No. 17-___

IN THE

Supreme Court of the United States

UNITED STATES OF AMERICA EX REL. JOHN KING AND TAMMY DRUMMOND, ET AL.

Petitioners,

v.

SOLVAY PHARMACEUTICALS, INC.,

Respondent.

On Petition for a Writ of Certiorari
to the United States Court of Appeals
for the Fifth Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

In this False Claims Act (FCA) case, petitioners allege that respondent Solvay Pharmaceuticals, Inc. caused the government to pay for three of its prescription drugs by unlawfully marketing those drugs for off-label indications. Petitioners had firsthand knowledge of Solvay's multi-million dollar multi-year off-label promotion efforts, but not of specific claims for payment presented to the government. They disclosed what they knew to the government before suing. Through government subpoenas and discovery, petitioners obtained additional evidence that Solvay's off-label marketing resulted in claims to the government.

The lower courts granted summary judgment to Solvay. With respect to two drugs, the Fifth Circuit held that circumstantial evidence cannot prove that an off-label marketing campaign caused the submission of false claims. With respect to the third drug, the court held that the FCA's public disclosure bar applied, and that petitioners could not qualify as "original sources" because their disclosure to the government did not connect the underlying frauds to false claims. The questions presented are:

1. Whether and when circumstantial evidence may be used to prove that a defendant's illegal conduct caused another to submit false claims.

2. Whether a relator can qualify as an "original source" for purposes of the FCA's public disclosure bar when the relator has knowledge of a fraudulent scheme, and good reason to believe that false claims were submitted to the government, but no direct knowledge of such claims.

PARTIES TO THE PROCEEDING

In addition to the United States, petitioners were relators for the following states and the District of Columbia: California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Wisconsin.

Respondent Solvay Pharmaceuticals, Inc. is now known as AbbVie Products LLC. The sole member of AbbVie Products LLC is AbbVie Inc., a publicly traded company.

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Petitioners John King and Tammy Drummond respectfully petition for a writ of certiorari to review the judgment of the U.S. Court of Appeals for the Fifth Circuit.

OPINIONS BELOW

The Fifth Circuit's opinion (Pet. App. 1a-31a) is reported at 871 F.3d 318. The district court entered nine separate partial summary judgment orders, two of which are pertinent here. Both are unreported but available at 2015 WL 925612 (Pet. App. 32a-56a) and 2016 WL 1258401 (Pet. App. 57a-91a). The district court's remaining partial summary judgment orders are not pertinent, and are likewise unreported.

JURISDICTION

The court of appeals' judgment was entered on September 12, 2017. Pet. App. 1a. The court denied a timely petition for rehearing on October 27, 2017. Pet. App. 93a. On January 10, 2018, Justice Sotomayor granted a timely application to extend the time for this petition to be filed to and including March 26, 2018. No. 17A728. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

The relevant statutory provisions are reproduced in the appendix to this petition. Pet. App. 94a-98a. They include the effective versions of the False Claims Act, 31 U.S.C. § 3729, and the public disclosure bar, 31 U.S.C. § 3730(e)(4).

STATEMENT OF THE CASE

I. Legal Background

1. The False Claims Act (FCA), 31 U.S.C. § 3729, *et seq*., is "the government's primary civil remedy to redress false claims for government funds."[1] The statute creates liability for any person who, *inter alia*, "knowingly presents, or causes to be presented, a false claim for payment or approval." 31 U.S.C. § 3729(a)(1). The phrase "causes to be presented" means that the FCA applies even to those who do not directly submit claims for payment to the government, but cause third parties to do so.

That circumstance arises frequently in the healthcare context—and specifically with respect to pharmaceutical companies. Drug companies make billions of dollars every year by inducing others to seek government payments: they market their drugs to doctors; doctors prescribe the drugs; and the pharmacies that fill the prescriptions seek payment from insurance, including government programs like Medicare and Medicaid. Much of that money finds its way back up the supply chain to the manufacturer. Thus, when a drug manufacturer's promotional activities cause physicians to prescribe drugs to patients for uses that are not eligible for reimbursement by the government, and those prescriptions are nevertheless billed to the government, the manufacturer can be liable under the FCA.

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[1] U.S. Dep't of Justice (DOJ), *Justice Department Recovers Over $3.7 Billion From False Claims Act Cases in Fiscal Year 2017* (Dec. 21, 2017), https://www.justice.gov/opa/pr/justice-department-recovers-over-37-billion-false-claims-act-cases-fiscal-year-2017.

One federal enforcement priority is against "off-label" promotion of drugs. The Food and Drug Administration (FDA) evaluates drugs for safety and efficacy in a rigorous process, and approves them for particular indications only, which are listed on the drug's label. For years, however, pharmaceutical manufacturers have padded their profits by promoting drugs for other indications. This off-label promotion is wasteful and often dangerous because the FDA has not determined that the drugs are effective or safe for the target patient population. That is why, with few exceptions, off-label promotion is illegal. The FDA interprets the "misbranding" provision of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 352, to prohibit most off-label promotion. Medicaid and Medicare regulations also prohibit reimbursement for off-label uses that are not medically accepted—which means that requests for such reimbursements, when made with scienter, violate the FCA. *See* 42 U.S.C. § 1395y(a)(1)(A) (limiting reimbursement to items and services that are "reasonable and necessary"); 42 U.S.C. § 1395w-102(e) (explaining that drugs are covered if used for a "medically accepted indication").

Off-label enforcement is a priority for the United States because it implicates patient safety, "the integrity of the [FDA] drug and device approval process," and "the doctor-patient relationship."[2]

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[2] DOJ, *Principal Deputy Assistant Attorney General Benjamin C. Mizer Delivers Remarks at the 16th Pharmaceutical Compliance Congress and Best Practices Forum* (Oct. 22, 2015), https://www.justice.gov/opa/speech/principal-deputy-assistant-attorney-general-benjamin-c-mizer-delivers-remarks-16th.

Recently, the government reiterated its intent to "vigorously investigate and prosecute firms that make false or misleading statements to prescribers or patients," and to prioritize off-label cases where the defendant's conduct threatens public health.[3] For example, the federal government and many states are suing opioid manufacturers, alleging, *inter alia*, that the manufacturers have promoted their drugs for dangerous off-label uses (*e.g.*, the long-term treatment of chronic pain, when the drugs are approved only to treat acute pain).[4]

Off-label cases, however, are "complex and resource intensive, often involving nationwide conduct and complicated legal and factual issues."[5] Often, nobody will have the entire picture: the government will know how much it reimbursed (but not which reimbursements are off-label); physicians will know which prescriptions are off-label, but only for their own patients; and pharmaceutical company employees will know that they promote off-label indications to physicians who treat large numbers of Medicaid and Medicare patients, but may not know the identities of

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[3] DOJ, *Deputy Assistant Attorney General Ethan P. Davis Delivers Remarks to the FDAnews Off-Label Communication: Top Tips for Compliance Conference* (Feb. 28, 2018), https://www.justice.gov/opa/speech/deputy-assistant-attorney-general-ethan-p-davis-delivers-remarks-fdanews-label.

[4] DOJ, *Attorney General Sessions Announces New Prescription Interdiction and Litigation Task Force* (Feb. 27, 2018), https://www.justice.gov/opa/pr/attorney-general-sessions-announces-new-prescription-interdiction-litigation-task-force.

[5] *Supra* note 2.

specific patients or the details of their insurance plans. In the wake of large judgments against multiple pharmaceutical companies, companies have also "learned not to leave paper trails, making it harder to prove misconduct."[6]

In light of these difficulties, FCA whistleblower claims are critical.[7] Insiders at pharmaceutical companies (often members of the marketing and sales force) see and hear firsthand how company management requires and facilitates off-label promotion, and they have access to internal materials and sales data that provide insight into the details of these schemes. To date, the Department of Justice (DOJ) has recovered over $6 billion for the federal government, and billions more for state governments, from drug manufacturers in FCA cases challenging off-label promotion; almost all of these recoveries have been in cases initiated by relators.[8]

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[6] Jeff Overley, *What the DOJ's Elite Health Fraud Squads Are Watching*, Law360 (Sept. 21, 2017), https://www.law360.com/articles/960133/what-the-doj-s-elite-health-fraud-squads-are-watching.

[7] *See* DOJ, *Johnson & Johnson to Pay More Than $2.2 Billion to Resolve Criminal and Civil Investigations* (Nov. 4, 2013), https://www.justice.gov/opa/pr/johnson-johnson-pay-more-22-billion-resolve-criminal-and-civil-investigations.

[8] *See* DOJ, *Fact Sheet: Significant False Claims Act Settlements and Judgments, Fiscal Years 2009-2016*, https://www.justice.gov/opa/press-release/file/918366/download (detailing individual significant settlements; the $6 billion figure represents amounts recovered under the FCA in cases involving off-label promotion; it does not include criminal fines or amounts recovered for states). All-in, DOJ has recovered more than $36 billion in health care

2. One feature of the FCA is a limitation on actions called the "public disclosure bar." The relevant version provided that:

> No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions . . . unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

31 U.S.C. § 3730(e)(4)(A) (2006). The statute defined the term "original source" as "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." *Id.* § 3730(e)(4)(B) (2006).[9]

The purpose of the public disclosure bar is to prevent "parasitic" actions based on information that the government already had when the suit was brought. *See Schindler Elevator Corp. v. United States ex rel. Kirk*, 563 U.S. 401, 412 (2011). It also encourages whistleblowers to come to the government early.

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fraud enforcement since 1986; more than $30 billion of that has been in qui tam cases. *See* DOJ, *Fraud Statistics – Health and Human Services* 2 (Dec. 19, 2017), https://www.justice.gov/opa/press-release/file/1020116/download.

[9] The statute was amended in 2010. Those amendments to Section 3730 are not applicable to pending cases like this one. The import of the amendments is discussed at pages 35-37, *infra*.

II. Facts and Procedural History

1. This case arises out of the off-label marketing of three drugs manufactured by respondent Solvay.

Luvox is a selective serotonin reuptake inhibitor ("SSRI"), like Prozac or Zoloft, but at the time of its launch, it was the only SSRI that was not indicated for depression—a major disadvantage. ROA79669; ROA80438.[10] Instead, the FDA approved Luvox to treat obsessive compulsive disorder (OCD), a rare condition treated mostly by psychiatrists. Pet. App. 13a.

Solvay sought to increase market share by driving primary care physicians to prescribe Luvox. But primary care doctors rarely treated OCD at that time. ROA80443. So Solvay marketed Luvox for myriad off-label uses including depression, anxiety disorders, and other conditions including autism and attention-deficit disorder that it represented were in the "spectrum" of OCD. *See* Pet. App. 13a, 81a; ROA80439-40. Solvay deployed this off-label marketing strategy even though the FDA had disapproved of launch advertising materials stating that Luvox had been studied to treat illnesses that Solvay claimed were on the OCD spectrum. ROA79431-32; ROA79440.

Documents obtained in discovery and reviewed by petitioners' expert show that Solvay spent millions of dollars detailing Luvox to primary care physicians. In their pitches, Solvay's salespeople stressed that Luvox is an SSRI first, capitalizing on primary care physicians' familiarity with other SSRIs. ROA79425. Solvay's marketing and sales force also told doctors that

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[10] Citations to "ROA" refer to the Record on Appeal before the Fifth Circuit, by Bates number.

Luvox was used to treat "[o]bsessive and compulsive symptoms" or "obsessions and compulsions" as opposed to only diagnosed "OCD," so that they could suggest the use of Luvox for other mental health conditions (*e.g.*, anxiety and depression). ROA80440; ROA79669.

As Solvay knew, these efforts succeeded in driving prescriptions, including Medicaid prescriptions. According to government data, Medicaid reimbursed approximately $200 million for Luvox from 1994 through 2003. ROA80441. And according to data compiled by IMS Health, approximately 63% of all Luvox prescriptions were off-label. ROA80442. Those prescriptions resulted from Solvay's promotional practices. Indeed, in a case that Solvay brought against contractors for failing to detail Luvox, Solvay itself alleged that detailing is the single most important means of increasing the number of prescriptions written for a drug. ROA79621; ROA80423.

Aceon is approved by the FDA to treat essential hypertension. Pet. App. 13a, 81a. Because the market for hypertension drugs was very competitive, Solvay initiated multiple off-label marketing campaigns, stating in the process that Aceon improved arterial walls, prevented secondary strokes, and was better for the kidneys of diabetic patients than alternatives. *Id.* at 13a-14a.

These representations were either false or unsupported. For example, in 1999 the FDA sent a letter to Solvay indicating that its claims about arterial walls were misleading because they were not based on substantial evidence, and because they suggested greater efficacy than the evidence showed. ROA79736-37. Solvay also sought a study, called PROGRESS, to bolster its claims that Aceon would lower the risk of

stroke—but admitted internally that the study did not support its claim, even as it hyped the results to physicians. ROA79203; ROA80432-33.

AndroGel is a testosterone gel approved to treat hypogonadism, a relatively rare condition that typically arises from severe injury or loss of the testes, or genetic abnormalities. Pet. App. 48a; ROA2833. However, Solvay has also marketed AndroGel for depression, and as a lifestyle drug for men who naturally produce less testosterone as they age. ROA2836; ROA2844-45. Marketed this way, AndroGel might be prescribed to the vast majority of males, middle-aged or older. Thanks to this successful marketing campaign, the drug was a blockbuster, and annual sales approached or exceeded $1 billion.[11] Those sales dropped somewhat, partially because the FDA expressed serious concern in 2014 and 2015 that AndroGel and similar treatments are risky to patients' hearts.[12]

Off-label promotion was critical to AndroGel's success. In essence, Solvay fabricated a medical condition (dubbed "andropause") to describe normal aging, and then urged physicians to prescribe AndroGel to treat that condition. Early product plans for AndroGel thus stated that part of the strategy was to

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[11] *See* Arlene Weintraub, *Testosterone Suits Soar Past 2,500 as Legal Milestone Looms for AbbVie*, Forbes (Oct. 30, 2015), https://www.forbes.com/sites/arleneweintraub/2015/10/30/testosterone-suits-soar-past-2500-as-legal-milestone-looms-for-abbvie/#64e7798a1199.

[12] FDA, *FDA Drug Safety Communication* (Jan. 31, 2014), https://wayback.archive-it.org/7993/20161022203724/http://www.fda.gov/Drugs/DrugSafety/ucm383904.htm; FDA, *FDA Drug Safety Communication* (Mar. 3, 2015), https://www.fda.gov/Drugs/DrugSafety/ucm436259.htm.

provide free samples of the gel, in part, to encourage off-label use. ROA80422. Solvay's business plan likewise concluded that detailing frequently prompted physicians to first prescribe AndroGel. ROA80423. That same plan attributed a substantial part of the growth in the testosterone replacement market to the promotional efforts behind AndroGel. *Ibid*.

Solvay spent millions to promote these drugs for off-label uses. As explained above, its detailers visited doctors, urging them to consider Solvay's drugs for off-label indications. Solvay also paid physicians to attend lavish dinners and speaker events about its drugs, and paid physicians who prescribed its drugs. ROA69395-402 (expense reports from speaker programs); ROA68298-561 (documenting payments to physicians).

2. Petitioners John King and Tammy Drummond were employees of Solvay's sales and marketing force. Pet. App. 2a. They witnessed Solvay's nationwide off-label promotion of all three of these drugs, and were terminated in 2002 after expressing concern to Solvay about its practices. *Id.* at 33a.

Prior to filing suit, petitioners contacted the government to discuss their allegations. Thus, in 2002, petitioners and their counsel communicated with FDA enforcement officials about Solvay's off-label marketing. Then, on June 9, 2003, petitioners and their counsel hosted two agents from the FDA's criminal division for a ten-hour meeting, where petitioners provided information underlying their allegations about the off-label marketing of Aceon, Luvox, and AndroGel, including with a PowerPoint presentation that was later transmitted to the government. ROA50888-89 (declaration of petitioners' attorney Joel

Androphy); ROA51161 (declaration of FDA agent Mark Supple).

3. On June 10, 2003, petitioners sued Solvay, alleging violations of the FCA and its state counterparts.[13] As amended, the complaint asserted that Solvay engaged in off-label promotion, paid unlawful kickbacks, improperly lobbied for its drugs to be listed on certain formularies, and retaliated against petitioners. Pet. App. 2a, 4a. The complaint was unsealed after the United States declined to intervene in 2009. *Id.* at 33a. State governments likewise declined.

During the litigation, petitioners obtained strong circumstantial evidence that Solvay's off-label marketing resulted in the submission of false claims to the government. This included Medicaid data, incorporated into summary charts showing that Solvay's drugs had been prescribed to specific Medicaid patients with off-label diagnoses, whose prescribing physicians had received visits from Solvay's sales representatives who discussed off-label indications with them. ROA79027-111.

The evidence also included internal documents from Solvay describing the nationwide off-label promotion strategy and stressing the importance of pharmaceutical detailing and advocacy to drive off-label prescriptions. Illustrative documents were described and cited *supra* in connection with each relevant drug.

The evidence also included a nationwide collection of "call notes" where sales representatives described

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[13] The case originally was filed in Pennsylvania, but was transferred to the Southern District of Texas.

their visits with physicians—and those notes clearly explained that the representatives were pitching off-label indications, and doctors were discussing off-label uses with the representatives. ROA79974-80212 (notes for Luvox and Aceon).

Petitioners' evidence likewise included the expert report of Dr. Meredith Rosenthal, a professor of health care economics at the Harvard School of Public Health whose testimony has been accepted to prove causation in multiple off-label cases. ROA80411-45. The report concluded that Solvay's marketing campaign was likely to result in increased prescriptions and increased claims for reimbursement to the government. ROA80444.

Solvay filed nine separate motions for partial summary judgment, which the district court granted over a period of years to eliminate all of petitioners' claims. Two of those motions are relevant now.

First, the district court held that because the off-label marketing of AndroGel had been discussed in an article in the *New Yorker* prior to the filing of petitioners' complaint, the public disclosure bar applied. Pet. App. 45a (citing Jerome Groopman, *Hormones for Men*, The New Yorker (July 29, 2002)). The article itself discussed the fact that certain doctors prescribed AndroGel off-label as a lifestyle drug, and mentioned Solvay's role in funding such doctors' screening events—but it did not describe the kinds of marketing that relators knew about (pharmaceutical detailing and kickbacks). Nevertheless, the court held that petitioners' allegations were based on the public disclosure, so that the public disclosure bar applied. *Id.* at 47a-48a. The court further held that petitioners were not "original sources" who were exempt from the public

disclosure bar because their pre-suit disclosure to the government could not satisfy both the original source provision's "voluntary disclosure" requirement (31 U.S.C. § 3730(e)(4)(B) (2006)) and the FCA's general "mandatory disclosure" requirement (31 U.S.C. § 3730(b)(2) (2006)), which compels all qui tam relators (whether seeking original source status or not) to disclose their complaint and their evidence to the government. Pet. App. 53a-54a.

Second, the district court held that the evidence did not support claims that Solvay's conduct had caused off-label prescriptions for Luvox and Aceon. Pet. App. 57a. The court excluded substantial portions of petitioners' evidence, and deemed the remaining admissible evidence insufficient to sustain the claim because, in the court's view, the evidence did not "highlight[] enough claims that a reasonable jury could determine resulted from off-label promotion to support [petitioners'] claim of a nationwide scheme resulting in false Medicaid claims." *Id.* at 90a.

4. Petitioners appealed after final judgment. In a precedential, per curiam opinion, the Fifth Circuit affirmed—but on different grounds than the district court based its rulings.

With respect to the AndroGel public disclosure bar ruling, the Fifth Circuit assumed without deciding that a single disclosure can satisfy both the voluntary and mandatory disclosure requirements. Pet. App. 7a. But it concluded that the disclosure in this case was inadequate because the evidence describing the disclosure did not indicate that petitioners had communicated with the government about false claims to Medicaid, as opposed to off-label marketing of AndroGel and kickbacks. *Id.* at 10a-11a.

Second, the court of appeals assumed that all of petitioners' evidence was admissible, but concluded that their case for off-label marketing failed as a matter of law because circumstantial evidence cannot establish causation at summary judgment. Pet. App. 14a. According to the Fifth Circuit, petitioners' "circumstantial evidence suggests only the potential for a causal link between Solvay's alleged off-label marketing and off-label prescriptions but says nothing about whether the marketing scheme *actually caused* off-label prescriptions to Medicaid patients." *Ibid.* With respect to the call notes, which were the evidence the Fifth Circuit found most relevant, the court concluded that the notes "merely show physicians explaining their practices and how they prescribe the drug, which provides no insight into whether Solvay marketed the off-label uses to them, let alone caused them to make off-label prescriptions." *Id.* at 15a.[14]

The court of appeals denied rehearing en banc. Pet. App. 92a-93a.

This petition followed.

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[14] Petitioners highlighted eight examples of call notes correlated with Medicaid prescriptions, noting that many other examples were offered to the district court. The Fifth Circuit deemed reliance on any call note other than the eight examples waived. Pet. App. 15a n.8. That is puzzling, as there plainly was not space in a brief dealing with multiple summary judgment orders to lay out dozens of examples in detail. Anyway, the examples show that Solvay's nationwide off-label marketing campaign led to some Medicaid prescriptions. How many is a question of damages for the courts to address on remand.

REASONS FOR GRANTING THE WRIT

I. This Court Should Decide Whether and When Circumstantial Evidence Can Prove Causation in a False Claims Act Case.

With respect to Luvox and Aceon, petitioners had direct evidence that Solvay engaged in multiple sophisticated nationwide off-label marketing campaigns. But they had only circumstantial evidence that Solvay's promotional activities caused false claims for Medicaid reimbursement to be submitted. Specifically, they had an expert report explaining that off-label marketing is likely to cause claims to be submitted to Medicaid, as well as Solvay's internal documents stating that marketing and sales efforts were key to promoting off-label use; they also had call notes describing visits with physicians where off-label uses for drugs were discussed; and they had Medicaid data showing that the same physicians on the receiving ends of these sales visits subsequently prescribed Solvay's drugs for off-label indications, which were reimbursed by Medicaid.

The Fifth Circuit deemed this evidence insufficient because it was circumstantial. According to the court, such evidence cannot show "whether the marketing scheme *actually caused* off-label prescriptions to Medicaid patients." Pet. App. 14a.

That decision should be reversed because it presents a major impediment to off-label enforcement under the FCA—an area of exceptional importance—and also conflicts with this Court's precedents as well as other federal decisions.

A. The Question Presented Is Important.

This question is important and merits this Court's immediate attention because the implication of the Fifth Circuit's holding is as clear as it is distressing. The court of appeals decided that because petitioners' evidence was circumstantial, no reasonable jury could conclude that physicians prescribed Solvay's drugs off-label because of its marketing efforts—even though Solvay spent millions of dollars over a period of years to promote off-label uses of its drugs.

That holding deals a serious blow to off-label enforcement efforts. The only potential source of *direct* evidence about what caused a physician to write an off-label prescription is the physician himself. Thus, in order to satisfy the Fifth Circuit's standard, a relator or the government must find a physician who admits that he did not exercise independent medical judgment, but was instead swayed by a drug manufacturer's marketing. Physicians typically will not admit that, and pharmaceutical companies have no incentive to document such admissions either. In any event, it is highly unlikely that *large* numbers of physicians would say that they did anything other than exercise their best medical judgment. Thus, proving large-scale fraud against the government will become essentially impossible under the Fifth Circuit's rule. The consequence of the Fifth Circuit's rule, then, is to ignore the best-available evidence in off-label cases. *See* ROA72637 (petitioners' expert Dr. Rosenthal explains that direct evidence, in the form of physicians' testimony, is less reliable than data analysis because of physicians' conflicts of interest); ROA72253 (Dr. Rosenthal explains that the vast majority of literature on the causal effect of promotion on sales relies on data

over time, and not patient- and physician-specific factors).

As explained in the Statement of the Case, off-label promotion is a major law enforcement issue—especially when the promotion involves misleading information about dangerous drugs. The standard the Fifth Circuit adopted would have doomed major off-label enforcement actions that actually succeeded, and will make future enforcement extremely difficult—to the point where relators and the United States will rationally be deterred from bringing actions in the Fifth Circuit. The chilling effect is also unlikely to remain confined to that jurisdiction, because the decision below sends a message that without direct evidence of causation a case must fail as a matter of law. Even the risk that other courts would impose the same high bar as the Fifth Circuit poses grave concern for potential whistleblowers deciding whether to jeopardize their careers and take on the effort, expense, and other risks of litigation.[15]

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[15] Indeed, the Fifth Circuit's sabotage of off-label enforcement may well have been intentional. For example, the court mused in a footnote that because Medicaid pays off-label claims, prescribing off-label is not "material to Medicaid's payment decisions under the FCA." Pet. App. 16a n.9. For reasons explained by the United States, this argument misapprehends the materiality standard. U.S. Amicus Curiae Br., *United States ex rel. Escobar v. Universal Health Servs., Inc.*, 842 F.3d 103 (1st Cir. 2016) (No. 14-1423), 2016 WL 4506190, at *24-25. But the fact that the court aired it—even though Solvay did not raise it—suggests hostility to claims based on off-label prescriptions. Similarly, the court took pains to note that federal law permits doctors to write off-label prescriptions, and that in some circumstances, the practice can be beneficial. Pet. App. 13a. It made these observations without even acknowledging

To minimize the importance of the issue, respondent may argue that the panel's holding does not forbid reliance on circumstantial evidence in all cases, but instead merely holds the evidence here insufficient. That reading is technically possible, but practically absurd because petitioners' circumstantial evidence is unusually strong—such that if the evidence here does not suffice, it is difficult to imagine a case in which circumstantial evidence would.

The panel's discussion of the call notes is illustrative. Even when a sales representative's notes document that he discussed an off-label prescription with a physician, and the physician subsequently prescribed the drug for that same off-label indication, the Fifth Circuit deemed the notes insufficient because it concluded that they "provide[d] no insight into whether Solvay marketed the off-label uses to [the physicians], let alone caused them to make off-label prescriptions." Pet. App. 15a. In other words, because Solvay's own employees wrote that they discussed the off-label use, instead of saying that they convinced the physician to prescribe off-label, the evidence was insufficient. As explained in the Statement of the Case, pharmaceutical companies have become more sophisticated in the wake of large off-label judgments—and so there will almost never be a smoking-gun paper trail of the kind the Fifth Circuit hypothesized. Because the Fifth Circuit's rule compels summary judgment even in the face of the strongest circumstantial evidence, it effectively requires direct evidence of causation.

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that Solvay's off-label indications are alleged to be wasteful and potentially dangerous.

B. The Fifth Circuit's Decision Conflicts With This Court's Precedents.

The Fifth Circuit's hostility to circumstantial evidence as proof of causation also conflicts with this Court's precedents. As this Court has explained, the purpose of the FCA is "to reach any person who knowingly assisted in causing the government to pay claims which were grounded in fraud, without regard to whether that person had direct contractual relations with the government." *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 544-45 (1943). Thus, any person whose actions are a substantial factor in causing the submission of a false claim can be liable under the statute.

Moreover, it is well-settled that, as a general matter and unless a statute specifies otherwise, any proposition, including causation, can be proved by a preponderance of the evidence—and that direct evidence is not necessary. In *Desert Palace, Inc. v. Costa*, 539 U.S. 90 (2003), this Court unanimously rejected the defendant's argument that plaintiffs in cases under Title VII of the Civil Rights Act of 1964 must provide direct evidence of discrimination to obtain a mixed-motive jury instruction. The Court began its analysis with the statutory text, and noted that "the statute does not mention, much less require, that a plaintiff make a heightened showing through direct evidence." *Id*. at 98-99. Contrasting the text of Title VII with certain other statutes, the Court observed that "Congress has been unequivocal when imposing heightened proof requirements in other circumstances." *Id*. at 99.

The Court thus applied the "conventional rule of civil litigation," *i.e.*, that a plaintiff must "prove his case

by a preponderance of the evidence using direct or circumstantial evidence." 539 U.S. at 99 (alterations and quotation marks omitted). "The reason for treating circumstantial and direct evidence alike is both clear and deep rooted: 'Circumstantial evidence is not only sufficient, but may also be more certain, satisfying and persuasive than direct evidence.'" *Id*. at 100 (quoting *Rogers v. Mo. Pac. R.R.*, 352 U.S. 500, 508, n.17 (1957)).

This Court's other cases are to the same effect. *See Gross v. FBL Fin. Servs., Inc.*, 557 U.S. 167, 177-78 (2009) ("A plaintiff must prove by a preponderance of the evidence (which may be direct or circumstantial) that age was the 'but-for' cause of the challenged employer decision."); *Herman & MacLean v. Huddleston*, 459 U.S. 375, 390 n.30 (1983) (noting that "circumstantial evidence can be more than sufficient" to prove scienter); *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 463 n.24 (1976) (holding that "a showing [of market manipulation] may be by circumstantial as well as direct evidence"); *Michalic v. Cleveland Tankers, Inc.*, 364 U.S. 325, 330 (1960) (holding that "direct evidence of a fact is not required"); *see also Wyatt v. Cole*, 504 U.S. 158, 174 (1992) (Kennedy, J., concurring) (stating that, at summary judgment, "a plaintiff may rely on circumstantial rather than direct evidence to make his case"); *Siegert v. Gilley*, 500 U.S. 226, 236 (1991) (Kennedy, J., concurring in the judgment) (same). Indeed, circumstantial evidence alone can be sufficient even in a criminal case, where the burden of proof is much higher. *See Holland v. United States*, 348 U.S. 121, 140 (1954).

The FCA is no different from Title VII or the other statutes discussed in these cases. The FCA provides that "[i]n any action brought under section 3730, the

United States shall be required to prove all essential elements of the cause of action, including damages, by a preponderance of the evidence." 31 U.S.C. § 3731(d). Private relators must carry the same burden of proof. *See* 5B Fed. Proc., L. Ed. § 10:76. That statutory language invokes ordinary burdens of persuasion.

On the other hand, nothing in the statute suggests the need for direct evidence, or disparages the use of circumstantial evidence, to prove any element of a claim. Indeed, the language was inserted into the statute in 1986 precisely because some courts had erroneously been imposing a heightened burden of proof on FCA plaintiffs. *See* S. Rep. No. 99-345, at 31 (1986) (codifying "the traditional civil burden of proof"). Thus, in an FCA case, the general rule applicable to civil litigation applies: facts must be proved by a preponderance of the evidence, and circumstantial evidence alone can be adequate to prove any fact. Had that rule been applied below, petitioners would have been entitled to a trial on their off-label claims.

C. The Fifth Circuit's Decision Conflicts With Other Federal Decisions.

The Fifth Circuit's decision also conflicts with other federal decisions in this area. With respect to off-label claims under the FCA specifically, no circuit court has issued a directly contrary decision—but that is only because the vast majority of off-label FCA cases have settled without any appeal. Two district court cases conflict directly with the holding below, and illustrate well the dangers of allowing the Fifth Circuit's decision to stand.

In *United States ex rel. Franklin v. Parke-Davis*, 2003 WL 22048255 (D. Mass. Aug. 22, 2003), the relator

alleged that the defendant had promoted the drug Neurontin to physicians for off-label uses, resulting in false Medicaid claims. Holding that the "FCA does not provide a special definition for causation," the court applied "common-law tort causation concepts" and denied the defendant's motion for summary judgment because the evidence created a genuine question of material fact as to whether the defendant's "conduct was a substantial factor in causing the presentation of false Medicaid claims." *Id*. at *4-5.

In particular, "Relator has produced circumstantial evidence (*e.g.*, the rates of off-label prescriptions before and after physician conferences hosted by Parke-Davis) and direct evidence (the 'Verbatim' market-research reports recording doctors' state of mind after marketing meetings)." 2003 WL 22048255, at *5. Although the court described the research reports as "direct" evidence of causation, the reports did not link specific meetings to specific prescriptions. Indeed, the reports were indistinguishable from the call notes in this case, which recorded physicians' reactions to detailing visits by Solvay employees.

The court further held that the filing of false Medicaid claims was foreseeable to the defendant because "the participation of doctors and pharmacists in the submission of false Medicaid claims was not only foreseeable, it was an intended consequence of the alleged scheme of fraud." 2003 WL 22048255, at *5 (quotation marks omitted). And even though the plaintiff had presented a "sample of ten doctors" to support inferences about "over 3000 physicians in fifty states," the court held that this issue related to damages, not liability. *Ibid*.

In 2004, after the summary judgment motions were denied, *Franklin* (and related litigation) settled for over $430 million.[16] The government commented that the case was important because the off-label promotion scheme "deprived federally-funded Medicaid programs across the country of the informed, impartial judgment of medical professionals—judgment on which the program relies to allocate scarce financial resources to provide necessary and appropriate care to the poor."[17] There is no chance that the off-label claims in *Franklin* would have been decided the same way under the Fifth Circuit's rule.

Franklin was litigated in the First Circuit. In support of the decision below, the Fifth Circuit cited the First Circuit's decision in *United States ex rel. Booker v. Pfizer, Inc.*, 847 F.3d 52 (1st Cir. 2017). Pet. App. 15a. But a close examination reveals that the Fifth Circuit's decision is, at best, a radical extension of *Booker*—and at least arguably inconsistent with that decision. In *Booker*, the plaintiff *only* presented "aggregate data reflecting the amount of money expended by Medicaid for" off-label prescriptions of a drug. 847 F.3d at 58. The plaintiff did not present any evidence analogous to the call notes or internal documents here, nor did he identify specific claims that had been submitted to Medicaid. The First Circuit held that the data alone was insufficient to sustain the claim at summary judgment. The court acknowledged that it had previously "held

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[16] DOJ, *Warner-Lambert to Pay $430 Million to Resolve Criminal & Civil Health Care Liability Relating to Off-Label Promotion* (May 13, 2004), https://www.justice.gov/archive/opa/pr/2004/May/04_civ_322.htm.

[17] *Id*. (quotation marks omitted).

that plaintiffs could use aggregate data together with strong circumstantial evidence to overcome summary judgment on the distinct issue of whether there was a *causal link* between fraudulent marketing and demonstrated off-label prescriptions in the distinct context of a civil RICO case," but stated that it had not held "that such proof could be used to demonstrate the *existence* of false claims in an FCA case." *Ibid*. Whatever the correctness of that decision, the First Circuit's statement about the use of circumstantial evidence to prove causation is inconsistent with the Fifth Circuit's decision here. And of course, in this case, there is evidence of specific false claims.

The RICO cases cited by the First Circuit are revealing as well. The plaintiffs' expert in those cases used statistical analysis to establish that an off-label marketing campaign had caused fraudulent claims to third-party payors—and that evidence, together with other circumstantial evidence, was deemed sufficient to defeat summary judgment. *See, e.g.*, *In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 60, 69 (1st Cir. 2013). The expert was Dr. Meredith Rosenthal, petitioners' expert here. *Id.* at 63.

In *United States ex rel. Brown v. Celgene Corp.*, 226 F. Supp. 3d 1032 (C.D. Cal. 2016), the relator accused Celgene of marketing two of its cancer drugs for cancers other than the FDA-approved indications. The district court denied summary judgment to a drug manufacturer challenging causation on the same grounds Solvay raised here, *i.e.*, that the claim failed because the plaintiff "fail[ed] to identify a particular false claim that was presented as a result of its off-label promotion." *Id*. at 1040. The court concluded, however, that the plaintiff was "not required to identify a

particular false claim caused by Celgene's off-label promotion" in order to survive summary judgment; it was enough for the plaintiff to present "sufficiently detailed circumstantial evidence" that a false claim had been submitted. *Id*. at 1041 (quotation marks omitted). The circumstantial evidence in *Brown* showed that the defendant had "engaged in a systematic campaign to promote off-label prescriptions of its drugs, that physicians who received more promotional contacts prescribed at a higher rate than those who received fewer contacts, and that claims for off-label prescriptions were presented to the government in the hundreds of thousands following Celgene's promotional activities." *Ibid*. The court deemed it sufficient to establish causation.

In *Brown*, the United States twice filed statements of interest: at the motion to dismiss stage and at the summary judgment stage. Each time, the United States argued that direct evidence of false claims was not necessary to prove causation in an FCA case. Thus, at the pleading stage, the United States argued that "causation is satisfied if the defendant's conduct was a substantial factor in producing the false claims and it was foreseeable that false claims would result," and that "[t]here is no one single template that a relator should have to use to demonstrate that a drug manufacturer's illegal conduct 'caused' the submission of a false or fraudulent claim." Statement of Interest at 13, *Brown*, 226 F. Supp. 3d 1032 (No. 10-cv-3165) (C.D. Cal. June 12, 2014), Dkt. No. 129. The government thus explained that:

> Like any other element of a case, causation can be established by circumstantial evidence sufficient to allow a reasonable jury to conclude

> that it is more likely than not that a causal connection existed . . . . For example, a defendant drug manufacturer could reasonably foresee that a comprehensive marketing scheme involving large number of salespeople furnishing large numbers of physicians with information about off-label use of a drug in a manner which is not a medically accepted indication could cause providers to prescribe the drug for those off-label indications.

Id. at 14. At the summary judgment stage, the government reiterated that plaintiffs need not "prove causation by direct proof, physician-by-physician." Statement of Interest at 13, *Brown*, 226 F. Supp. 3d 1032 (No. 10-cv-3165) (C.D. Cal. Aug. 29, 2016), Dkt. No. 328. "Indeed, because off-label marketing schemes are often large-scale endeavors targeting thousands of doctors (who rarely will admit that their medical decisions were influenced by a marketing campaign), requiring direct, individualized proof would . . . embolden drug companies to engage in large scale fraud." *Id*. at 14.

After the court denied summary judgment, the *Brown* case settled last year. The company agreed to pay $280 million to the United States to resolve the allegations.[18] In connection with the settlement, the government explained that "[p]atients deserve to know

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[18] DOJ, *Celgene Agrees to Pay $280 Million to Resolve Fraud Allegations Related to Promotion of Cancer Drugs for Uses Not Approved by FDA* (July 24, 2017), https://www.justice.gov/usao-cdca/pr/celgene-agrees-pay-280-million-resolve-fraud-allegations-related-promotion-cancer-drugs.

their doctors are prescribing drugs that are likely to provide effective treatment, rather than drugs marketed aggressively by pharmaceutical companies," and noted that the "recovery again spotlights the importance of the [FCA] in preserving precious government health plan resources."[19]

The contrast between the decision below and the decisions in *Franklin* and *Brown* highlights persistent disagreement about how the government and relators can prove false claims when a defendant causes a third party to submit such claims. The Fifth Circuit's decision represents a dangerous break with the consensus view that circumstantial evidence of the sort used here is sufficient to carry such claims forward. Certiorari should be granted to address the conflict and bring the Fifth Circuit's precedents into line with this Court's.

II. This Court Should Decide Whether a Relator Who Has Direct and Independent Knowledge of Illegal Activity Can Qualify as an Original Source Even Without Knowledge of False Claims.

The lower courts granted summary judgment with respect to AndroGel under the public disclosure bar. Before they filed suit, petitioners presented the government with direct and independently obtained information about Solvay's marketing of AndroGel, including evidence that Solvay had engaged in off-label promotion and evidence that Solvay had engaged in kickbacks. But the Fifth Circuit held "[f]or Relators to satisfy the FCA's voluntary pre-suit disclosure requirement of disclosing information underlying their

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[19] *Id*. (quotation marks omitted).

FCA action, their disclosure must—at a minimum—connect direct and independent knowledge of information about Solvay's conduct to false claims submitted to the government, *i.e.*, suggest an *FCA violation*." Pet. App. 10a. Petitioners' disclosure was insufficient, the court held, because the information disclosed to the government only discussed off-label marketing, kickbacks, and petitioners' terminations; it did not disclose false claims. *Id.* at 10a-11a.

That decision, which requires relators to present direct and independent knowledge of false claims themselves, as opposed to the underlying fraudulent conduct that makes the claims false, deepens a circuit split and imposes a nearly insurmountable bar on relators.

A. The Fifth Circuit's Public Disclosure Bar Holding Deepens A Circuit Split.

There is a four-to-five circuit split over the meaning of the "original source" requirement. In four circuits, relators that present firsthand knowledge of an underlying fraudulent scheme to the government may qualify as an "original source" even if they have no direct knowledge of specific false claims. In five circuits, including the Fifth, relators must know about specific statements or claims actually submitted to the government.

1. Four circuits hold that a relator can qualify as an original source where the relator discloses direct and independent knowledge of the fraud underlying an FCA violation, regardless of whether the relator also points to a specific transaction.

In *United States ex rel. Springfield Terminal Railway Co. v. Quinn*, 14 F.3d 645, 656-57 (D.C. Cir.

1994), the D.C. Circuit held that under the "plain meaning" of the statute, it was not necessary to possess direct and independent knowledge of "*all* of the vital ingredients to a fraudulent *transaction*" but instead only of "*any* essential element of the underlying fraud transaction." There, the relator alleged that an arbitrator had falsely billed the government for days he had not worked. The public disclosure bar applied because the relator learned of the arbitrator's bills during the course of civil discovery in litigation. *Id*. at 647-48. Suspicious, the relator investigated the billing, including conducting interviews with others who had interacted with the arbitrator. *Id*. at 648. The court found it "beyond question that [the relator] qualifie[d] as an original source" because it "had direct and independent knowledge of essential information underlying the conclusion that fraud had been committed." *Id*. at 657. The D.C. Circuit has reaffirmed the correctness of *Springfield Terminal* in more recent precedents. *See, e.g.*, *United States ex rel. Oliver v. Philip Morris USA Inc.*, 826 F.3d 466, 476 (D.C. Cir. 2016).

Relying on *Springfield Terminal*, the Eighth Circuit recently reversed the dismissal of a qui tam claim similar to the one here. *In re Baycol Prods. Litig*., 870 F.3d 960 (8th Cir. 2017). There, a whistleblower at Bayer Corp. alleged that Bayer had concealed known risks of one of its drugs and fraudulently induced the Department of Defense (DOD) to purchase the drug. *Id*. at 961. The district court dismissed the claim because Bayer's concealment had been publicly disclosed, and the relator did not have "'direct or independent knowledge of any communication between Bayer and

the [DOD] that form the basis of the fraudulent inducement claim.'" *Id.* at 962.

The Eighth Circuit reversed, holding that "[o]ur precedent . . . does not require [the relator] to have direct and independent knowledge of Bayer's allegedly false communications to the [DOD]." 870 F.3d at 962. The court explained that "[t]he Act requires the relator to possess direct and independent knowledge of the 'information' on which her allegations are based, not of the 'transaction.'" *Ibid.* The court further explained that a harsher rule "would not seem to serve the purposes of the Act, for the government already knows about communications made to the government by an alleged defrauder." *Id*. *Baycol* also relied on *Minnesota Ass'n of Nurse Anesthetists v. Allina Health System Corp.*, 276 F.3d 1032, 1050 (8th Cir. 2002), a Medicare case holding that relators qualified as original sources because they had "[d]irect knowledge of the [defendant] anesthesiologists' operating room practices," notwithstanding an argument that "the anesthetists did not have direct knowledge of the anesthesiologists' billing practices."

In *United States ex rel. Antoon v. Cleveland Clinic Foundation*, the Sixth Circuit likewise held that "3730(e)(4)(B) does not require that the *qui tam* relator possess direct and independent knowledge of *all* the vital ingredients to a fraudulent *transaction*." 788 F.3d 605, 619 (6th Cir. 2015) (quoting *Springfield Terminal*, 14 F.3d at 656-57). The court denied original source status only because the plaintiff did "not have any direct or independent knowledge of any of the essential elements of an FCA claim." *Id*. at 620.

The Tenth Circuit has likewise rejected the position that "a relator must have direct and independent

knowledge of the *actual* fraudulent submission to the government," criticizing it as a "flawed understanding of the FCA's definition of direct and independent knowledge." *United States ex rel. Stone v. Rockwell Int'l Corp.*, 282 F.3d 787, 802 (10th Cir. 2002), *rev'd on other grounds*, 549 U.S. 457 (2007). In *Rockwell*, the Tenth Circuit stated that "the FCA is clear that for a relator to be an original source he need only possess 'direct and independent knowledge of the *information on which the allegations are based*.'" *Ibid.* (quoting 31 U.S.C. § 3730(e)(4)(B)). Thus, a relator who knew of the predicate "environmental, health and safety violations" at a government contractor-operated nuclear weapons plant, though not of "the actual submission of inaccurate claims" fraudulently concealing those violations, could be an original source. *Ibid.* It was sufficient that relator had directly observed the violations through his duties at the plant, including reviewing designs and operations for safety and cost effectiveness.[20]

In a later decision, the Tenth Circuit held that the proper approach is to "evaluate the relator's independently discovered information against the entirety of the allegations on which he based his claim and sustain the relator's invocation of subject matter jurisdiction only if his contribution in terms of direct and independent knowledge was substantial." *In re Nat. Gas Royalties*, 562 F.3d 1032, 1046 (10th Cir. 2009).

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[20] This Court reversed because it determined that the relator did not witness even the underlying misconduct firsthand. *See* 549 U.S. at 475-76. But the Court never expressed any doubt about the principle that partial knowledge is adequate to support original source status.

2. By contrast, five circuits—the Third, Fourth, Fifth, Seventh, and Ninth—require relators to know of and communicate a specific false statement or transaction made to the government in order to qualify as an original source.

The Third Circuit held that to be an original source, a relator must know about specific statements to the government, in addition to information on which the fraud allegations are based. *United States ex rel. Mistick PBT v. Hous. Auth. of Pittsburgh*, 186 F.3d 376 (3d Cir. 1999). Mistick, a construction company general contractor for the Pittsburgh Housing Authority, alleged that the Housing Authority used a product that was ineffective to remediate lead paint and misrepresented its knowledge about the product's unsuitability to the Department of Housing and Urban Development, causing false claims as to the cost of abatement work. Mistick had firsthand knowledge of the misrepresented facts underlying false claims, including through company representatives that had attended meetings with the Housing Authority where the scheme was disclosed. Nevertheless, the Third Circuit held that Mistick could not be an original source, because it lacked "direct and independent knowledge" of actual statements made to the government. *Id.* at 388-89.

The Fourth Circuit likewise requires that a relator have direct and independent knowledge of a defendant's "particular false or fraudulent claim to the government." *Vuyyuru v. Jadhav*, 555 F.3d 337, 353 (4th Cir. 2009). Knowledge of "underperformance of medical care" that formed the basis of fraudulent Medicare billing was insufficient to confer original source status to a relator. *Ibid.* Because such knowledge

was not connected "with an actual claim upon the public fisc by any of the Defendants," the court stated that the relator raised a "mere suspicion that there must be a false or fraudulent claim lurking around somewhere." *Ibid.* As the dissent put it, the court essentially "require[d] that the Relator prove the particulars of the individual Medicare or Medicaid claims in order to prove how he had direct and independent knowledge of the facts giving rise to those claims." *Id.* at 362 (Reidinger, J., dissenting).

Similarly, in *Glaser v. Wound Care Consultants, Inc.*, 570 F.3d 907, 921-22 (7th Cir. 2009), the Seventh Circuit held that an FCA plaintiff must have direct and independent knowledge of fraudulent billing, not merely the faulty medical treatment underlying the scheme. The Ninth Circuit also holds knowledge of the ultimate transaction to be critical. In a Medicare fraud case, that court held that, in order to be an original source, a relator must have information specifically about claim submission. *United States ex rel. Aflatooni v. Kitsap Physicians Servs.*, 163 F.3d 516, 526 (9th Cir. 1999). Thus, a relator who "could not recall the name of any Medicare patient who was allegedly charged for unnecessary medical services" did not qualify as an original source. *Ibid.*

That same rule barred petitioners' claim in the Fifth Circuit. Although petitioners had firsthand knowledge of Solvay's off-label promotion and kickbacks, the court held that their FCA claim was barred because they could not connect that information to false claims in their pre-suit presentation.

B. The Fifth Circuit Incorrectly Decided An Important Question Of Federal Law.

1. Certiorari should also be granted because the Fifth Circuit incorrectly decided an important question of federal law. As explained in the Statement of the Case, there are frauds—including off-label frauds—for which no relator will have the whole picture, but different people may nevertheless have significant insights.

In this context, it makes no sense to require a qui tam relator—acting without the benefit of discovery or any investigation by the government—to come forth with information supporting all the elements of an FCA claim. Indeed, it is highly likely that *nobody* could satisfy the original source requirement under these circumstances, because almost nobody knows about both the fraud (which occurs at the pharmaceutical manufacturer) and the claims (submitted by the pharmacy).

That result is not remotely compelled by the statutory text (which requires relators only to communicate "the information on which the allegations are based . . . before filing an action under this section which is based on the information," 31 U.S.C. § 3730(e)(4)(B) (2006)), and it is flatly at odds with the policy behind the FCA, which is to encourage relators with valuable information to blow the whistle.

Moreover, as both the D.C. and Eighth Circuits have explained, there is very little point to requiring relators to come forth with knowledge of claims made to the government, because the government has ready access to that information on its own. *See Baycol*, 870 F.3d at 962; *Springfield Terminal*, 14 F.3d at 657. The

missing piece of the puzzle is not which claims were made, but instead the reason that claims are false or fraudulent. Those are the lies that fraudsters conceal, and that is where whistleblowers add value.

This case is a good illustration. Any time a pharmaceutical manufacturer causes innocent third parties (*e.g.*, pharmacies) to submit false claims, the focus of the investigation should be on the manufacturer, not the pharmacies. Here, relators had detailed information about the manufacturer's activities, which they communicated to the government in their pre-suit disclosure. This included substantial information that was not reported in the public disclosures in the *New Yorker*, *e.g.*, specifics about the pharmaceutical detailing visits with physicians, which the *New Yorker* article never mentioned. Those activities constitute the core of the AndroGel allegations in the complaint, and relators had direct and independent knowledge of them from their work at Solvay.

Requiring relators to have knowledge of false claims is also pointless because it is a virtual certainty that when a pharmaceutical manufacturer runs a nationwide off-label promotion scheme, *some* false claims will be submitted to the government as a result. That is the point of the scheme. Thus, by providing details about the off-label promotion and kickbacks, relators effectively draw the necessary connection to false claims. Requiring them to provide more granular information before suit is filed—without access to discovery or government data—imposes an unrealistic and counterproductive burden.

2. The best argument against certiorari is that the statute, including the definition of an original source,

was amended in 2010. As amended, the public disclosure bar is no longer jurisdictional, the government has the discretion to waive the bar in individual cases, and the definition of an original source is broader. That definition now provides that an original source is:

> an individual who either (i) 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.

31 U.S.C. § 3730(e)(4)(B).

The amendment does not diminish the need for certiorari, however, because cases governed by the old statute are still being adjudicated. FCA cases take a long time because the government typically investigates for a period of years before the complaint is unsealed and served. This case provides an illustration: the complaint was filed in 2003; it was not unsealed until 2009; and summary judgment was not complete until 2016.

This case is also not unusual. Statistics compiled by DOJ show that from 2003 through 2009, 2734 new qui

tam actions were filed.[21] At the end of 2009, more than 1000 cases were still awaiting the government's decision whether to intervene—and 200 of those "have to do with pricing and marketing pharmaceuticals."[22] Because the amendments to the public disclosure bar are not retroactive, all of these cases (as well as some filed in 2010) are still governed by the former version of the statute today, and the meaning of the previous version of the original source exception remains critically important.

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[21] DOJ, *Fraud Statistics Overview* (Dec. 19, 2017), https://www.justice.gov/opa/press-release/file/1020126/download.

[22] Sen. Chuck Grassley, *More Than a Thousand Fraud Cases Await Government Action* (Oct. 7, 2009), https://www.grassley.senate.gov/news/news-releases/more-thousand-fraud-cases-await-government-action.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

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