United States Court of Appeals
For the Eighth Circuit

No. 13-2509

United States ex rel. Lonnie Paulos, MD

Plaintiff - Appellant

v.

Stryker Corporation; I-Flow Corporation

Defendants - Appellees

Orthofix International, as Successor to Breg, Inc.

Defendant

No. 13-2647

United States ex rel. Lonnie Paulos, MD

Plaintiff - Appellee

v.

Stryker Corporation; I-Flow Corporation

Defendants - Appellants

Orthofix International, as Successor to Breg, Inc.

Defendant

Appeal from United States District Court
for the Western District of Missouri - Kansas City

Submitted: April 17, 2014
Filed: August 7, 2014

Before RILEY, Chief Judge, BENTON and KELLY, Circuit Judges.

RILEY, Chief Judge.

In the early 2000s, doctors saw a spike in the number of patients developing chondrolysis—a rare and "painful medical condition whereby an individual loses articular cartilage in a joint," Mack v. Stryker Corp., 748 F.3d 845, 848 (8th Cir. 2014). Concern then surfaced that this spike was related to the use of medical devices known as "pain pumps" to deliver anesthetics via catheter into patients' joint spaces (the area surrounding a joint).[1] See, e.g., id. at 848, n.3; Huggins v. Stryker Corp., 932 F. Supp. 2d 972, 978 (D. Minn. 2013). This concern triggered several studies on the effects of placing pain pumps in patients' joint spaces and also bred numerous product liability lawsuits against pain pump manufacturers like Stryker Corporation (Stryker) and I-Flow Corporation (I-Flow). See, e.g., Mack, 748 F.3d at 847-48; Rodriguez v. Stryker Corp., 680 F.3d 568, 570 (6th Cir. 2012); Meharg v. I-Flow Corp., No. 1:08-CV-184-WTL-TAB, 2010 WL 711317 (S.D. Ind. Mar. 1, 2010) (unpublished).

[1]Like the parties and the district court below, we use the terms "intra-articular space," "synovial cavity," and "joint space" interchangeably.

Unlike most pain pump litigants, who raise product liability claims, Dr. Lonnie Paulos (an orthopedic surgeon and former consultant at Stryker) alleges Stryker and I-Flow violated the False Claims Act (FCA) by marketing their pain pumps to encourage the placement of pain pumps directly into patients' joint spaces after orthopedic procedures. The district court[2] dismissed Dr. Paulos's claims under 31 U.S.C. § 3730(e)(4)(A), concluding Dr. Paulos's allegations had been publicly disclosed and Dr. Paulos was not excepted under 31 U.S.C. § 3730(e)(4)(B) as an "original source" of the information.[3] Dr. Paulos appeals, challenging both conclusions. We exercise our appellate jurisdiction under 28 U.S.C. § 1291 and affirm.

I. BACKGROUND

The parties agree the Food and Drug Administration (FDA) has given "§ 510(k)" clearance[4] to market pain pumps *generally* for "intraoperative" use. Dr. Paulos claims the FDA has consistently refused to approve marketing pain pumps *specifically* for orthopedic placement in joint spaces.[5] Dr. Paulos filed this suit on January 10, 2011, and according to his amended complaint, Stryker and I-Flow

---

[2]The Honorable Ortrie D. Smith, United States District Judge for the Western District of Missouri.

[3]The district court dismissed additional claims against Stryker and I-Flow as well as claims against other defendants not relevant to this appeal.

[4]"The '510(k)' process is named after the section number given to this process in the Medical Device Amendments of 1976." Mack, 748 F.3d at 855 n.7. Such clearance permits the marketing of a device without pre-market safety testing where "a substantially similar product is currently in use for that purpose." Id. at 855 (internal quotations omitted).

[5]Whether joint space use is included in the broader term of "intraoperative" area use is another question, see, e.g., Rodriguez, 680 F.3d at 574 (concluding "the indication for use that the FDA *did* approve—using the pump at the 'intra-operative site'—covers the use of the pump in a joint"), which we need not address today.

marketed pain pumps for placement specifically in joint spaces while knowingly (1) "[f]ail[ing] to disclose . . . material information" about the dangers of using pain pumps in joint spaces or to disclose the lack of safety testing for joint space use; (2) providing "[f]alse[] indicati[ons] that the pain pumps were approved [by the FDA] for use" in joint spaces; and (3) providing "[f]alse labeling and promotion materials" suggesting such use. Dr. Paulos alleges these marketing efforts constituted intentional fraud and induced many healthcare providers to use pain pumps in their patients' joint spaces. He claims that because many of these healthcare providers sought reimbursement for the pain pumps through federal programs like Medicaid or Tricare, Stryker and I-Flow thereby caused the submission of "false or fraudulent claim[s] for payment" in violation of 31 U.S.C. § 3729(a).

Dr. Paulos also asserts he and a colleague, Dr. Charles Beck, were among the first to suspect and investigate the placement of pain pumps as a cause for chondrolysis after Dr. Beck approached Dr. Paulos with this theory. Dr. Paulos claims Stryker knew of the increased risk of chondrolysis early on and alleges he warned Stryker of his and Dr. Beck's concern that the uptick in chondrolysis could be related to the use of pain pumps.

After the district court unsealed Dr. Paulos's *qui tam* complaint, Stryker and I-Flow filed a joint motion to dismiss pursuant to 31 U.S.C. § 3730(e)(4)(A) and contended (1) the same fraud alleged in Dr. Paulos's complaint had been publicly disclosed, and (2) Dr. Paulos was not excepted as an "original source" of the information underlying his claims. Over Dr. Paulos's counterarguments on both points, the district court granted the motion and dismissed Dr. Paulos's claims. Dr. Paulos timely appeals.[6]

[6]In their cross-appeals, Stryker and I-Flow both challenge the district court's adverse conclusions on other bases for dismissal, effectively raising alternative arguments for affirmance. Because we agree with the district court's conclusion on the public disclosure bar, we need not confront these alternative arguments.

II. DISCUSSION

In the FCA, Congress included what is nicknamed a "public disclosure bar" which prevents *qui tam* relators from suing for fraud against the government when that fraud is already publicly known. In principle, the FCA's *qui tam* provision "'is designed to promote private citizen involvement in exposing fraud against the government, while at the same time,'" the public disclosure bar works to "'prevent parasitic suits by opportunistic late-comers who add nothing to the exposure of the fraud.'" Costner v. URS Consultants, Inc., 153 F.3d 667, 675-76 (8th Cir. 1998) (quoting United States ex rel. Rabushka v. Crane Co., 40 F.3d 1509, 1511 (8th Cir. 1994)). The FCA provides:

> (A) The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed—
>
> > (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;
> >
> > (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or
> >
> > (iii) from the news media.

31 U.S.C. § 3730(e)(4).[7] A relator's claim is excepted from this public disclosure bar, however, if the relator is an "original source of the information." Id. § 3730(e)(4)(A). This original source exception applies in two situations—where the relator

[7]At Paulos's "urging, this court assumes, without deciding, that the current version of the FCA applies." United States ex rel. Kraxberger v. Kan. City Power & Light Co., ___ F.3d ___, ___ n.2, No. 13-2759, 2014 WL 2898465, at *2 n.2 (8th Cir. June 27, 2014).

> either ([1]) prior to a public disclosure under subsection (e)(4)([A]), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.

Id. § 3730(e)(4)(B). Dismissal under the public disclosure bar is thus required if (1) the defendant has shown public disclosure under § 3730(e)(4)(A), and (2) the relator does not fit § 3730(e)(4)(B)'s definition of "original source." We review de novo the district court's conclusions on both points. See Kraxberger, ___F.3d at ___, 2014 WL 2898465, at *1.

A. Public Disclosure

Dr. Paulos's claims were publicly disclosed "if substantially the same allegations or transactions" as he alleges were "publicly disclosed" in § 3730(e)(4)(A)'s enumerated channels. The district court found these requirements were met because numerous media reports, FDA reports, and federal regulatory disclosures essentially revealed the allegations of fraudulent marketing forming the basis for Dr. Paulos's claims. Dr. Paulos does not challenge the district court's use of these sources as falling within the statute's listed channels of disclosure. Instead, he argues the specific fraudulent acts at issue here were not publicly disclosed and only appear substantially similar to the public disclosures at the "highest level of generality." We disagree.

First, Dr. Paulos seems to maintain the public reports did not disclose his allegations that (1) "surgeons were not being told that the devices could cause joint damage," (2) "surgeons were told the devices were approved for use," and (3) "the devices were being marketed off label." As the district court discussed in detail, the public documents laid out precisely these points. These independent sources show

the following allegations and transactions: (1) various pain pump manufacturers attempted numerous times to obtain FDA approval to market pain pumps for placement in joint spaces, and in every instance the FDA refused approval; (2) Stryker and I-Flow nevertheless encouraged healthcare providers to use pain pumps in joint spaces; (3) neither company disclosed the lack of FDA approval for this use; (4) both companies knew the pumps had never been safety-tested for such use; and (5) both companies continued to market pain pumps for such use even after learning of a possible connection to chondrolysis.

Attempting to distinguish his fraud claims from these public disclosures, Dr. Paulos contends the public disclosures "do not establish the key part of this False Claims case: specifically, [Stryker's and I-Flow's] scienter." Dr. Paulos maintains the disclosures do not allege "any physician (specifically, Dr. Paulos and/or Dr. Beck) told the manufacturers that their course of conduct was directly causing" physicians to use pain pumps in a way that injured patients. On the contrary, one report expressly discloses that Dr. Beck suggested the causal connection to the pain pump manufacturers as early as 2005, and another report alleges I-Flow admittedly knew of a 2006 study linking chondrolysis to joint space use of pain pumps. Many of the cited documents clearly implicate the companies' knowledge of the pain pumps' connection to chondrolysis and the lack of FDA approval.

Dr. Paulos finally proposes that, unlike his claims, the public disclosures fail to allege that the companies misled healthcare providers about the absence of FDA approval. The record contradicts this proposition, revealing several public allegations that the FDA had not approved the joint space use of pain pumps and that Stryker's and I-Flow's marketing practices hid this lack of approval while promoting joint space use.

Finding no meaningful distinction between the public disclosures and Dr. Paulos's claims, we conclude the district court did not err in finding a public

disclosure sufficient to meet § 3730(e)(4)(A).[8] Therefore, Dr. Paulos's "claim[s] succeed[] only if he is an 'original source'" under § 3730(e)(4)(B). Kraxberger, ___F.3d at ___, 2014 WL 2898465, at *3.

B. Original Source Exception

Dr. Paulos qualifies as an "original source" if (1) before the public disclosures, he "voluntarily disclosed to the Government the information on which" his claims' "allegations or transactions . . . are based," or (2) he "has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and . . . has voluntarily provided the information to the Government before filing [this] action." 31 U.S.C. § 3730(e)(4)(B). Dr. Paulos does not claim to have volunteered his information to the government before the public disclosures of fraud, so we need only discuss his potential qualification as the second type of "original source."

---

[8]The district court noted "there were no public disclosures that doctors and hospitals submitted claims for payment" to the federal government, but the district court reasoned this additional fact merely "add[ed] some color" and supplied further detail but did not materially distinguish Dr. Paulos's FCA claim from the public disclosures of the underlying fraud. See, e.g., United States ex rel. Poteet v. Bahler Med., Inc., 619 F.3d 104, 115 (1st Cir. 2010); Dingle v. Bioport Corp., 388 F.3d 209, 215 (6th Cir. 2004). The district court further reasoned, "The logical consequence of the[alleged] misrepresentations (assuming the correctness of [Dr. Paulos's] depiction of the repayment programs' requirements and other legal theories) is that any doctor or hospital seeking payment from these federal programs would be submitting a false claim for payment." We have indicated, under a prior version of the public disclosure bar statute, that a relator's claim cannot be "'based upon . . . public disclosure of allegations or transactions'" where the public disclosure fails to reveal "the false claim itself," United States ex rel. Hixson v. Health Mgmt. Sys., Inc., 613 F.3d 1186, 1188 (8th Cir. 2010) (omission in original) (quoting 31 U.S.C. § 3730(e)(4)(A) (2008)), but Dr. Paulos does not challenge the district court's reasoning or conclusion. We therefore neither address it nor express an opinion on the continuing applicability of Hixson's standard under the current version of the statute.

At scattered points throughout his opening brief, Dr. Paulos appears to claim independent knowledge of (1) the connection between pain pumps and chondrolysis after assisting Dr. Beck's initial research in the area, and (2) Stryker's scienter by way of having informed a Stryker executive of the suspected connection between its pain pumps and chondrolysis. Even assuming Dr. Paulos's knowledge is independent, his information on these points does not "materially add[] to the publicly disclosed allegations or transactions." Id. § 3730(e)(4)(B)(2).

First, Dr. Paulos bases much of his "original source" argument on his claim that he was among the first to suspect and investigate a causal connection between pain pumps and chondrolysis. Dr. Paulos's complaint shows that from an early point, he was involved in discussions with colleagues on the chondrolysis issue and that during this time he treated at least one patient suffering from chondrolysis (and was referred several others). Dr. Paulos also claims to have spoken with Dr. Beck about Dr. Beck's early research investigating the connection. A relator is not an original source of information under the statute simply because he discovered or suspected it *first*. See 31 U.S.C. § 3730(e)(4)(B) (containing no requirement or exception for early discoveries or suspicions).

The connection between device and disease (and details of the science and studies supporting it) can be found in numerous news media and FDA reports. Other than the causal connection itself, Dr. Paulos has not clarified what information his own conversations or research revealed, what these details add to the public knowledge base, or how any such additions are material to his FCA claims. With the key facts to Dr. Paulos's FCA claims—i.e., the lack of safety testing and causal connection between device and disease—already thoroughly revealed and without any clear sense about what new information Dr. Paulos brings to the table, we cannot say his knowledge (even if gained early and independently) materially contributes anything of import to the public knowledge about the alleged fraud. See Kraxberger, ___F.3d at ___, 2014 WL 2898465, at *3 (concluding relator's knowledge did not

"materially add to what was publicly disclosed" because essentially all of relator's knowledge relevant to his FCA claim appeared in existing public disclosures); see also New Oxford American Dictionary 18, 1079 (3d ed. 2010) (defining "add" as to "put (something) in or on something else so as to improve or alter its quality or nature" and to "contribute (an enhancing quality) to something"; defining "materially" as "substantially; considerably").

The focus of FCA liability is on knowing fraud in seeking federal funds, see 31 U.S.C. § 3729(a)(1)(A)-(G); In re Baycol Prods. Litig., 732 F.3d 869, 875 (8th Cir. 2013), and the FCA is generally unconcerned with claims of negligence or underlying "regulatory noncompliance," see U.S. ex rel. Vigil v. Nelnet, Inc., 639 F.3d 791, 795-96 (8th Cir. 2011); Hays v. Hoffman, 325 F.3d 982, 991 (8th Cir. 2003). We fail to see how the addition of Dr. Paulos's personal insight on the science behind chondrolysis would contribute much more than tangentially relevant information to the central questions of Dr. Paulos's fraud claim.

Second, Dr. Paulos asserts he has independent knowledge relating to Stryker's scienter in that he warned Stryker executives of a connection between the pain pumps and chondrolysis. Dr. Paulos's complaint focuses on one communication in particular—a 2005 fax and e-mail he sent to a Stryker executive in which Dr. Paulos claimed to know of several cases in which patients unexpectedly developed chondrolysis and explained "[t]he only common link [wa]s the pain-dripping devices [pain pumps] with Marcaine or Lidocaine and Epinephrine." He also shows that a Stryker executive passed along Dr. Paulos's warning and noted the concern "that Marcaine w[ith] epi[nephrine]" may be "rotting the cartilage in shoulders." Dr. Paulos seems to assume his communications alerted Stryker about the danger of placing pain pumps in joint spaces, but "there was no mention whatsoever in these . . . communications regarding pain pump *placement*" as relevant to Dr. Paulos's chondrolysis concerns. See Phillippi v. Stryker Corp., No. 2:08-CV-02445-JAM-KJN, 2010 WL 2650596, at *2 (E.D. Cal. July 1, 2010) (unpublished) (emphasis

added) (examining Dr. Paulos's same communications in a pain pump product liability case), aff'd, 471 F. App'x 663 (9th Cir. 2012) (mem. op.) (reviewing the district court's grant of summary judgment de novo and concluding, "as the district court found, [plaintiff] provided insufficient evidence to raise a known or knowable risk of chondrolysis at the time of [plaintiff's] surgery"). Instead, Dr. Paulos singled out the use of certain *drug combinations* with the pain pump, specifying this was the "*only common link*" between Dr. Paulos's chondrolysis patients. (Emphasis added). See id. Although scienter in presenting false or fraudulent claims is certainly a necessary and important element in any FCA claim, see 31 U.S.C. § 3729(a)(1)(A)-(G); Baycol, 732 F.3d at 875, we, like the court in Phillippi, determine Dr. Paulos's warnings on the use of certain anesthetics in pain pumps was unhelpful and largely irrelevant in assessing whether Stryker knew the dangers of using pain pumps in *joint spaces*.

To the extent Dr. Paulos's independent warning can be said to have put Stryker on notice of the chondrolysis issue generally, the public reports discussed above indicate Stryker already had reason to know of the pain pumps' connection to chondrolysis after orthopedic uses while also disclosing allegations that (1) Dr. Beck supplied the results of his study to the pain pump manufacturers, and (2) Stryker *knowingly* misrepresented the dangers of pain pump placement. Given the limited value of Dr. Paulos's communication in proving Stryker acted knowingly and also the extent of the public disclosure on the issue, we are not convinced Dr. Paulos's warning added significantly to the scienter issue. See, e.g., New Oxford American Dictionary, supra, at 18, 1079.

Because Dr. Paulos's proposed independent knowledge cannot be said to "materially add[] to the publicly disclosed allegations or transactions," he is not an "original source" under 31 U.S.C. § 3730(e)(4)(B)(2).

C. Procedural Issues

Finally, Dr. Paulos faults the district court for looking to materials outside the pleadings in resolving Stryker and I-Flow's motion to dismiss. Even though Dr. Paulos opposed the motion by submitting his own additional materials outside the pleadings, he complains the district court should not have looked to the public disclosure documents. He contends the motion essentially "amount[ed] to a [Federal Rule of Civil Procedure] 12(b)(6) motion" so that the district court should have converted the motion to one for summary judgment pursuant to Rule 12(d).

Assuming the motion is best viewed as one made under Rule 12(b)(6), a court "may [still] consider 'matters incorporated by reference or integral to the claim, items subject to judicial notice, [and] matters of public record.'" Kraxberger, ___F.3d at ___, 2014 WL 2898465, at *6 (second alteration in original) (quoting Miller v. Redwood Toxicology Lab., Inc., 688 F.3d 928, 931 n.3 (8th Cir. 2012)). And "[s]ince the FCA *requires* a court to dismiss a claim based on public disclosure, a court necessarily considers the alleged public documents in its dismissal." Id. Because the documents utilized by the district court "are integral to the claim, subject to judicial notice, matters of public record, or evidence of public disclosure the court properly considered under 31 U.S.C. § 3730(e)(4)," we reject this claim of procedural error. Id.

III. CONCLUSION

We affirm.
