United States Court of Appeals
For the Eighth Circuit

No. 16-1452

United States of America

Plaintiff

Shane Lager

Plaintiff - Appellant

v.

CSL Behring, L.L.C.; CSL Limited; Accredo Health, Incorporated; Coram LLC

Defendants - Appellees

Appeal from United States District Court
for the Eastern District of Missouri - St. Louis

Submitted: December 15, 2016
Filed: May 5, 2017

Before WOLLMAN and SMITH,[1] Circuit Judges, and WRIGHT,[2] District Judge.

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[1]The Honorable Lavenski R. Smith became Chief Judge of the United States Court of Appeals for the Eighth Circuit on March 11, 2017.

[2]The Honorable Wilhelmina M. Wright, United States District Judge for the District of Minnesota, sitting by designation.

SMITH, Circuit Judge.

Relator Shane Lager brought this *qui tam* action pursuant to the False Claims Act (FCA), 31 U.S.C. §§ 3729 *et seq.*, alleging that drug manufacturer CSL Behring, LLC, and its parent corporation CSL Behring Limited (collectively, "CSL Behring") conspired with pharmacies Accredo Health, Inc., ("Accredo") and Coram LLC ("Coram") to submit false claims to the United States for reimbursement for prescription drugs. The government declined to intervene. CSL Behring, Accredo, and Coram (collectively, "defendants") moved to dismiss the complaint based on, among other things, the FCA's public disclosure bar, 31 U.S.C. § 3730(e)(4)(A). The district court[3] granted the motion. Lager appeals this dismissal, and we affirm.

I. *Background*

"We accept as true the material allegations in the complaint and present the facts in the light most favorable to [Lager]." *Kulkay v. Roy*, 847 F.3d 637, 640 (8th Cir. 2017). Lager worked for CSL Behring for 14 years in sales and sales management. CSL Behring manufactures and distributes protein-based therapies, including Vivaglobin and Hizentra. These drugs are self-administered by patients through a pump. This pump qualifies as "Durable Medical Equipment" (DME) under the Medicare statutes. CSL Behring began marketing and distributing Vivaglobin in 2006 but discontinued Vivaglobin in 2011. CSL Behring introduced Hizentra in 2010 and continues to manufacture it. Seventy percent of CSL Behring's sales of Vivaglobin and Hizentra are made to Coram and Accredo.

Pharmacies that dispense drugs to beneficiaries of government health care programs (such as Medicare) submit claims for reimbursement to the federal

[3]The Honorable Carol E. Jackson, United States District Judge for the Eastern District of Missouri.

government. Since Congress's enactment in 2003 of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), 42 U.S.C. §§ 1395w-21–1395w-28, most drugs that Medicare and other government health programs cover are reimbursed based on the average sales price (ASP). *See* 42 U.S.C. §§ 1395u(o), 1395w-3, 1395w-3a, 1395w-3b. However, the MMA excluded DME infusion drugs, such as Vivaglobin and Hizentra; instead, reimbursements for these drugs are based on 95 percent of the average wholesale price (AWP). While the ASP is based on actual sales data, the AWP is based on figures that the drug manufacturer reports to third-party publishers, such as Red Book. Office of Inspector Gen., U.S. Dep't of Health & Human Servs., OEI-12-12-00310, *Part B Payments for Drugs Infused Through Durable Medical Equipment* at 2–3 (2013) ("2013 OIG Report"). And, while the ASP is defined by law, the AWP is not. *See* Office of Inspector Gen., U.S. Dep't of Health & Human Servs., OEI-03-05-00200, *Medicaid Drug Price Comparison: Average Sales Price to Average Wholesale Price* (2005) ("2005 OIG Report"). The ASP is "substantially lower" than the AWP. *Id*. at 8. For example, in 2004, "[f]or 2,077 national drug codes with ASP and AWP data, ASP [was] 49 percent lower than AWP at the median." *Id*.

"Initially, AWP was the average price charged by wholesalers to providers, like doctors and pharmacies." *In re Pharm. Indus. Average Wholesale Price Litig*., 491 F. Supp. 2d 20, 33 (D. Mass. 2007), *aff'd*, 582 F.3d 156 (1st Cir. 2009). The AWP was "derived from the markup charged by wholesalers over their actual acquisition cost, sometimes called the 'Wholesale Acquisition Cost' or 'WAC.'" *Id*. Historically, providers added a 20 to 25 percent markup to the price that they paid to manufacturers. *Id*. "At some point, though, because of consolidation and competition among wholesalers, these standard markups on branded drugs no longer reflected actual wholesaler margins, which were reduced to 2 to 3 percent." *Id*. As a result, the actual AWP that wholesalers charged "to providers was much lower than the 20 or 25 percent markup over WAC." *Id*.

Lager brought this *qui tam* action pursuant to the FCA against CSL Behring, Accredo, and Coram, alleging that they agreed to and engaged in a joint action to defraud the government over the course of several years. Specifically, Lager alleges that CSL Behring reported inflated AWPs for Vivaglobin and Hizentra to third-party publishers when, in actuality, the "true selling price" at which CSL sold the drugs was "substantially less than their falsely reported amounts." Lager alleges that CSL Behring used the "spread" between the actual cost and the reported AWPs to induce their customers, including Accredo and Coram, to buy its products. Lager alleges that Accredo and Coram then sought out patients covered by government health programs to take advantage of the spread. As a result of the defendants' conduct, Lager claims that the federal government has overpaid in excess of $100 million for Vivaglobin and in excess of $180 million for Hizentra.

After the United States declined to intervene in Lager's suit, the defendants moved to dismiss the complaint (1) under the FCA's public disclosure bar, 31 U.S.C. § 3730(e)(4)(A); (2) for failure to plead fraud with particularity under Federal Rule of Civil Procedure 9(b); and (3) for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6).[4] The district court dismissed Lager's complaint pursuant to the FCA's public disclosure bar, which bars an action or claim "if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed" in qualifying sources. 31 U.S.C. § 3730(e)(4)(A). First, the court discussed the "public disclosures regarding DME infusion drugs, generally." *United States ex rel. Lager v. CSL Behring, LLC*, 158 F. Supp. 3d 782, 789 (E.D. Mo. 2016). The court recognized that "[m]ultiple government sources have long disclosed that AWP does not represent the actual prices of drugs." *Id.* at 788. The district court also cited several media sources as previously reporting that AWPs do not reflect actual drug prices. *Id*. And the court found that "multiple disclosures" showed that

[4]CSL Behring additionally moved to dismiss for insufficient process pursuant to Federal Rule of Civil Procedure 12(b)(5).

"manufacturers used the difference between actual costs and AWPs to influence sales." *Id*. The court cited *Wholesale Price Litigation* (a 2007 decision) as explaining the negative effect of AWP-based reimbursements. *Id*. at 789 (citing *Wholesale Price Litig.*, 491 F. Supp. 2d at 30–31).

Second, the district court discussed "public disclosures regarding the AWP and ASP for Vivaglobin and Hizentra." *Id*. at 789. According to the court, "[t]he third-party publications publish AWPs, while the Centers for Medicare & Medicaid Services (CMS) publishes ASPs for drugs on a quarterly basis." *Id*. Based on publicly available figures derived from CMS and Red Book, Coram had provided the following table to the district court:

Quarter	Vivaglobin AWP	Vivaglobin ASP	Hizentra AWP	Hizentra ASP
2007Q4	$127.57	$66.75	N/A	N/A
2008Q4	$119.82	$66.06	N/A	N/A
2009Q4	$119.96	$67.85	N/A	N/A
2010Q4	$119.95	$68.42	N/A	$68.72
2011Q4	N/A	N/A	$151.07	$68.74
2012Q4	N/A	N/A	$150.66	$68.74
2013Q4	N/A	N/A	$150.96	$72.44

Id. at 790. The court characterized this table as "showing the significant spread between ASPs and AWPs for Vivaglobin and Hizentra for the years 2007 through 2013." *Id.* at 789.

Third, in response to Lager's argument that his allegations of fraud are based on the difference between the "actual AWPs" and the "reported AWPs" and *not* based on the "simple, irrelevant disparity between the ASPs and the reported AWPs" for the drugs, the district court found that "the term 'actual AWP' is meaningless in the absence of any statutory or regulatory definitions." *Id*. at 791. The court also found

that the "target of relator's allegations is the difference between the AWPs and what he calls the drugs' 'true selling prices'"; according to the court, "true selling prices" are the same as the ASPs for the drugs. *Id*.

Having reviewed all the sources that the defendants put forth, the district court concluded that "[a]ll the essential elements of relator's claims were publicly disclosed before he filed suit." *Id*.

The district "[c]ourt decline[d] to address defendants' remaining arguments in any detail," but it did note that Lager's complaint lacked a "single, specific instance of fraud, much less any representative examples" and therefore failed to satisfy Rule 9(b). *Id*. at 793 (quoting *United States ex rel. Joshi v. St. Luke's Hosp., Inc*., 441 F.3d 552, 557 (8th Cir. 2006)). The court denied Lager's request to amend his complaint and granted the defendants' motion to dismiss.

II. *Discussion*

On appeal, Lager argues that the district court erroneously applied the public disclosure bar to his FCA claim because the disclosures that the district court relied on (1) do not readily identify the defendants in this case; and (2) do not contain "substantially the same allegations or transactions," 31 U.S.C. § 3730(e)(4)(A), as those contained in Lager's complaint or reveal any of the defendants' fraudulent activity.

The FCA imposes civil liability on one who "knowingly presents . . . a false or fraudulent claim [to the government] for payment or approval." 31 U.S.C. § 3729(a)(1)(A). "Almost unique to the FCA are its *qui tam* enforcement provisions, which allow a private party known as a 'relator' to bring an FCA action on behalf of the Government." *State Farm Fire & Cas. Co. v. United States ex rel. Rigsby*, 137 S. Ct. 436, 440 (2016). The FCA also provides that the Attorney General may "intervene in a relator's ongoing action or . . . bring an FCA suit in the first instance."

Id. The FCA's *qui tam* enforcement provision "is designed to benefit both the relator and the Government. A relator who initiates a meritorious *qui tam* suit receives a percentage of the ultimate damages award, plus attorney's fees and costs." *Id*. Additionally, private enforcement "strengthen[s] the Government's hand in fighting false claims." *Id*. (quoting *Graham Cty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 298 (2010)).

However, "[t]he FCA places a number of restrictions on suits by relators." *Id*. "At the same time that the statute encourages whistleblowers, it discourages 'opportunistic' plaintiffs who 'merely feed off a previous disclosure of fraud.'" *United States v. Walgreen Co.*, 846 F.3d 879, 880 (6th Cir. 2017) (quoting *United States ex rel. Poteet v. Medtronic, Inc*., 552 F.3d 503, 507 (6th Cir. 2009)). As a result, "individual plaintiffs cannot bring *qui tam* complaints based upon information already in the public domain." *Id*. Section 3730(e)(4)(A)—known as the public disclosure bar—provides that a

> 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,
>
> 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) (footnote omitted).

"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.'" *United States ex rel. Paulos v. Stryker Corp.*, 762 F.3d 688, 692 (8th Cir. 2014).[5] We apply de novo review to the district court's determination that the public disclosure bar applies to a relator's complaint. *Id*.

A. *Identification of the Defendants*

We will first address Lager's contention that the public disclosures that the district court relied on do not identify the defendants. According to Lager, the public disclosure bar is inapplicable when the disclosures fail to specifically identify the defendants named in the *qui tam* action with the specific fraud at issue. He asserts that 15 of the 17 disclosures that the district court relied on make no mention of the defendants or of transactions involving Vivaglobin and Hizentra. According to Lager, only two disclosures "specifically discuss the Defendants and Specified Drugs at issue in this litigation" without tying them to the specific fraud. He additionally maintains that only in "very limited circumstances" have courts "applied the public disclosure bar in cases where the defendants named in the *qui tam* action were *identifiable*, though not specifically named in the disclosures." He urges that these cases are inapplicable to the present case because they concern "defendants operating in very narrow industries, and where the public disclosures were of industry-wide fraud."

"Several circuits have . . . addressed the issue of unnamed wrongdoers in the context of the FCA's public disclosure bar . . . ." *United States ex rel. Branch*

[5]The district court concluded that Lager failed to satisfy the original source exception to the public disclosure bar. *CSL Behring*, 158 F. Supp. 3d at 793. Lager has not challenged this conclusion on appeal.

Consultants v. Allstate Ins. Co., 560 F.3d 371, 379 (5th Cir. 2009) (citing *United States ex rel. Gear v. Emergency Med. Assocs. of Ill., Inc.*, 436 F.3d 726, 729 (7th Cir. 2006) (holding industry-wide public disclosures of Medicare fraud barred *qui tam* actions "against any defendant who is directly identifiable from the public disclosures"); *United States v. Alcan Elec. & Eng'g, Inc.*, 197 F.3d 1014, 1019 (9th Cir. 1999) (holding public disclosures of fraud failing to identify specific defendants but pertaining to "a narrow class of suspected wrongdoers—local electrical contractors who worked on federally funded projects over a four-year period"—triggered the public disclosure bar as to those contractors); *United States ex rel. Fine v. Sandia Corp.*, 70 F.3d 568, 571–72 (10th Cir. 1995) (holding where public disclosures "revealed that at least two of [the laboratory's] eight sister laboratories were engaged in" a fraud, the government would have little trouble "examining the operating procedures of nine, easily identifiable, [Department of Energy]-controlled, and government-owned laboratories"); *United States ex rel. Cooper v. Blue Cross & Blue Shield of Fla., Inc.*, 19 F.3d 562, 566 (11th Cir. 1994) (per curiam) (holding allegations of widespread Medicaid fraud made in disclosures in which a particular insurance company was not specifically named or otherwise directly identifiable were insufficient to trigger the public disclosure bar)).

Lager asserts that *Cooper* articulates the appropriate standard for identifying defendants for purposes of the public disclosure bar. *See* 19 F.3d at 566. In *Cooper*, a "working aged" federal employee (the relator) "qualified for both Medicare and the Federal Employees Health Benefits Program," which the defendant administered. *Id.* at 564. Over a two-year period, when the relator submitted a claim for medical bills to the defendant, the defendant would typically return the claim to the relator with instructions to submit the claim to Medicare first. *Id.* After the relator learned that the defendant was required to pay on his claims before sending the balance to Medicare, he filed suit under the FCA, alleging that the defendant "committed fraud against the government by submitting his claims to Medicare when [the defendant] knew it was required to pay primary." *Id.* at 564–65. The defendant moved to dismiss, arguing that

the allegations were publicly disclosed by several sources that mentioned similar activities to the ones that the relator alleged. *Id*. at 565. Some of these source materials mentioned the defendant by name, while others made general allegations of fraud against the healthcare industry. *Id*. at 566–67.

The Eleventh Circuit "consider[ed] it to be crucial whether [the defendant] was mentioned by name or otherwise specifically identified in public disclosures" and "consider[ed] separately those sources in which it was identified and those in which it was not." *Id*. at 566. The court held that "[t]he allegations of widespread . . . fraud made in sources in which [the defendant] was *not specifically named or otherwise directly identified* are insufficient to trigger the jurisdictional bar." *Id*. (emphasis added). The court explained:

> Requiring that allegations specific to a particular defendant be publically disclosed before finding the action potentially barred encourages private citizen involvement and increases the chances that every instance of specific fraud will be revealed. To hold otherwise would preclude any *qui tam* suit once widespread—but not universal—fraud in an industry was revealed. The government often knows on a general level that fraud is taking place and that it, and the taxpayers, are losing money. But it has difficulty identifying all of the individual actors engaged in the fraudulent activity.

Id.

"*Cooper*'s holding has its limits," as evidenced in *Fine*, where the Tenth Circuit distinguished *Cooper*. *United States ex rel. Kester v. Novartis Pharm. Corp*., No. 11 CIV. 8196 CM, 2015 WL 109934, at *14 (S.D.N.Y. Jan. 6, 2015) (citing *Fine*, 70 F.3d at 569–72). In *Fine*, a former government auditor filed a *qui tam* action under the FCA, asserting that a laboratory under the Department of Energy's (DOE) control had "misappropriated nuclear waste funds in violation of the Nuclear Waste Policy

Act." 70 F.3d at 569. The relator conceded that a General Accounting Office (GAO) report and a congressional hearing were types of disclosures that invoke the public disclosure bar. *Id*. at 571. Nonetheless, he argued that those disclosures "merely described the national laboratories' practice of 'taxing' Nuclear Waste Funds for discretionary . . . projects"; by contrast, his complaint alleged that the defendant "in particular 'taxed' nuclear waste funds" in certain fiscal years. *Id*. The Tenth Circuit held that the GAO report and congressional hearing "sufficiently alerted the government to the likelihood that [the defendant] would . . . 'tax' nuclear waste funds in the future" "[b]ecause these disclosures detailed the mechanics of the practice, revealed that at least two of [the defendant's] eight sister laboratories were engaged in it, and indicated the DOE's acquiescence." *Id*. The court distinguished *Cooper*, stating, "When attempting to identify individual actors, little similarity exists between combing through the private insurance industry in search of fraud and examining the operating procedures of nine, easily identifiable, DOE-controlled, and government-owned laboratories." *Id*. at 572.

Similarly, in *Gear*, the Seventh Circuit was "unpersuaded by an argument that for there to be public disclosure, the specific defendants named in the lawsuit must have been identified in the public records." 436 F.3d at 729. In that case, the relator alleged that one medical school and its affiliates "fraudulently billed Medicare for services performed by residents [in a teaching hospital's] residency program as if those services had been performed by attending physicians." *Id*. at 727. The relator argued that the public disclosures failed to "expose any transactions from which the government . . . could infer that the particular entities he ha[d] named were fraudulently billing Medicare." *Id*. at 729. But the Seventh Circuit disagreed. It concluded that prior nationwide news reports, an investigation, and audits of how teaching hospitals billed Medicare for services that residents performed already exposed "allegations that Medicare was being billed for services provided by residents as if attending physicians had actually performed the services." *Id*. at 728. According to the court, these public "disclosures . . . were of industry-wide abuses

and investigations. *Defendants were implicated*. Industry-wide public disclosures bar *qui tam* actions against any defendant who is *directly identifiable* from the public disclosures." *Id*. at 729 (emphases added). The "industry" at issue was composed of "[t]eaching hospitals associated with the nation's 125 medical schools." *Id*. at 728. The court held that the realtor's claims were based on the public disclosures about the industry. *Id*. at 729.

The aforementioned precedent can be reconciled as follows:

> In *Cooper*, the disclosures in question were directed at an entire industry in which the government may very well have "difficulty identifying all of the individual actors engaged in the fraudulent activity," 19 F.3d at 566, and a specific reference would thus be necessary for the government to identify and prosecute the fraud. In *Gear*, the defendants did not need to be named for the public disclosure bar to be triggered because the specific defendants were already implicated by the disclosures. 436 F.3d at 729. The cases further agree that publicly disclosed allegations from which specific defendants cannot be identified do not invoke the jurisdictional bar.

United States ex rel. Branch Consultants, L.L.C. v. Allstate Ins. Co., 668 F. Supp. 2d 780, 794 (E.D. La. 2009).

Based on our review of the case law, we conclude that "[i]n order to bar claims against a particular defendant, the public disclosures relating to the fraud must either explicitly identify that defendant as a participant in the alleged scheme, *or provide enough information about the participants in the scheme such that the defendant is identifiable*." *Kester*, 2015 WL 109934, at *8. This means that "the public disclosures must 'set the government squarely on the trail' of a specific and identifiable defendant's participation in the fraud." *Id*. (quoting *In re Nat. Gas Royalties*, 562 F.3d 1032, 1041 (10th Cir. 2009)). In applying this standard, we consider "public disclosures contained in different sources" as a whole to determine whether they

collectively "provide information that leads to a conclusion of fraud." *United States ex rel. Gilligan v. Medtronic, Inc.*, 403 F.3d 386, 390 (6th Cir. 2005); *see also United States ex rel. Ondis v. City of Woonsocket*, 587 F.3d 49, 54 (1st Cir. 2009) ("The two states of facts may come from different sources, as long as the disclosures together lead to a plausible inference of fraud."); *Dingle v. Bioport Corp*., 388 F.3d 209, 214 (6th Cir. 2004) ("The fact that the information comes from different disclosures is irrelevant. All that is required is that public disclosures put the government on notice to the possibility of fraud.").

As the district court observed, the "[d]efendants identify a number of disclosures made in qualifying sources." *CSL Behring*, 158 F. Supp. 3d at 787. Some of these governmental and media sources predate the marketing and distribution of Vivaglobin and Hizentra, which began in 2006 and 2010, respectively. These sources "have long disclosed that AWP does not represent the actual prices of drugs," *id*. at 788, and revealed the resulting controversy over drug manufacturers reporting the AWP.[6]

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[6]*See, e.g.*, *Wholesale Price Litig*., 491 F. Supp. 2d at 41 (quoting a 1984 OIG Report concerning self-administered drugs that reported that the "AWP cannot be the best—or even an adequate—estimate of the prices providers generally are paying for drugs. AWP represents a list price and does not reflect several types of discounts, such as prompt payment discounts, total order discounts, end-of-year discounts and any other trade discounts, rebates, or free goods that do not appear on the pharmacists' invoices"); *Medicaid Prescription Drug Reimbursement: Why the Government Pays Too Much: Hearing Before Subcomm. on Oversight & Investigations of the H. Comm on Energy & Commerce*, 108th Cong. 2 (2004) (statement of Chairperson Joe Barton) ("[T]he committee has uncovered evidence that several manufacturers either inflate their AWPs or actively market their products not based on the lowest price but on the difference between the price and the reimbursement amount, better known in the industry as the spread. . . . [T]he existence of substantial spreads remains a fixture of Medicaid prescription drug reimbursement."); *id*. at 74 (statement of Rep. Henry Waxman) ("It was an early recognition that the AWP was an essentially bogus price that bore little relationship

to the actual acquisition police [sic] of drugs."); *Patients First: A 21st Century Promise to Ensure Quality and Affordable Health Coverage: Joint Hearing Before the Subcomm. on Health & Subcomm. on Oversight & Investigations of the H. Comm. on Energy & Commerce*, 107th Cong. 269 (2001) (statement of Rep. James C. Greenwood) ("[W]e have these drugs that are covered by Medicare, that are reimbursed at statutorily determined phrase, 'average wholesale price,' and yet it appears quite obvious that there is nothing average or wholesale about that price and it is based on absolutely nothing, it is a fiction. It appears to be designed fundamentally to create the largest spread possible between what the physician provider actually pays and what Medicare is reimbursed in order to get market share, and it is costing us billions of dollars."); *Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers: Joint Hearing Before the Subcomm. on Health & Subcomm. on Oversight & Investigations of the H. Comm. on Energy & Commerce*, 107th Cong. 11 (2001) (statement of Representative Sherrod Brown) ("[T]he so-called average wholesale price scam looks like a textbook case of fraud, waste and abuse. AWP is a bit like the Holy Roman Empire we learned about in school. The Holy Roman Empire to be sure was not holy, and it wasn't really Roman, and you could hardly call it an empire. It is the same with the average wholesale price. They aren't the average of anything, they certainly aren't wholesale, and, in fact, they aren't even prices. They are a marketing tool."); *Health Care Waste, Fraud, and Abuse: Hearing Before the Subcomm. on Health of the H. Comm. on Ways & Means*, 105th Cong. 63 (1997) (statement of Michael F. Mangano, an OIG official) ("[T]he published wholesale prices that are currently being used . . . to determine [Medicare] reimbursement rates bear little or no resemblance to actual wholesale prices."); *id*. at 57 ("The AWP . . . is easily manipulated and greatly inflated."); Office of Inspector Gen, U.S. Dep't of Health & Human Servs, OEI-03-97-00290, *Excessive Medicare Payments for Prescription Drugs* iii (1997) ("1997 OIG Report") (identifying "Medicare [payments made in 1995] that were 11 to 900 percent greater than drug prices available to the physician and supplier communities"); Bill Alpert, *Hooked on Drugs: Why Do Insurers Pay Such Outrageous Prices for Pharmaceuticals?*, Barron's, June 10, 1996, at 15, 18 (reporting that "[i]f most health-care providers can get these prices, is it any wonder an industry wag says that AWP really means 'Ain't What's Paid'?" and stating that "infusion firms like . . . *Coram Healthcare* . . . owe their sensational profit margins, to various degrees, to their drug spreads" (emphasis added)); Steve Bailey, *Profits vs. People*, Boston Globe, Apr. 10, 2002, at C1 (recounting a 2001 "report by the inspector general's office of the US Department of

In addition to the pre-2006 "public disclosures regarding DME infusion drugs, generally, there have been public disclosures regarding the AWP and ASP for Vivaglobin and Hizentra." *CSL Behring*, 158 F. Supp. 3d at 789. Data from the Red Book and CMS (set forth in the table above) "show[s] the *significant spread* between

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Health and Human Services[, which] found that Medicaid programs are overpaying pharmacies hundreds of millions of dollars for prescription drugs" and stating that "[w]hile Medicaid payments are based on average wholesale prices, doctors and pharmacies received big discounts and never paid those prices, the report found. In the industry, average wholesale price, or AWP, is an open joke that stands for 'Ain't What's Paid'"); Bill Brubaker, *Firms in Talks on Overbilling for Medicare, Medicaid Drugs*, Wash. Post, May 11, 2000, at E03 (reporting that "[f]ederal and state agencies are in discussions with major pharmaceutical companies over allegations that they misrepresented the prices of drugs they sold within the multibillion-dollar Medicaid and Medicare insurance programs," explaining that the issue was "the formula used to calculate what the federal and state health insurance programs pay for drugs," identifying the AWP as the "key component," and reporting that "[s]ome government officials say AWP actually stands for 'ain't what's paid,' because they assert it is neither average nor wholesale"); Alice Dembner, *Medicare Waste Raises Cost of Drugs By $1B, Congress To Hear Report on Overpayment Excess*, Boston Globe, Sept. 21, 2001, at A2 (reporting that "prosecutors at the US attorney's office in Boston and the Massachusetts attorney general's office are investigating whether at least 20 pharmaceutical companies committed fraud by manipulating the prices of drugs reimbursed through Medicare and Medicaid" and that "in the industry, many joke that AWP stands for 'Ain't what's paid'"); Edward Lotterman, *Insurance Firms Struggle to Avoid Moral Hazard*, St. Paul Pioneer Press, June 30, 2002, at D2 (reporting that a "doctor's professional judgment on the best drug or device is distorted by the financial incentive of which manufacturer offers the most lucrative 'spread' between the price charged . . . and the much higher 'average wholesale price'"); Lisa Richwine, *Medicare Moves to Cut U.S. Drug Payments*, Reuters, June 1, 2000 (reporting that "[o]ne federal probe charged that AWPs were between 11 percent and 900 percent greater than the prices offered to physicians" and that drug makers responded that "they have obeyed the law and that officials have known for two decades that AWPs were only a 'sticker price' and that some buyers received discounts").

ASPs and AWPs for Vivaglobin and Hizentra for the years 2007 through 2013." *Id*. (emphasis added). Furthermore, the 2013 OIG Report addressed excessive payments for DME infusion drugs, although it did not specifically name the defendants or Vivaglobin and Hizentra. The 2013 OIG Report found that "Medicare payment amounts for DME infusion drugs exceeded ASPs by 54 to 122 percent annually." While it recognized that for "one-third of DME infusion drugs in each year, the payment amounts were below their ASPs," it also reported that "[m]ost individual drugs had Medicare payment amounts that exceeded ASPs, many by more than two times, in each year." The OIG's "results once again show[ed] that AWPs are unrelated to actual prices in the marketplace and that the reliance on an AWP-based payment methodology has cost Medicare hundreds of millions of dollars." The report cited prior OIG work on the topic of DMEs and AWPs, providing, "Since 1997, OIG has released numerous reports showing that AWPs greatly exceed acquisition costs." In explaining the data-collection method that the OIG used, the 2013 OIG Report stated:

> We used CMS's payment amount files to select the HCPCS[7] codes that were paid on the basis of DME infusion payment limits (i.e., 95 percent of AWPs from October 1, 2003) in each quarter between 2005 and 2011. As previously stated, during that time, *31 to 38 HCPCS codes* were classified as "DME infusion drugs" in any given quarter.

(Emphasis added.)

Viewed collectively, the pre- and post-2006 public disclosures "provide enough information about the participants in the scheme" to directly identify the defendants and the subject drugs. *See Kester*, 2015 WL 109934, at *8. The pre-2006 public disclosures alleged industry-wide fraud through the use of AWPs. *See supra* note 6. The link between the public disclosures made *prior* to the subject drugs'

[7]Healthcare Common Procedure Coding System Code.

distribution and an allegation that the defendants are engaged in fraud by inflating AWPs for Vivaglobin and Hizentra—as Lager's complaint alleges—comes primarily from the 2013 OIG Report. It identifies a narrow class of DME infusion drugs—31 to 38. *See Gear*, 436 F.3d at 728 (stating industry was composed of "[t]eaching hospitals associated with the nation's 125 medical schools"). From this narrow class of DME infusion drugs, one could identify both the drugs and the manufacturer of those drugs. The 2013 OIG Report states that the study's results "*once again* show[ed] that AWPs are unrelated to actual prices in the marketplace and that the reliance on an AWP-based payment methodology has cost Medicare hundreds of millions of dollars." (Emphasis added.) This statement shows that the DME infusion drug companies were *continuing* to issue high AWPs, as reported pre-2006. The Red Book and CMS data shows that Vivaglobin and Hizentra are DME infusion drugs with *substantial* differences between their AWPs and ASPs.

In summary, we conclude that the pre- and post-2006 disclosures collectively would have "set the government squarely on the trail" of the defendants' participation in the purported fraudulent reporting of prices for DME infusion drugs. *See In re Nat. Gas Royalties*, 562 F.3d at 1041 (quoting *Fine*, 70 F.3d at 571).[8]

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[8]Lager cites as "on point" a case in which a district court denied the defendants' motion to dismiss a relator's FCA claim under the public disclosure bar. *See United States ex rel. Ven-A-Care v. Actavis Mid. Atl. LLC*, 659 F. Supp. 2d 262 (D. Mass. 2009). In that case, the false claims that the relator alleged arose "from tens of millions of Medicaid transactions for almost 1400 generic drugs . . . manufactured by the Defendants over a period of 16 years, which were offered to [the relator] at prices substantially below the Average Wholesale Price ('AWP') and Wholesale Acquisition Cost ('WAC') reported by the Defendants." *Id*. at 265. The defendants jointly moved to dismiss the action based on the FCA's public disclosure bar. *Id.* at 266. The defendants relied on a 1997 OIG Report finding, in the court's words, "that pharmacies' actual acquisition costs for generic drugs were, on average, 42.5% less than reported AWPs." *Id*. The defendants identified "a number of similarities between the Complaint and information in the 1997 report and other OIG and HHS reports." *Id*.

B. *Identification of the Subject Matter of the Fraud*

Lager also argues that, unlike his complaint, none of the public disclosures that the district court relied upon reveal any of the defendants' *fraudulent* activity. According to Lager, the disclosures that the district court relied upon "simply state that AWP does not represent actual wholesale prices" and do not "address fraudulent activity."

The district court denied the motion to dismiss, finding that the reports failed to identify the specific defendants or the drugs at issue. *Id*. at 267. The defendants argued that the reports need not disclose the specific drugs or manufacturers because the disclosures were "[i]ndustry wide public disclosures" from which the defendants were "directly identifiable." *Id.* (alteration in original) (quoting *Gear*, 436 F.3d at 729). The court rejected the defendants' argument. First, it noted that "the 9th and 11th Circuits have required more targeted disclosure." *Id*. Second, it concluded that cases such as *Fine* and *Natural Gas* "cabin an industry-wide disclosure bar to very small industries." *Id*. at 268. Finally, the court found that "even if the Defendants were right about the law, they [were] wrong about the facts" because "[t]he Defendants and the drugs at issue are not readily identifiable from the generalized discussions of averages in the reports." *Id*. According to the court, the public disclosures that the defendants offered "discuss AWP and WAC in generalized industry-wide terms" without "alleg[ing] or disclos[ing] industry-wide wrongdoing." *Id*. The public disclosures also "reported as average figures" "the differences between AWP and actual acquisition cost" and failed to disclose "[w]hich drugs and which manufacturers caused the averages to be at the levels reported." *Id*.

This case is factually distinguishable from *Ven-A-Care*. The public disclosures in that case "merely note[d] an average difference between reported AWP and actual acquisition cost" for drugs generally across the Medicaid program. *Id*. at 267. By contrast, the present case involves *several* disclosures, including (1) the pre-2006 disclosure specifically identifying Coram, (2) Red Book and CMS data identifying the prices of Vivaglobin and Hizentra, and (3) the 2013 OIG Report identifying the narrow class of 31 to 38 DME infusion drugs.

"[T]he preclusive effect of section 3730(e)(4)(A) . . . appl[ies] only when 'the critical elements of the fraudulent transaction themselves [are] in the public domain.'" *United States ex rel. Rabushka v. Crane Co.*, 40 F.3d 1509, 1512 (8th Cir. 1994) (third alteration in original) (quoting *United States ex rel. Springfield Terminal Ry. v. Quinn*, 14 F.3d 645, 654 (D.C. Cir. 1994)). "[M]ere disclosure of the subject matter transaction [is] . . . insufficient to prevent a *qui tam* suit." *Id*. (citing *Springfield*, 14 F.3d at 653). Instead, "the essential elements exposing the transaction as fraudulent must be publicly disclosed as well." *Id*.

Here, Lager's complaint alleges that the defendants "engaged in a joint action and an explicit or tacit agreement to defraud the government" through CSL Behring's intentional and knowing inflation of prices that it reported to third-party publications for its sales of Vivaglobin and Hizentra to Accredo, Coram, and other customers. Lager alleges that CSL Behring's intent was "to cause the AWP's reported by the Pricing Compendia to be substantially higher than the actual price at which the products are sold at wholesale." According to Lager, CSL Behring knew "that the inflated governmental payment amounts w[ould] substantially exceed the actual wholesale pricing that such payment amounts are supposed to equal." As to the subject drugs, Lager alleges that CSL Behring reported a $133 AWP for Vivaglobin to the third-party publications during the period in question, while "the true selling price at which CSL sold Vivaglobin . . . rang[ed] from $65 to $70." This resulted in an "approximately 190% to 204%" "'spread' between the reported AWP and the true selling price of Vivaglobin." "For Hizentra," Lager alleges that CSL Behring reported a $151 AWP to the third-party publications during the period in question, while "the true selling price of Hizentra by CSL to their customers was approximately . . . $65 [to] $70." This resulted in an "approximately 215% and 232%" "'spread' between the reported AWP and the true selling price." Lager claims that "CSL [actually] sold the drugs for the far lower true prices, rather than at the published AWP." And "because each [reimbursement claim] was supported by, and the reimbursement amount was determined from, the false and misleading price information provided by Defendants

in connection with the Specified Drugs," Lager alleges that "[e]ach of the claims at issue is a false claim."

We conclude that all elements critical to Lager's complaint theory were already in the public domain before Lager brought suit. Lager's allegations of purported fraud on the part of the defendants are substantially the same as those revealed in the public disclosures, both pre- and post-2006. *Cf. United States ex rel. Morgan v. Express Scripts, Inc.*, 602 F. App'x 880, 881, 883 (3d Cir. 2015) (affirming district court's dismissal of relator's FCA claim that pharmaceutical companies profited from "artificially inflated . . . AWPs. . . for brand-name drugs" because the prior disclosure "of a specific, industry-wide markup shift provided [the relator] with all the 'essential elements' needed to arrive at a 4.16% price differential"). First, by the time that Lager filed suit, public disclosures revealed the common knowledge that AWP prices were substantially greater than actual prices. *See, e.g*, Alpert, *supra*, at 15 (AWP stands for "Ain't What's Paid"); Brubaker, *supra*, at E03 (same); Dembner, *supra*, at A2 (same); Bailey, *supra*, at C1 (same). It was also known that Coram, in particular, "owe[d] [its] sensational profit margins, to various degrees, to [the] drug spreads." Alpert, *supra*, at 18.

Second, several of the public disclosures also questioned the *legality* of manufacturers' use of the AWP. In 2007, multi-district class litigation ensued in which a class composed of patients, third-party payors, benefit plans, pharmacies, and governmental entities alleged that pharmaceutical manufacturers violated the FCA by overpricing drugs based on the AWP. *Wholesale Price Litig*., 491 F. Supp. 2d at 29. The district court overseeing that litigation found that pharmaceutical companies submitted "false, inflated AWPs" that "caused real injuries to the government, insurers, and patients who were paying grossly inflated coinsurance payments for critically important, often life-sustaining, drugs." *Id*. at 31. The court found that pharmaceutical companies used the "flawed AWP system" to "establish[] secret mega-spreads between the fictitious reimbursement price they reported and the actual

acquisition costs of doctors and pharmacies." *Id*. Additionally, media reports set forth allegations that inflated AWPs were fraudulent. *See, e.g.*, Dembner, *supra*, at A2 (reporting that federal prosecutors "investigat[ed] whether at least 20 pharmaceutical companies committed fraud" through their use of the AWP). And, at congressional hearings, the AWP pricing scheme was referred to as a "textbook case of fraud." *Medicaid Prescription Drug Reimbursement: Why the Government Pays Too Much*, *supra*, at 2 (calling the AWP "an essentially bogus price"); *Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers*, *supra*, at 11.

Finally, we, like the district court, find it "apparent from the complaint that the target of [Lager's] allegations is the difference between the AWPs and what he calls the drugs' 'true selling prices.'" *CSL Behring*, 158 F. Supp. 3d at 791. The 2013 OIG Report examined the subject drugs and concluded that the AWP figures for roughly two-thirds of those drugs were higher than their actual sales prices. In turn, Red Book and CMS data reveal that Vivaglobin and Hizentra fall into this category. As recognized above, this data "show[s] the significant spread between ASPs and AWPs" for the subject drugs. *Id*. at 789. The ASP for Vivaglobin ranged from $66.06 to $68.42 during the period in question, while its AWP ranged from $119.82 to $127.57. Likewise, the ASP for Hizentra ranged from $68.72 to $72.44, while its AWP ranged from $150.66 to $151.07. As the district court correctly observed, Lager's "'true selling prices' of $65 to $70 are the same as the ASPs for the drugs. This is not a coincidence, because the ASP is intended to be a proxy for providers' acquisition costs." *Id*. at 791 (citation omitted).

In summary, we find that the following essential elements of Lager's claims were publicly disclosed prior to him filing suit:

> DME infusion drugs are reimbursed based on AWPs; AWPs are not based on actual sales data but are based on figures supplied by manufacturers to the third-party publishers; using AWP-based reimbursement results in inflated payments to providers; manufacturers

> and providers profit from the spread between AWP-based reimbursement rates and actual costs; providers seek out patients covered by federal programs in order to maximize their reimbursements; and the AWPs for Vivaglobin and Hizentra are approximately twice the ASPs for the drugs. This state of affairs has been labeled as a scam and fraud by the press and in multiple civil lawsuits.

Id.

III. *Conclusion*

Accordingly, we affirm the judgment of the district court.
