[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 15-15497

D.C. Docket No. 1:10-cv-01614-AT

UNITED STATES OF AMERICA EX REL.,
CHESTER SALDIVAR,

Petitioner-Appellant,

versus

FRESENIUS MEDICAL CARE HOLDINGS, INC.,
d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA,

Respondent-Appellee.

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

(November 8, 2016)

Before ED CARNES, Chief Judge, JORDAN, Circuit Judge, and LAMBERTH,* District Judge.

ROYCE C. LAMBERTH, District Judge:

* Honorable Royce C. Lamberth, United States District Judge for the District of Columbia, sitting by designation.

Relator Chester Saldivar appeals the district court's order granting summary judgment to defendant Fresenius Medical Care Holdings, Inc. (Fresenius). This case is a *qui tam* action arising under the False Claims Act (FCA), 31 U.S.C. §§ 3729–3733. This is an appeal of a final judgment pursuant to 28 U.S.C. § 1291. Whether or not jurisdiction ultimately exists in this case is the focus of this opinion.

I.

Fresenius is a provider of End Stage Renal Disease (ESRD) outpatient services. As part of these services, Fresenius administers the drugs Epogen and Zemplar, both of which are distributed in vials. These vials contain slightly more of the drug than is indicated on the packaging, referred to as "overfill." In the course of providing its services, Fresenius administered this overfill to patients, and sought and received reimbursement for such overfill from the Centers for Medicare and Medicaid Services (CMS).

Relator, Chester Saldivar, filed the instant *qui tam* action claiming Fresenius violated the FCA by billing the government for overfill that it received for no cost—allegedly a violation of the statutes governing CMS billing. *See U.S. ex rel. Saldivar v. Fresenius Med. Care Holdings, Inc.*, 972 F. Supp. 2d 1339, 1348 (N.D. Ga. 2013) (*Saldivar I*). Saldivar filed suit in the United States District Court for

the Northern District of Georgia in 2010. In March 2011, the Government declined to intervene in this case, its right under the FCA. 31 U.S.C. § 3730(b).

Fresenius maintained that the action should be dismissed for lack of subject matter jurisdiction due to the Public Disclosure Bar in the FCA, an argument they raised—unsuccessfully—twice. *U.S. ex rel. Saldivar v. Fresenius Med. Care Holdings, Inc.*, 157 F. Supp. 3d 1311, 1313 (N.D. Ga. 2015). The Public Disclosure Bar prevents *qui tam* actions if the allegations in question were publicly disclosed. 31 U.S.C. § 3730(e)(4). In determining there was jurisdiction under § 3730(e)(4), the district court concluded that while Saldivar's allegations of overfill billing were publicly disclosed and the disclosed information was the basis of Saldivar's suit, Saldivar was an "original source" under § 3730(e)(4)(B) and was thus not barred from bringing this action. 157 F. Supp. 3d at 1317-1325.

Specifically, Saldivar alleged improper *billing* for overfill based on his personal experience tracking the *use* of overfill along with conversations he had with other Fresenius employees and his knowledge of corporate policies. The district court found that Saldivar's allegations—that Fresenius was not just using, but billing, for overfill—had been disclosed to the government through several communications between Fresenius and CMS as well as publicly disclosed through a complaint in another case. *Id.* at 1318–1321. Moreover, the district court held that given our precedent on the issue, the disclosed information was the basis of

Saldivar's suit. *Id.* at 1321–1323. However, the district court found that Saldivar was an original source based on (a) his experience ordering and otherwise managing inventory for Zemplar and Epogen, (b) discussions with supervisors and coworkers about overfill use and billing, and (c) his familiarity with Fresenius corporate policies and clinic rankings that factored in the use of overfill. *Id.* at 1323–1326.

The proceedings were bifurcated and the parties filed motions for summary judgment on multiple distinct issues. The parties first filed motions for summary judgment on the questions of (a) if submission of claims for free overfill violated the Medicare Act and (b) if it was thus a false claim. The district court found that the submissions did violate the Medicare Act and were, as a result, false claims. *Saldivar I*. Next, the parties filed motions for summary judgment on the question of whether Fresenius's actions met the intent requirement under the FCA: that the party "knowingly" take an action. 31 U.S.C. § 3729; *U.S. ex rel. Saldivar v. Fresenius Med. Care Holdings, Inc.*, 145 F. Supp. 3d 1220 (N.D. Ga. 2015) (*Saldivar II*). The court found that Fresenius's actions did not meet the intent requirement and thus granted its motion for summary judgment. *Saldivar II*. Saldivar appeals that decision to this Court and, in its briefing, Fresenius argues again that there is no jurisdiction due to the public disclosure bar.

II.

In 2007, Saldivar started working at Fresenius as an equipment technician for two clinics, where he later became the chief technician. As an equipment technician, Saldivar repaired dialysis machines and completed other tasks as directed, including placing orders for Epogen and Zemplar. In addition to ordering the drugs, Saldivar was asked to report the "Zemplar analysis" which included an inventory form. Saldivar would input the vial count at the beginning and end of the month as well as the dosages administered. The form then automatically calculated and displayed the amount of overfill utilized throughout the month. In 2009, Saldivar began inventorying Epogen as well, though he was only responsible for inputting the vial counts—others entered the doses administered throughout the month.

With respect to these inventory forms, Saldivar was told the forms were of particular importance because they were the basis for billing medicare. Indeed, conversations about overfill and billing seem to have been fairly common. Saldivar stated that Fresenius employees talked about the company's overfill policy in meetings, in one-on-one conversations with managers, and in monthly as well as quarterly reports.

Despite being told about overfill billing and the relationship between his inventory forms and billing, Saldivar was not himself directly involved in billing. At his deposition, when asked if the inventory forms he filled out were provided to the government for billing purposes, he responded, "I have no idea. I'm pretty sure they filled out a different form for reimbursement." When asked if he had any facts, other than what he was told by managers, to suggest the inventory forms were used as the basis for billing he responded, "No. I just go by what my managers told me." At multiple points when asked about billing practices he responded that he "was not in the billing department."

Starting before Saldivar was ever hired, overfill was the subject of much discussion. Indeed, a July 2008 BNA article in "Pharmaceutical Law & Industry Report" stated that the use of overfill was "certainly not a secret," that Fresenius had publicly acknowledged its utilization—including in a disclosure to the Securities and Exchange Commission (SEC), and that overfill had been discussed in two Office of the Inspector General (OIG) reports. Fresenius was also in communication with the OIG about its overfill practices due to a "corporate integrity agreement" between Fresenius and the OIG which was in place from 2000 to 2008. During a deposition with an official from CMS, Fresenius asked specifically about CMS's knowledge of Fresenius' overfill practices. Specifically, Fresenius asked, "throughout the time period of 2000 to 2010 CMS was aware that

outpatient dialysis facilities were administering and billing for overfill for Epogen and Zemplar, right?" to which the CMS official responded "Yes." Fresenius later asked "there's simply no question that Fresenius fully disclosed to you that it was using and billing for Zemplar and Epo overfill, right?" Response: "they did disclose that to me, yes." That same official later stated he "wasn't aware of any CMS policy that prohibited the use of billing overfill," that he was under the impression Fresenius had been and still was billing for overfill as of March 2007, and that Fresenius "disclose[d] to [him] that they were using and billing for overfill Epogen and Zemplar."

Complicating the facts of this case is the 2003 passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). MMA, Pub. L. 108–173, 117 Stat. 2066 (codified in scattered sections of 42 U.S.C. and 26 U.S.C.). As part of this act, Zemplar and Epogen reimbursement were calculated by the "Average Sales Price" (ASP) beginning in 2006. In 2010, CMS announced a proposed rule, to be effective January 1, 2011, which "clarified" that billing for ESRD overfill drugs was improper under ASP. Saldivar thus argues that the operative question is Fresenius's behavior and disclosures after ASP reimbursement went into effect in 2006.

III.

We review a district court order granting summary judgment de novo, viewing the evidence and all reasonable inferences drawn from it in the light most favorable to the nonmoving party. *Battle v. Bd. of Regents for Ga.*, 468 F.3d 755, 759 (11th Cir. 2006). However, "to survive summary judgment, the nonmoving party must offer more than a mere scintilla of evidence for its position; indeed, the nonmoving party must make a showing sufficient to permit the jury to reasonably find on its behalf." *Urquilla-Diaz v. Kaplan Univ.*, 780 F.3d 1039, 1050 (11th Cir. 2015). Additionally, "[a]s courts of limited jurisdiction, we are obliged to 'scrupulously confine [our] own jurisdiction to the precise limits which the statute has defined.'" *Underwriters at Lloyd's, London v. Osting-Schwinn*, 613 F.3d 1079, 1086 (11th Cir. 2010) (quoting *Healy v. Ratta*, 292 U.S. 263, 270 (1934)). As with summary judgment, we review a district court's ruling on questions of jurisdiction de novo, *Holston Investments, Inc. B.V.I. v. LanLogistics Corp.*, 677 F.3d 1068, 1070 (11th Cir. 2012), with the burden of establishing jurisdiction being on the party bringing the claim, *Sweet Pea Marine, Ltd. v. APJ Marine, Inc.*, 411 F.3d 1242, 1247 (11th Cir. 2005).

At the time of the underlying events in this case, the FCA read, in pertinent part:

> (A) No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, 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.
>
> (B) For purposes of this paragraph, "original source" means 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)(A)-(B) (2006).[1] This Court uses a three-part inquiry to determine if jurisdiction exists under 31 U.S.C. § 3730(e): "(1) have the allegations

[1] This section was amended in 2010. The district court found that the old version of the statute applied in this case, citing *Graham Cty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson*, 559 U.S. 280, 283 (2010). Neither party has challenged that ruling. But because the pre-2010 version of the public disclosure bar was jurisdictional and subject matter jurisdiction cannot be created by waiver or forfeiture, we must determine for ourselves whether the district court was correct. *See In re Bayou Shores SNF, LLC*, 828 F.3d 1297, 1328 (11th Cir. 2016) ("When the lower court lacks jurisdiction, we have jurisdiction on appeal, not of the merits but merely for the purpose of correcting the error of the lower court in entertaining the suit.") (internal quotation marks omitted).

"United States Supreme Court decisions . . . clearly indicat[e] that statutes that affect substantive, vested rights—even when framed in jurisdictional terms—are still presumed to apply only prospectively." *Johnson v. Conner*, 754 F.3d 918, 921 (11th Cir. 2014). The 2010 amendments to the public disclosure bar changed the scope of the public disclosure defense available to Fresenius under the prior version of the False Claims Act. *See United States ex rel. May v. Purdue Pharma L.P.*, 737 F.3d 908, 914–19 (4th Cir. 2013). For that reason, we conclude that it is not retroactive and that Fresenius' conduct should be evaluated under the law as it existed at the time Fresenius submitted its allegedly false claims.

As a result, we agree with the district court that the old version of the statute applies to the portion of Saldivar's claims arising from Fresenius' billing before the March 23, 2010 effective date of the 2010 amendments. *See ex rel. May*, 737 F.3d at 914–19. We do not imply any view about whether the issues would be decided differently under the new version of the statute, except to the extent stated in the next paragraph, below.

We need not decide what version of the statute applies to Fresenius' post-March 23, 2010 conduct, because Saldivar does not have any viable claims arising from it. Saldivar was

made by the plaintiff been publicly disclosed; (2) if so, is the disclosed information the basis of the plaintiff's suit; (3) if yes, is the plaintiff an 'original source' of that information." *Cooper v. Blue Cross & Blue Shield of Fla., Inc.*, 19 F.3d 562, 565 n. 4 (11th Cir.1994).

As jurisdiction is a necessary prerequisite to addressing the merits, *Capron v. Van Noorden*, 6 U.S. (2 Cranch) 126 (1804), the Court must begin its inquiry by analyzing each part of the *Cooper* framework.

a. Have the allegations made by the plaintiff been publicly disclosed?

The district court correctly held that the allegations made had been publicly disclosed. Fresenius maintains that its practices were publicly disclosed in a number of different forums including articles, litigation, and directly to the government through the "corporate integrity agreement." As the district court properly noted and as highlighted in deposition excerpts above, it is clear from the record below that OIG was aware that Fresenius was billing for overfill. OIG affirmed that they were aware of the practice generally and that Fresenius specifically was billing for overfill. Indeed, OIG noted that Fresenius disclosed

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terminated on December 18, 2009, so any knowledge he had about Fresenius' billing after that date must have been obtained secondhand or from public disclosures. And his independent knowledge does not materially add to what was already in the public domain. As a result, Saldivar is not an original source as to any of Fresenius' post-March 23, 2010 conduct under either version of the statute.

overfill billing for both Zemplar and Epogen, the two drugs at issue in this case. This information, albeit in a more limited form, made its way into public reports. For example, the 2004 OIG report on Medicare Reimbursement for Existing End-Stage Renal Disease Drugs stated "providers reported that they are able to lower actual acquisition costs through the utilization of overfill." Moreover, Fresenius was identified in the previously mentioned July 2008 BNA article that discussed the use and profitability of overfill. Geoffrey R. Kaiser, *Overfill: A Drug Sample in Sheep's Clothing*, PHARMACEUTICAL LAW & INDUSTRY REPORT, July 2008. Fresenius has also noted that information was disclosed through an SEC filing and through prior litigation.

While it is true the law changed with the passage of the MMA, Fresenius' overfill billing was nonetheless disclosed through the avenues discussed above. The fact that the 2011 rule "clarified" the billing procedure does not change this. While sympathetic to the idea that a disclosure could grow stale due to an intervening change in law, there were repeated disclosures in this case, both before and after the passage of the MMA.[2] Moreover, the statute has no requirement that

[2] Both Fresenius and the District Court note that CMS officials knew—due to the OIG investigation—that Fresenius was billing for overfill between 2000 and 2010. We need not reach the question of whether that alone is sufficient, *see United States v. Chattanooga-Hamilton Cty. Hosp. Auth.*, 782 F.3d 260 (6th Cir. 2015), given that there were a number of public disclosures in this case.

information be repeatedly or regularly disclosed. Finally, the fact that a new rule was required to clarify ASP billing practices belies the argument Fresenius should have offered some further disclosure. Accordingly, we agree with the district court that the use and billing of overfill was publicly disclosed and decline to analyze each instance of possible public disclosure.

b. Is the disclosed information the basis of the plaintiff's suit?

The district court was likewise correct in holding that the disclosed information is the basis of Saldivar's suit. We have explained that the language of the FCA "is most naturally read to preclude suits based in *any part* on publicly disclosed information," *Cooper*, 19 F.3d at 567, and that this second prong of the inquiry is a "quick trigger to get to the more exacting original source inquiry," *id.* at 568 n. 10. Here, the claim is based on Fresenius billing Medicare for overfill it received at no cost. The public disclosures reveal it was "no secret" Fresenius was using and billing for overfill. Accordingly, the disclosed information is the basis of the plaintiff's suit.

c. Is plaintiff an original source of the information?

The third prong of the inquiry is whether plaintiff is an "original source," allowing for jurisdiction to exist even when the information has been disclosed. The statute defines an original source as one who has "direct and independent

knowledge of the information on which the allegations are based." 31 U.S.C. § 3730(e)(4)(B) (2006). Here, our holding differs from that of the district court, which held that Saldivar was an original source of the information.

Two of our prior cases help guide our thinking. In *Osheroff* there was a public disclosure that clinics were providing certain free services. *U.S. ex rel. Osheroff v. Humana Inc.*, 776 F.3d 805 (11th Cir. 2015). Relator, who was not an employee of one of clinics in question, conducted his own investigation into the value of the services being provided. *Id.* at 808. We held plaintiff was not an original source as "background information that helps one understand or contextualize a public disclosure is insufficient to grant original source status." *Id.* at 815.

Conversely, in *Cooper* there was widespread disclosure of fraud associated with Medicare Secondary Provider (MSP) laws though none against the specific defendant in question. 19 F.3d at 566. Relator filed suit after repeatedly informing defendant of the regulations and then being sent back his claims with instructions stating Medicare must pay first—a violation of MSP. *Id.* at 564. In holding relator was an original source we cited with approval "it is not necessary for a relator to have all the relevant information in order to qualify as 'independent.'" *Id.* at 568 (citing and quoting *U.S. ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v. Prudential Ins. Co.*, 944 F.2d 1149, 1160 (3d Cir. 1991)).

In this case, Saldivar alleges that Fresenius improperly billed for Zemplar and Epogen overfill. Saldivar was directly responsible for inventory sheets for Zemplar and Epogen. He tracked beginning and end of month inventory, and in the case of Zemplar, included the total dosage administered on his form. There is no dispute that he had direct and independent knowledge of the *administration* of overfill, as his inventory sheet automatically populated the overflow numbers. Saldivar was also responsible for placing orders for Zemplar and Epogen as inventory ran low. However, he stated he was not privy to price-related contracts between Fresenius and the drug distributors, and his only firsthand interaction with pricing appears to be seeing per-box prices on packing slips. With respect to billing the government, both Saldivar and the district court highlight that Saldivar was told that the "forms are the basis of billing Medicare." Moreover, Saldivar had discussions with coworkers about the use of overfill and was aware of corporate policies and reports that rewarded clinics using overfill efficiently. Fresenius claims Saldivar is not an original source because Saldivar's knowledge of the allegation—improper billing—was not direct and independent.

In order to show that a fraud has occurred, one generally must present a submitted statement or claim (X) and the true set of facts (Y), which shows that X is untrue. These two things together allow the conclusion (Z) that fraud has occurred. *See U.S. ex rel. Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645, 654

(D.C. Cir. 1994). In this instance the false claim was the bill to the government. However, the alleged true set of facts was not that overfill was administered, but rather that Fresenius was obtaining drugs at no cost to themselves yet nonetheless billing the government for those same drugs.[3] Given that Saldivar's firsthand knowledge related to inventory and administration of overfill not costs and billing, we now approach a question we have not explicitly addressed previously: whether Saldivar's secondhand knowledge is sufficient to make him an original source.

Several of our sister circuits have addressed this issue. The Tenth Circuit has held that secondhand information is insufficient. *In re Nat. Gas Royalties*, 562 F.3d 1032, 1045–46 (10th Cir. 2009) ("We conclude that this secondhand knowledge . . . does not constitute 'direct and independent' knowledge."). It has further explained that "to be independent, the relator's knowledge must not be derivative of the information of others, even if those others may qualify as original sources." *U.S. ex rel. Fine v. Advanced Scis., Inc.*, 99 F.3d 1000, 1007 (10th Cir. 1996). Likewise, the Eighth Circuit has held "a person who obtains secondhand information from an individual who has direct knowledge of the alleged fraud does not himself possess direct knowledge and therefore is not an original source under

[3] For example, in his Statement of the Case Saldivar wrote: "In this False Claims Act (FCA) case, the Relator Chester Saldivar, standing in the shoes of the United States, alleged that Fresenius violated the FCA by billing the government for the overfill of injectable drugs it received from manufacturers at no cost." Saldivar's brief does not argue that the use of overfill was fraudulent.

the Act." *U.S. ex rel. Barth v. Ridgedale Elec., Inc.*, 44 F.3d 699, 703 (8th Cir. 1995). The Eighth Circuit also took note of the False Claims Act legislative history, which explained original sources as those who were "either close observers or otherwise involved in the fraudulent activity." *Id.* (citing S. Rep. No. 345, 99th Cong., 2d Sess. 4 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5269.).

Similarly, the Third Circuit has stated that relators must have direct and independent knowledge of the "most critical" elements of their claim and that "[w]hile it is not necessary for a relator to have all the relevant information in order to qualify as 'independent,' a relator cannot be said to have direct and independent knowledge of the information on which [its fraud] allegations are based if the relator has no direct and independent knowledge of the allegedly fraudulent statements." *U.S. ex rel Mistick PBT v. Hous. Auth. of City of Pittsburgh*, 186 F.3d 376, 389 (3d Cir. 1999) (internal citations omitted).

Finally, in *Glaser v. Wound Care Consultants, Inc.*, plaintiff was a patient who was treated several times by a physician's assistant. 570 F.3d 907 (7th Cir. 2009). She filed an FCA claim alleging that defendant was overbilling Medicare by having the physician's assistants bill at the rate for doctors. *Id.* at 911. While the case was extreme in that plaintiff had no knowledge at all of defendant's billing practices until contacted by a lawyer, the Seventh Circuit's holding—that plaintiff

needed to have direct and independent knowledge of the *billing*, not just the treatment, *id.* at 921, is persuasive.

We find the reasoning of our sister circuits persuasive when reading the statute. The phrase "direct and independent" is most naturally read as creating an extreme limit on secondhand knowledge that is sufficient to qualify as an "original source." Being told what another department is doing is almost necessarily not direct knowledge of that department's behavior. In this case, Saldivar was told that inventory spreadsheets were used for billing purposes. This is not direct knowledge of the alleged improper billing. Indeed, it is on its face indirect; he was told by another that his work product was used, and it appears he had no direct knowledge of how billing occurred or even how his inventory was factored into the billing.

In addition to being told his inventory was used for billing purposes, Saldivar heard about overfill billing practices from others. This likewise is indirect. Saldivar was the chief technician for two clinics, and while he appears to have had a number of different tasks he stated multiple times that he was not in the billing department and thus could not speak to many billing related practices. As he himself attested, he went "by what [his] managers told [him]." This too is attenuated, rather than direct, knowledge.

Finally, Saldivar saw various reports that ranked or scored clinics, including by their efficiency in utilizing overfill. The Court does not doubt that one could easily infer from these, particularly when combined with what was being said by managers and publicly disclosed, that Fresenius was charging for overfill. However, to hold that merely reading a company's quarterly reports grants direct knowledge to the underlying activity would be to create a large aperture, rendering the word "direct" in the statute near meaningless.

The FCA requires the Attorney General to investigate alleged violations. 31 U.S.C. § 3730(a). That is, the mere act of a relator filing under the FCA triggers government action. To open the meaning of "direct" into something broader would thus not only run contrary to the "cardinal" canon of construction that the legislature "means in a statute what it says there," *Con. Nat. Bank v. Germain*, 503 U.S. 249, 253–254 (1992), but potentially upset the Congressionally determined balance between incentivizing *qui tam* suits on the one hand and flooding the Department of Justice with required investigations on the other.

While Saldivar had independent knowledge of the administration of overfill, his knowledge of the critical component—the alleged billing for drugs Fresenius received at no cost—was derived from secondhand sources. To the extent Saldivar's information is not secondhand, it appears to be more akin to *Osheroff*'s background information, e.g., what inventory forms looked like or how they were

filled out, than the direct knowledge in *Cooper*. Saldivar thus fails to meet an essential element of the original source requirement, that he have "*direct and independent knowledge* of the information on which the allegations are based." 31 U.S.C. § 3730(e)(4)(B) (2006) (emphasis added).

IV.

As we find that the allegations that are the basis of this complaint were publicly disclosed and that Saldivar is not an original source, the Court lacks jurisdiction to hear this case. We do not reach the merits of the motion for summary judgment granted by the court below.

The district court's grant of summary judgment on the merits is **REVERSED** and the case is remanded for entry of an order dismissing the case for lack of subject matter jurisdiction.

REVERSED AND REMANDED