 centimeters while Guidant's stents came with a 75 centimeter catheter. But the fact that the catheters were not the correct size for the biliary system is in no way "critical" to perceiving that the stents themselves also had the wrong dimensions for biliary use. Both clues revealing the off-label purpose are presented as independent faults in Colquitt's pleadings.

Colquitt contends that even if the information supporting his fraudulent inducement claim was publicly disclosed, he was an original source of this information. To be an original source, a person must have direct and independent knowledge of the information on which the allegations are based. *Little*, 690 F.3d at 292. If someone relies upon the public disclosures at issue, then his or her knowledge is not independent. *United States ex rel. Fried v.*

West Indep. Sch. Dist., 527 F.3d 439, 442–43 (5th Cir. 2008). Colquitt attempts to show that his allegations derive from what he observed while working for Abbott and not just the 510(k) documents. What he observed, however, were efforts by Guidant to promote the biliary stents for vascular use. This is information bearing on his false presentment claim discussed below, not information about the alleged misrepresentations to the FDA in the approval process that form the basis of his fraudulent inducement claim. Colquitt had no involvement in, and thus no original information about, the FDA approval process.

The district court correctly dismissed the false inducement claim under the public disclosure bar.

IV.

A.

When it ruled on Abbott's motion to dismiss, the district court stayed its hand as to Colquitt's false presentment claim. Unlike his false inducement claim which was based on alleged false statements made to the FDA, Colquitt's false presentment claim was based on the accusation that Abbott's marketing schemes caused healthcare providers to submit false claims to Medicare for its stents. The court found that although the facts about Abbott's promotion of the stents had been publicly disclosed (in the 510(k) summaries, advertisements Abbott placed in medical journals, and an FDA warning letter), he was an original source of these allegations.

The court explained that Colquitt's allegations were based in part on his independent and direct knowledge. Regarding independence, the district court remarked that much of what Colquitt brought to the table was not included in the warning letter, advertisements, or 510(k) documentation. It stressed that he knew the inside baseball: he had training to show physicians how to use the stents off-label and got bonuses for off-label promotion. As to directness, the

court also emphasized that he gained his knowledge firsthand as an Abbott employee.

When Abbott later moved for partial summary judgment, it tailored its motion to the district court's previous ruling and asserted that Colquitt was not an original source as to periods before and after his employment and as to Abbott Laboratories proper, that is, other than in its role as a successor in interest to Guidant. The court accepted this argument and found Colquitt's evidence to the contrary to be too thin to allow a jury to infer that he was an original source.

Colquitt now argues not only that he was an original source but also challenges the court's earlier public disclosure finding made in connection with Abbott's motion to dismiss. In the latter respect, Colquitt's arguments rehearse the position he took on his false inducement claim. He insists that "the mere promotion of the stents for off-label use was only one component" of his false presentment claim and does not show his claim's other components like fraudulent intent or materiality. *See Little*, 690 F.3d at 293 (holding that courts conducting public disclosure analysis must compare the scope and breadth of relators allegations with the public disclosures).

What Colquitt's false presentment claim boils down to, however, is that Abbott was pushing stents for vascular use that it had pretended to the FDA were for biliary use. Here again, "one could have produced the substance of the complaint merely by synthesizing the public disclosures' description." *McKesson*, 649 F.3d at 331. The district court noted correctly that these facts

were all disclosed by the FDA warning letter about off-label promotion, the advertisements in medical journals, and the 510(k) summaries.[3]

Returning to the original source question, Colquitt argues that he presented sufficient evidence to at least raise a fact issue for a jury. He directs the court's attention to evidence that he contends show that he gained direct knowledge of off-label promotion before and after his employment and of Abbott's parallel efforts before its acquisition of Guidant. He addresses each category of evidence separately.

Regarding what occurred before he arrived at Guidant, Colquitt asserts that when he arrived at Guidant, he encountered an ongoing plan to promote biliary stents for vascular use. He says that his training made clear to him that he was participating in an established effort and as he worked at Guidant, he found many of the pieces of the scheme already in place, such as consignments of biliary stents with vascular doctors.

Colquitt, however, overstates the evidence he offered to defeat summary judgment. Colquitt's affidavit and the Powerpoint presentation do make it unmistakable that Colquitt was hired and trained to sell biliary stents for vascular use and that Guidant wanted to grow its existing business in this regard. Likewise, the evidence supports Colquitt's assertions regarding consignments. He also presented evidence, in the form of a training Powerpoint, indicating that Guidant had a coding guide for providers and billing staff covering use by vascular surgeons. What a closer look at the evidence, including the contrary evidence offered by Abbott in support of its

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[3] The district court expressed hesitation about whether ads in specialty medical journals should be considered disclosures in the news media. On appeal, Colquitt does not challenge the district court's conclusion that such advertisements are properly considered as disclosures in the news media. *See generally Schindler Elevator Corp. v. United States ex rel. Kirk*, 131 S. Ct. 1885, 1887 (2011) (discussing meaning of "news media"). As this issue was not contested on appeal, our decision should not be construed as endorsing a particular interpretation of "news media" in FCA cases.

motion, shows, however, is that Colquitt could only claim that he had the impression that off-label promotion was taking place before his hiring. He did not have unmediated—that is to say, direct—knowledge of the promotion of stents for off-label use. *See United States ex rel. Fried v. W. Indep. Sch. Dist.*, 527 F.3d 439, 442–43 (5th Cir. 2008) ("In order to be 'direct,' the information must be firsthand knowledge."); *United States ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v. Prudential Ins. Co.*, 944 F.2d 1149, 1160 (3d Cir. 1991) (defining "direct" to mean "marked by absence of an intervening agency, instrumentality, or influence"); *United States ex rel. Findley v. FPC-Boron Emps. Club*, 105 F.3d 675, 690 (D.C. Cir. 1997); (defining it to mean "first-hand").

It must be remembered that original source is a subsidiary question that allows a relator to proceed despite the fact that the facts underlying his allegations were publicly disclosed. When the "investigation or experience of the relator . . . translate[s] into some additional compelling fact, or . . . demonstrate[s] a new and undisclosed relationship between disclosed facts," the relator may proceed as an original source despite public disclosure. *United States ex rel. Reagan v. E. Tex. Med. Ctr. Reg'l Healthcare Sys.*, 384 F.3d 168, 179 (5th Cir. 2004). That is because a relator who brings new evidence of wrongdoing that may already be in the public domain still strengthens the government's case—what more compelling evidence is there than the testimony of a witness providing an insider's account of the misconduct?—and thus should be allowed to share in the recovery she helped achieve. The district court shepherded the false presentment claims past Abbott's motion to dismiss for precisely this reason: Colquitt had experienced off-label promotion firsthand as Guidant's instrument for that purpose. This rationale does not support treating Colquitt as an original source for promotion that occurred prior to his employment.

The same fault bedevils the evidence that Colquitt identifies concerning his postemployment claims and claims against Abbott Laboratories apart from the actions of Guidant. He points to what he heard from a former coworker, who left Guidant to work for Abbott before the acquisition, and from an Abbott counterpart, but this is secondhand. *See United States ex rel. Saldivar v. Fresenius Med. Care Holdings, Inc.*, 841 F.3d 927, 936 (11th Cir. 2016) ("Saldivar [the relator] heard about overfill billing practices from others. This likewise is indirect."). He also highlights an Abbott report he received containing sales numbers and goals, but as the district court noted, this only showed off-label sales and not the allegedly improper off-label promotion that he observed as a Guidant employee. For periods after he quit the company, Colquitt argues from information he discovered through litigation or from conversations with former co-workers. This is not direct, independent knowledge but is either secondhand, *see Fried*, 527 F.3d at 442–43, or based on public disclosures. The district court did not err in limiting the time frame of the false presentment theory presented to the jury.

B.

Colquitt argues that the jury's rejection of that claim was marred by the erroneous exclusion of two pieces of evidence. We review those evidentiary rulings for abuse of discretion. *Baisden v. I'm Ready Prods., Inc.*, 693 F.3d 491, 508 (5th Cir. 2012). We will reverse only when an erroneous ruling had a substantial effect on the trial's outcome. *Bocanegra v. Vicmar Servs., Inc.*, 320 F.3d 581, 584 (5th Cir. 2003).

Abbott's defense relied on an open-secret theory, that everyone, including the government, knew that biliary stents were regularly used in veins and arteries. Part of Abbott's evidence was testimony about a tradeshow where FDA officials were present and such use of the stents was openly discussed. As rebuttal evidence, Colquitt wanted to show the jury a warning

letter that the FDA sent to Abbott in December 2007 rebuking it for off-label promotion as well as a compliance letter Abbott sent in return detailing steps it would take to mend its ways. The district court ruled that the evidence was irrelevant because it described events that occurred after Colquitt's employment ended and thus outside the range of false claims the jury was allowed to consider. Colquitt offered the letters again after Abbott elicited testimony that the FDA continued to allow the sale of the stents after Colquitt's suit was filed, but the district court ruled that the evidence was irrelevant and prejudicial because it was not probative of the attitudes of Medicare officials.

Colquitt says that excluding this evidence left him "unable to rebut Abbott's extrinsic evidence about the Government's knowledge and its arguments that the evidence meant Abbott had done nothing wrong." Abbott's objection, sustained by the district court, was that the evidence was irrelevant and prejudicial because it did not "have anything to do with whether [Medicare] believed that biliary stents were rightly covered." District courts enjoy wide discretion in making the relevancy and prejudice assessments that Rules 401 and 403 require. *Spring/United Mgmt. Co. v. Mendelsohn*, 552 U.S. 379, 384 (2008). The rationale of the objection—that the key issue was Medicare's policies, not those of the FDA, and a focus on the latter could confuse the jury about its ultimate focus—is sensible. The district court did not abuse its discretion by excluding the evidence. In any event, excluding the evidence did not leave Colquitt unable to rebut Abbott's open-secret position. At other times during trial, he was able to offer a different FDA letter expressing concerns about off-label promotion and had an expert tell the jury that the letter showed FDA did not condone and was trying to stop off-label promotion of the stents. Any prejudice to Colquitt was also minimized by a jury instruction to the effect that FDA attendance at conferences did not indicate that the FDA approved off-label marketing.

Colquitt also attacks the district court's decision to exclude evidence that a Guidant subsidiary, Endovascular Solutions, Inc., had earlier pleaded guilty to felony charges of making false statements to the FDA and failing to report bad outcomes that occurred with an aortic stent called the Ancure. The Ancure was not one of the biliary stents at issue in the trial. The district court granted Abbott's motion in limine to exclude the convictions on the grounds that they were too prejudicial and old.

Colquitt twice asked the district court to reconsider the limine ruling as that procedure contemplates. He first did so when Abbott's counsel called Guidant a "great, great company" and said that it gave the FDA every piece of data relevant to recalls of the biliary stents. Colquitt tried again when an Abbott witness, Richard Rapoza, testified that Guidant complied with FDA reporting requirements for its stents from 2004 to 2006.

Colquitt's theory for admission of the evidence is unclear. The strongest argument would seem to be that this testimony made Guidant's compliance with the FDA an issue, and Colquitt was entitled to rebut that (it would not be admissible as general evidence of Guidant's bad character). Whether these statements had fully opened the door to impeachment via the convictions or just resulted in a slight crack is one of those evidentiary rulings on which the trial court was likely entitled to rule either way. Indeed, the district court noted the closeness of the question, warning Abbott's counsel after opening statement that he was close to the point at which the court would change its pretrial ruling. As the trial court was in the best position to know how this issue fit within the 12-day trial, we find no abuse of discretion in its ruling that the convictions should not be used to impeach statements that were narrowly framed to encompass a timeframe of FDA compliance that included the biliary stents on trial but excluded those resulting in the earlier conviction.

C.

Colquitt also asserts that there should be a new trial because the court erred by not giving two jury instructions he requested. A trial court's decision not to accept a proposed jury instruction is generally reviewed for abuse of discretion. *Kanida v. Gulf Coast Med. Pers. LP*, 363 F.3d 568, 578 (5th Cir. 2004). But insofar as the legal accuracy of an instruction is at issue, we review de novo. *GE Capital Commercial, Inc. v. Worthington Nat'l Bank*, 754 F.3d 297, 301 (5th Cir. 2014). We will reverse only if the declined instruction was a substantially correct statement of law, not substantially covered in the charge as a whole, and concerned an important point at trial such that failure to give it seriously impaired the offering party's ability to present a claim or defense. *Kanida*, 363 F.3d at 578.

Colquitt's false presentment claim was based on the theory that Abbott violated the FCA by causing doctors and hospitals to submit claims to Medicare for vascular procedures using biliary stents that were ineligible for payment. Because Medicare does not pay for devices that are not reasonable and necessary for medical treatment, 42 U.S.C. § 1395y(a)(1)(A), the court instructed the jury that "no payment may be made . . . for any expenses incurred for items or services . . . [which] are not reasonable and necessary for the diagnosis of illness or injury . . . ." Colquitt told the court that this was not enough guidance for the jury and proposed the following instruction:

> For an item or service to be considered reasonable and necessary, the item or service must be:
> 1) safe and effective;
> 2) not experimental or investigational; and
> 3) appropriate.
>
> The third element (appropriateness) is not at issue in this case. If an item or service fails to meet the first or second element, it is not eligible for payment under Medicare.

Colquitt asserts that this was a correct statement of the law because it corresponded with language in the Medicare Program Integrity Manual issued to Medicare's payment contractors. The weight he gives the manual is misplaced, however, as Medicare itself has denied that it has the force of law. *See Douglas v. Centers for Medicare and Medicaid Servs.*, DAB No. CR2406, 2011 WL 3578669, at *5 (Departmental App. Bd. H.H.S., Aug. 3, 2011). Moreover, Colquitt does not otherwise cite statutes, regulations, or caselaw sufficient to show that his proposed definition of "reasonable and necessary" reflects the law; he has thus not shown that the district court abused its discretion by rejecting the instruction he proposed.

Colquitt also unsuccessfully requested this instruction, which he thought relevant to Abbott's open-secrets defense:

> You are instructed that, even if certain United States Government personnel knew the true facts, such knowledge is not a defense to Relator's claims under the False Claims Act. Even if one United States Government employee knew the truth does not mean that Defendants were authorized to make false statements or claims. Defendants had an obligation to tell the truth, and a failure to do so is not excused by an allegation that one or more United States Government employees knew that Defendants' statements were false or that claims for non-coronary vascular procedures using Defendants' biliary stents were false. In other words, if the Defendants knew that their statements or claims for procedures using their biliary stents were false, Government knowledge of the fact is not a defense on the issue of liability.

The instruction misstates the law; government knowledge can be a defense to an FCA suit. *See United States v. Bollinger Shipyards, Inc.*, 775 F.3d 255, 263 (5th Cir. 2014). In *Bollinger*, the court said that "under some circumstances, the government's knowledge of the falsity of a statement or claim can defeat FCA liability on the ground that the claimant did not act 'knowingly,' because the claimant knew that the government knew of the falsity of the statements and was willing to pay anyway." *Id.* (quoting *United States v. Southland*

Mgmt. Corp., 326 F.3d 669, 682 (5th Cir. 2003) (en banc) (Jones, J., specially concurring)).

Colquitt attempts to dodge *Bollinger* by arguing that "[i]f Abbott knew the claims were false, government knowledge is not relevant." This line of thinking draws support from the principle that scienter is established for FCA purposes by showing knowledge of the falsity of the statement at issue, without a requirement of intent to defraud. *See id.* at 259. Nonetheless, the logic of the government knowledge "defense"[4] is that there is no scienter when the defendant knows—not just that the statements are false—but that the government knows that the statements are false. *See id.* at 263; *Southland*, 326 F.3d at 682 (Jones, J., specially concurring) ("The government's knowledge and acquiescence in its contractor's actions in many of these cases was 'highly relevant,' to show that the contractor did not submit payment claims in deliberate ignorance or reckless disregard of their truth or falsity." (citation omitted)). We can see Colquitt attempting to work around *Bollinger* with the language he proposed—"*if the Defendants knew that their statements or claims for procedures using their biliary stents were false*, Government knowledge of the fact is not a defense on the issue of liability"—but the law shows that this is half-true at best. The instruction still falters because government knowledge can negate liability when the defendant knew not only that the statements at issue were false, but that the government knew it as well. *See United States ex rel. Durcholtz v. FKW Inc.*, 189 F.3d 542, 544–45 (7th Cir. 1999) ("The government's prior knowledge of an allegedly false claim can vitiate a FCA action. If the government knows and approves of the particulars of a claim for payment before that claim is presented, the presenter cannot be

[4] *Bollinger* notes it is "inaptly named because it is not a statutory defense to FCA liability but a means by which the defendant can rebut the government's assertion of the 'knowing' presentation of a false claim." 775 F.3d at 263.

said to have knowingly presented a fraudulent or false claim." (citations omitted)). The district court did not abuse its discretion in rejecting these instructions.

* * *

The judgment of the district court is AFFIRMED.