No. 19-__

IN THE
Supreme Court of the United States

UPMC; UNIVERSITY OF PITTSBURGH PHYSICIANS, D/B/A UPP DEPARTMENT OF NEUROSURGERY,

Petitioners,

v.

UNITED STATES OF AMERICA EX REL. J. WILLIAM BOOKWALTER, III, M.D.; ROBERT J. SCLABASSI, M.D.; ANNA MITINA,

Respondents.

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

The False Claims Act, 31 U.S.C. § 3729(a)(1)(A), imposes treble damages and a per-claim civil penalty on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim" seeking payment from the United States.

The question presented is:

Whether a plaintiff plausibly alleges scienter—that a defendant *knowingly* submitted false claims—when the plaintiff does not allege any facts to suggest the defendant had knowledge that it was in violation of an ambiguous regulatory provision.

PARTIES TO THE PROCEEDING

The caption contains the names of all the parties to the proceeding below.

RULE 29.6 DISCLOSURE STATEMENT

The University of Pittsburgh Medical Center ("UPMC") has no parent. UPMC is the sole parent of University of Pittsburgh Physicians.

RELATED PROCEEDINGS

The following proceedings are directly related to this petition:

United States ex rel. Bookwalter v. *UPMC*, No. 2:12-cv-00145-CB (W.D. Pa. Mar. 27, 2018) (available at 2018 WL 1509064), *rev'd*, No. 18-1693 (3d Cir. Sept. 17, 2019) (reported at 938 F.3d 397), *reh'g granted in part & reh'g en banc denied* (Dec. 20, 2019) (reported at 944 F.3d 965), *as amended* (Dec. 20, 2019) (reported at 946 F.3d 162).

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PETITION FOR A WRIT OF CERTIORARI

The University of Pittsburgh Medical Center and University of Pittsburgh Physicians d/b/a UPP Department of Neurosurgery respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Third Circuit in this case.

OPINIONS BELOW

The District Court's order dismissing the Amended Complaint is not reported but is available at 2017 WL 2672288. Pet. App. 93a–100a. The District Court's order dismissing the Second Amended Complaint is not reported but is available at 2018 WL

1509064. Pet. App. 89a–92a. The Third Circuit's initial opinion reversing and remanding the dismissal is reported at 938 F.3d 397. Pet. App. 35a–88a. The Third Circuit's order granting in part Petitioners' petition for rehearing is reported at 944 F.3d 965. Pet. App. 33a–34a. The Third Circuit's revised opinion reversing and remanding the dismissal is reported at 946 F.3d 162. Pet. App. 1a–32a.

JURISDICTION

The Third Circuit entered judgment on September 17, 2019. Petitioners filed a timely petition for rehearing, which was granted in part on December 20, 2019. On that date, the Third Circuit entered an amended judgment. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISION INVOLVED

Under the False Claims Act, 31 U.S.C. § 3729(a)(1)(A):

> [A]ny person who * * * knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval * * * is liable to the United States Government for a civil penalty * * *, plus 3 times the amount of damages which the Government sustains because of the act of that person.

INTRODUCTION

Relators' central thesis in this eight-year-old False Claims Act (FCA) case is that Petitioners' decision to compensate physicians the same way Medicare does—for their time and effort—knowingly violated the Ethics in Patient Referrals Act of 1989 (known as the Stark Act). As a result, Relators say, every claim

Petitioners submitted to Medicare and Medicaid seeking reimbursement for hospital services tied to these physicians' work was a *false* claim that opens them up to FCA liability. If this seems counterintuitive, it is.

The Third Circuit recognized as much, stating that this novel interpretation of the Stark Act "may not be obvious on the face of the statute and regulations." Pet. App. 17a. Yet it adopted that interpretation, held that Relators sufficiently pled FCA scienter, that is, that Petitioners *knowingly* submitted false claims, and sent this case into discovery. The Third Circuit did so even though Relators did not allege that Petitioners (or anyone else) were aware of its non-obvious interpretation of the Stark Act. And it did so even though the Centers for Medicare & Medicaid Services (CMS) had just issued a proposed rule to clarify the relevant provisions of the Stark Act, under which the Third Circuit's interpretation is incorrect.

Just four years ago, this Court promised that its decision interpreting the FCA to encompass a false certification theory of falsity—the theory Relators raise here—should not trouble entities that submit claims to the government. The Court recognized that this falsity theory raised "concerns about fair notice and open-ended liability." *Universal Health Servs., Inc.* v. *United States ex rel. Escobar*, 136 S. Ct. 1989, 2002 (2016). But "strict enforcement of the [FCA]'s materiality and scienter requirements," which this Court stressed were "rigorous," would "allay" any such concerns. *Id.* (internal quotation marks omitted).

The Third Circuit's scienter holding betrayed that promise, and this Court should correct it. Under its decision, all a relator needs to do is convince a court to adopt one interpretation of an ambiguous provision, and allege that a defendant knew certain facts that, under the newly-adopted interpretation, violated the provision. That is enough, according to the Third Circuit, to *plausibly allege* that the defendant submitted a claim *knowing* of the violation. But alleging that a defendant knew those facts does not show that the defendant knew (or had fair notice)—at the time it submitted a claim to the government—that it was acting improperly and submitting false claims.

For this reason, every other circuit to address this issue has held that something more is required to allege FCA scienter when there is clear regulatory ambiguity. Any other interpretation of the FCA's scienter requirement gives relators free rein to wield the threat of FCA liability and its "essentially punitive" penalties. *Id.* at 1996 (internal quotation marks omitted). The 51 titles of the U.S. Code and 186,374 pages of the Code of Federal Regulations[1] are filled with ambiguous provisions. Members of this Court have already described regulatory ambiguity as providing "a powerful weapon in an agency's regulatory arsenal." *City of Arlington* v. *FCC*, 569 U.S. 290, 314 (2013) (Roberts, C.J., dissenting). The

[1] The number is likely higher. *See* Fed. Register, Code of Federal Regulations: Total Pages 1938-1949, and Total Volumes and Pages 1950-2017, http://bit.ly/2017fedreg (last visited Mar. 19, 2020) ("C.F.R. Total Pages and Volumes") (noting 2017 data).

Third Circuit's decision makes these provisions powerful weapons in *relators'* arsenals too. Federal contractors, suppliers, and grantees are subject to a host of regulatory requirements, many of them ambiguous. They routinely submit claims to the government that, after *Escobar*, may be treated as impliedly certifying compliance with these provisions. And the FCA contains a broad venue provision that allows relators to pick and choose where to sue. Unless this Court steps in, these weapons can be trained on the 74 Fortune 100 companies—and countless others—that are headquartered or incorporated within the Third Circuit.

STATEMENT

This FCA case rests on Relators' allegations that Petitioners' standard compensation agreement for physicians violates the Stark Act.[2] The standard agreement entitles a physician to a base salary and a bonus of $45 per wRVU above a minimum number of wRVUs. Pet. App. 6a. A wRVU (work relative value unit) is "the basic unit[] that Medicare uses to measure how much a medical procedure is worth." *Id.* Medicare assigns each medical service a number of wRVUs: "[t]he longer and more complex the service, the more [wRVUs] it is worth." *Id.*

A. Statutory and Regulatory Background

1. The FCA imposes civil liability on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). It thus requires: (1) pre-

[2] This Statement is based on Relators' allegations because this petition arises out of Petitioners' motion to dismiss.

sentment, (2) of a false or fraudulent claim, (3) with knowledge of its falsity. *See Escobar*, 136 S. Ct. at 1996. "The Act's scienter requirement defines * * * 'knowingly' to mean that a person has 'actual knowledge of the information,' 'acts in deliberate ignorance of the truth or falsity of the information,' or 'acts in reckless disregard of the truth or falsity of the information.' " *Id.* (quoting 31 U.S.C. § 3729(b)(1)(A)). If these requirements are met, the FCA's penalties are "essentially punitive in nature." *Id.* (internal quotation marks omitted). It provides for treble damages and civil penalties per false claim. *See id*; *see also* Civil Monetary Penalties Inflation Adjustment, 83 Fed. Reg. 3944, 3945 (Jan. 29, 2018) (setting the current inflation-adjusted penalty range as $11,181 to $22,363 per claim).

The FCA is enforced directly by the United States or indirectly by a private party (relator) on its behalf. When a relator sues, the FCA allows the government to investigate and decide whether to intervene. *See* 31 U.S.C. § 3730(b). If the government decides a relator's claim does not warrant intervention, the relator can continue with the suit. *See id.* § 3730(c)(3). This is not an act of altruism—a relator receives a sizeable percentage of any recovery. *See id.* § 3730(d)(1)-(2).

2. The FCA has become the primary vehicle for enforcement of the Stark Act, which does not contain its own cause of action. Pet. App. 12a.

The Stark Act was enacted to address the risk that physicians might make patient referrals for their own financial gain, rather than as medically necessary and appropriate. It prohibits a physician from making a referral for designated health services

payable by Medicare to an entity he has a financial relationship with, unless an exception applies, and it prohibits that entity from billing Medicare for the services. *See* 42 U.S.C. § 1395nn(a)(1). The Act is aimed at referrals based on a physician's financial interest in *third-party* providers and suppliers. *See* Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships, 66 Fed. Reg. 856, 871 (Jan. 4, 2001). A physician thus does not make a prohibited referral when *he* performs a service on *his own* patient. *See* 42 C.F.R. § 411.351 (services "personally performed or provided by the referring physician").

A two-step process governs whether these prohibitions apply. The Stark Act first defines "financial relationship" and then sets out a series of exceptions to that definition. Pet. App. 11a. CMS describes its "intent in interpreting and implementing * * * the Act" as "to interpret the referral and billing prohibitions narrowly and the exceptions broadly," a position from which it has "not vacillated." *See* Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations ("Proposed Rule"), 84 Fed. Reg. 55,766, 55,771 (proposed Oct. 17, 2019) (internal quotation marks and brackets omitted).

A "financial relationship" includes a "compensation arrangement," which is exactly what it sounds like. 42 U.S.C. § 1395nn(a)(2)(B), (h)(1)(A)-(B). As relevant here, a financial relationship can be "indirect." 42 C.F.R. § 411.354(c). That is, a physician can have a "financial relationship" that triggers the Stark Act with an entity that bills Medicare, even if he is compensated by another entity. *See id.*

By regulation, an "indirect compensation arrangement" has three elements. There must be "an unbroken chain of * * * financial relationships" between the physician and the entity providing, and billing for, the referred services. *Id.* § 411.354(c)(2)(i). The physician must receive "aggregate compensation * * * that varies with, or takes into account, the volume or value of referrals." *Id.* § 411.354(c)(2)(ii). And the entity must know, recklessly disregard, or deliberately ignore that the physician's compensation "varies with, or takes into account, the volume or value of referrals." *Id.* § 411.354(c)(2)(iii).

The exceptions to what counts as a Stark Act financial relationship are in the Act and also in CMS's regulations. *See, e.g.*, *id.* § 411.357(l); 42 U.S.C. § 1395nn(e)(2). Four exceptions are relevant here. Pet. App. 11a, 31a. Each requires "that * * * compensation not exceed fair market value and not take into account the volume or value of referrals." *Id.* at 31a.

Despite their importance, neither the Stark Act nor the regulations define these key terms—"takes into account the volume or value of referrals" and "fair market value." CMS has long acknowledged that entities like Petitioners face uncertainty when trying to comply with the Act. When it defined an "indirect compensation arrangement," it recognized that applying it would "require * * * education and experience." Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II) ("Phase II Regulations"), 69 Fed. Reg. 16,054, 16,058 (Mar. 26, 2004). And recently, CMS stated that "[o]ver the years," it received "requests for clarification * * * with respect

to * * * under what circumstances compensation is considered to take into account the volume or value of referrals * * * and how to determine the fair market value of compensation." Proposed Rule, 84 Fed. Reg. at 55,789.

Despite this ambiguity, CMS signaled that performance-based employment compensation did not trigger the Act's prohibitions. It said that "a productivity bonus based on personally performed work would not be based on the volume or value of 'referrals.' " Phase II Regulations, 69 Fed. Reg. at 16,067. And it stated that the mere fact that a physician who works at a hospital will generate referrals for hospital services related to *his own* work—if a surgeon performs a surgery, for example, the hospital will provide his patient with necessary associated services—"would not invalidate an employed physician's personally performed work, for which the physician may be paid a productivity bonus." *Id.* at 16,089.

B. Procedural Background

1. The University of Pittsburgh Medical Center (UPMC) is a world-renowned nonprofit healthcare system. It contains 20 academic, community, and regional hospitals, with more than 2,700 physicians. Pet. App. 5a.[3] Its flagship teaching hospital, UPMC Presbyterian Shadyside, houses one of this country's top neurosurgery departments. *See UPMC Presby-*

[3] The UPMC system has grown since this case began. *See* UPMC, UPMC Fast Facts, https://upmc.me/2Uf6sFt (Mar. 2020) ("UPMC operates 40 academic, community and specialty hospitals, 700 doctors' offices and outpatient sites, employs 4,900 physicians, and offers an array of rehabilitation, retirement, and long-term care facilities.").

terian Shadyside, U.S. News & World Report, https://tinyurl.com/usnewsupmc (last visited Mar. 19, 2020).

This case involves thirteen neurosurgeons, most of whom practice at UPMC Presbyterian Shadyside, all of whom are compensated by UPMC-affiliated entities. *See* Pet. App. 5a–6a. Relators alleged that these neurosurgeons were compensated under a standard form contract with a base salary and, for every wRVU above a set minimum, an additional $45 per wRVU. *Id.* at 6a. Each had to complete a minimum number of wRVUs, or risk his base salary being reduced the next year. *Id.*

Performance-based compensation is the industry standard. A recent study found that 72% of national physician postings offered a salary and productivity bonus. *See* Merrit Hawkins, 2017 Review of Physician and Advanced Practitioner Recruiting Incentives, at 5, 12 (2017) (2016/2017 period), *available at* https://tinyurl.com/MerritHawkins17 (study of more than 3,287 physician postings, 2,301 of which were in hospitals or physician groups). It concluded that "volume-based incentives, particularly Relative Value Units (RVUs), continue to be the most frequently utilized physician productivity metric." *Id.* at 4. In fact, 52% of postings that offered a productivity bonus did so based on wRVUs. *See id.* at 13.

2. Relators, who had worked in the UPMC system, brought this FCA suit in 2012. At first, they alleged that certain neurosurgeons had billed for procedures that were not performed, or billed for more complex procedures than were actually performed. Pet. App. 6a–8a. The United States investigated these claims, and Petitioners settled certain claims related to

physician services, without admitting liability. *Id.* at 8a.[4] The United States declined to intervene with respect to the claims for hospital services. *Id.*

Relators amended their complaint to allege a new theory. They alleged that the neurosurgeons' contracts created a Stark Act "indirect financial relationship" that prohibited the physicians from referring any Medicare patient for hospital services at any UPMC hospital. C.A. J.A. 61–62 (Am. Compl. ¶¶ 152–155). Relators alleged that, as a result, every claim submitted to Medicare for those hospital services was a false claim under the FCA. *Id.* at 53–56.

2. The District Court dismissed the Amended Complaint. It agreed with Petitioners that Relators had not pled a Stark Act violation and that, even if they had, Relators had not alleged that Petitioners *knowingly* violated the Stark Act. Pet. App. 94a–95a, 97a–98a. The District Court gave Relators the chance to amend their complaint again. *Id.* at 95a, 99a–100a.

The District Court dismissed the Second Amended Complaint. It explained that although Relators had added a few allegations, deleted some, and moved others, the third complaint essentially mirrored the second one. *See id.* at 92a n.3; 114a–115a. The District Court agreed with Petitioners that it should be dismissed for essentially the same reasons, this

[4] The settled claims included some that UPMC voluntarily disclosed to the U.S. Attorney's Office beyond the scope of Relators' original complaint. *See* C.A. J.A. 202 (Settlement Agreement ¶ C).

time with prejudice. *Id.* at 89a–92a. Relators appealed.

3. The Third Circuit initially reversed in a divided opinion. *Id.* at 35a–88a. The panel majority focused on the second requirement of an indirect compensation arrangement: whether "aggregate compensation * * * varies with, or takes into account, the volume or value of referrals." 42 C.F.R. § 411.354(c)(2)(ii). It defined its task as "to tease out the difference between *varies with* and *takes into account*." Pet. App. 50a.

As to "varies with," the panel majority adopted a "natural reading," relying on statistics textbooks, judicial opinions, and a Truth In Lending Act regulation. *Id.* at 51a–53a. Under that reading, any time a physician's compensation correlates with referrals, it "varies with" referrals. *Id.* Because UPMC paid the neurosurgeons based on effort—i.e., they were paid more for performing more procedures—and because Relators alleged that hospital-based procedures involve associated referrals for hospital services, "the surgeons' salaries rose and fell with their referrals." *Id.* at 56a.

As to "takes into account," the panel concluded that the phrase was satisfied if a "causal" relationship existed between referrals and compensation. *Id.* at 50a. It concluded that "aggregate compensation that exceeds fair market value" was "smoke" that "suggests" that "compensation takes referrals into account." *Id.* at 59a. That was just "common sense." *Id.* at 58a–59a. Even so, the panel acknowledged that its interpretation "may not be obvious on the face of the statute and regulations," which "often treats *fair market value* as a concept distinct from

taking into account the volume or value of referrals." *Id.* at 58a.

The panel identified five allegations that "viewed together" provided more smoke; this smoke indicated that "the surgeons' pay exceeded their fair market value." *Id.* at 59a–60a. Those were that: (1) "some" neurosurgeons' "pay exceeded their collections"; (2) "many" neurosurgeons' "pay exceeded the 90th percentile of neurosurgeons nationwide"; (3) "many" neurosurgeons "generated [wRVUs] far above industry norms"; (4) the $45/wRVU bonus "exceeded what" Petitioners received for "most" of the services; and (5) "the government's choice to intervene after years of investigation and its allegations in the settlement [we]re cause for suspicion." *Id.* at 59a–60a, 64a–65a. That was "plenty of smoke" for the panel and "suggest[ed] that * * * pay took their referrals into account." *Id.* at 64a–65a.

The panel's discussion of scienter was considerably shorter.[5] It found that Relators had alleged that Petitioners shared "common control," had taken "part in forming, approving, and implementing the surgeons' pay packages," and "had a central coding and billing department." *Id.* at 65a–66a. Because they "had all the data right in front of them," the panel could "plausibly infer" that Petitioners "knew the surgeons' compensation varied with or took into account their referrals," that is, formed an indirect

[5] The Stark Act's definition of "indirect compensation arrangement" includes a scienter requirement that mirrors the FCA's. *See* Phase II Regulations, 69 Fed. Reg. at 16,061–62. The Third Circuit opinions include sections on Stark Act scienter and FCA scienter. For simplicity, this Petition refers to both together.

compensation arrangement that the Stark Act prohibited. *Id.* at 66a.

In the panel's view, the Stark Act's many exceptions had *no role* to play at the pleading stage. "[I]f an exception * * * applies, then the claim is not false. And if the defendant thinks that an exception applies, then the defendant does not know that the claim is false." *Id.* at 71a. Petitioners argued that, as a result, a relator must allege facts to show that a defendant could not have believed (or did not believe) that it fell outside an exception. *See id.* Although this logic had "force," the panel rejected it. *Id.* Even though the FCA contains a scienter element, the panel held that the exceptions were affirmative defenses that could come into play only on summary judgment. *Id.* at 38a–39a, 45a–46a, 71a; *see id.* at 86a (Ambro, J., concurring in the judgment). And it found that because the relevant exceptions required that "compensation not exceed fair market value" and "not take into account the volume or value of referrals," its falsity analysis "already explained" why Relators had pleaded that the contracts here did not meet those requirements. *Id.* at 71a–72a.

Judge Ambro concurred in the judgment. He disagreed with the panel majority's interpretation of the Stark Act regulations' "varies with" language. *Id.* at 78a–88a & n.1. On his reading, the term required "an actual causal relationship." *Id.* at 88a. The majority's contrary interpretation could make "most of the top hospitals in the country, many of whom likely employ similar compensation schemes to UPMC's * * * vulnerable to a * * * lawsuit that could survive a motion to dismiss and proceed to discovery." *Id.* at 86a. He agreed, however, with the

majority's analysis of the "takes into account" language, though he saw it as a "close question." *Id.* at 76a; *see id.* at 80a n.1. "[M]any of the factors the majority" identified as smoke "would likely be present in many cases where nothing untoward has occurred." *Id.* at 76a–77a.

4. After Petitioners sought rehearing, supported by the American Hospital Association and others as amici, the panel issued a new opinion, and Judge Ambro withdrew his concurrence. *Id.* at 34a.

Just before the rehearing petition was filed, CMS released a proposed rule to clarify its regulations defining an indirect compensation arrangement. The rehearing petition identified three aspects of the proposed rule as most relevant. First, CMS proposed removing the phrase "varies with" from the definition. *See* Proposed Rule, 84 Fed. Reg. at 55,841–42 (to be codified at 42 C.F.R. § 411.354(c)(2)). Second, CMS explained that "takes into account the value or volume of referrals" is an objective test: "[O]nly when the mathematical formula used to calculate the amount of the compensation includes as a variable referrals * * *, and the amount of the compensation correlates with the number or value of the physician's referrals * * *, is the compensation considered to take into account the volume or value of referrals * * * ." *Id.* at 55,793. And CMS noted that it was "not the case" that it considered compensation above market value as compensation that necessarily took into account referrals. *Id.* at 55,789. CMS made clear that the "takes into account" and "fair market value" requirements are "separate and distinct" standards. *Id.* at 55,789, 55,797.

The new panel opinion was slightly more modest than the original. The panel declined to interpret the "varies with" language in the definition of an indirect compensation arrangement, deleting nearly seven pages of its opinion. *Compare* Pet. App. at 16a–17a, *with id.* at 51a–58a. But it left in place its holding that Relators adequately pled falsity, based on its view that Relators had pled facts that were "smoke" suggesting compensation above fair market value, which in turn was "smoke" that suggested that the neurosurgeons' compensation "takes into account" their referrals. *Compare id.* at 18a–19a, 23a, *with id.* at 59a–60a, 64a–65a. It also left in place its recognition that this interpretation of the Stark Act "may not be obvious on the face of the statute and regulations." *Id.* at 17a. The panel did not modify its discussion of scienter. *Compare id.* at 23a–25a, *with id.* at 65a–67a. It did not acknowledge CMS's proposed rule.

The panel ended, as it did before, by making clear that it was holding only that Relators had satisfied their *pleading* standard. Because of the "smoke" it identified, "fire is plausible," and the "case deserve[d] to go to discovery." *Id.* at 32a. "[I]t may turn out that there is no fire." *Id.* But, in its view, this was "exactly the kind of situation on which the Stark and False Claims Acts seek to shed light." *Id.*

This petition followed.

REASONS TO GRANT THE PETITION

I. The Third Circuit's Lax Pleading Standard For Scienter Conflicts With This Court's Precedents And Other Circuits' Standards.

1. The Third Circuit's permissive view of the FCA's scienter requirement at the pleading stage cannot be reconciled with this Court's precedents.

This Court stated clearly in *Escobar* that the FCA's scienter requirement is a "rigorous" one. 136 S. Ct. at 2002. There, it rejected "a circumscribed view of what it means for a claim to be false or fraudulent" and accepted an implied false certification theory of falsity. *Id.* (internal quotation marks omitted). That reading of falsity, it knew, raised "concerns about fair notice and open-ended liability." *Id.* But this Court assured potential FCA defendants that "other parts of the False Claims Act allay" those concerns. *Id.* Those concerns could "be effectively addressed through strict enforcement of the Act's materiality and scienter requirements," which "are rigorous." *Id.* (internal quotation marks omitted).

The Third Circuit's analysis of whether Relators pled scienter instead treats scienter as a de minimis pleading requirement. Under that holding, a relator plausibly alleges that a defendant knowingly violated a statute or regulation merely by alleging that it knew facts that a court—after the fact—decides add up to a violation of an ambiguous provision. This does not just make it *easier* for a relator to plead scienter, it raises the precise concerns that *Escobar* said scienter should protect against. Under the Third Circuit's holding, UPMC is subject to discovery, the attendant pressures to settle, and potential

FCA liability, based only on allegations that it violated an interpretation of the Stark Act that did not exist until the panel created it.

This raises serious due-process concerns. "A fundamental principle in our legal system is that laws * * * must give fair notice of conduct that is forbidden or required." *FCC* v. *Fox Television Stations, Inc.*, 567 U.S. 239, 253 (2012). A defendant certainly does not have the kind of notice that might allow it to *avoid* a violation if the violation is not laid out until years after it has acted. *See United States ex rel. Purcell* v. *MWI Corp.*, 807 F.3d 281, 287 (D.C. Cir. 2015) ("[A] knowledge requirement can play an essential role as it may mitigate a law's vagueness, especially with respect to the adequacy of notice to the complainant that his conduct is proscribed." (internal quotation marks omitted)); *see also* Br. for the United States as Amicus Curiae Supporting Respondents at 26, *Escobar*, 136 S. Ct. 1989 (No. 15-7) ("But when the complexity of particular government funding programs gives rise to legitimate uncertainty as to a claimant's legal obligations, the FCA accommodates that concern by imposing liability only if the claimant acts 'knowingly.' " (quoting 31 U.S.C. § 3729(a)(1))).

The need for fair notice and to avoid open-ended liability extends beyond the FCA's civil penalty scheme. The FCA includes a parallel criminal provision. *See Cook County* v. *United States ex rel. Chandler*, 538 U.S. 119, 128 n.8 (2003) ("The FCA's civil and criminal provisions were bifurcated in 1878, and the latter provisions have since been recodified at 18 U.S.C. § 287." (internal citation omitted)). When a court interprets the FCA's basic elements—including

scienter—it is thus "actually construing the provisions of a criminal statute." *United States* v. *McNinch*, 356 U.S. 595, 598 (1958). This calls for interpreting these requirements *narrowly*, not broadly. *See id.* ("Such provisions must be carefully restricted * * *.").

This Court has already laid out the kind of careful approach to scienter that is required when the relevant regulatory scheme is ambiguous. In *Safeco*, this Court addressed the analogous scienter requirement in the Fair Credit Reporting Act (FCRA). *See Safeco Ins. Co. of Am.* v. *Burr*, 551 U.S. 47, 52 (2007). The FCRA authorizes a consumer to sue "[a]ny person who *willfully* fails to comply with" the Act for greater relief, including punitive damages. 15 U.S.C. § 1681n(a) (emphasis added). This Court first held that the term willfully "covers both knowing and reckless disregard of the law." *Safeco*, 551 U.S. at 59. It then interpreted the provision of FCRA that the plaintiffs claimed had been violated. *See id.* at 60–67.

Finally, this Court turned to scienter—willfulness—and held that a FCRA defendant "does not act in reckless disregard of it unless" there "is not only a violation" but a showing "that the company ran a risk of violating the law substantially greater than the risk associated with a reading [of FCRA] that was merely careless." *Id.* at 69. Safeco's reading of FCRA "ha[d] a foundation in the statutory text," even though this Court disagreed with it, and was "sufficiently convincing * * * to have persuaded the District Court." *Id.* at 69–70. And Safeco did not have "the benefit of guidance from the courts of appeals or the Federal Trade Commission * * * that

might have warned it away from the view it took." *Id.* at 70. "Given this dearth of guidance and the less-than-pellucid statutory text, Safeco's reading was not objectively unreasonable" and thus not reckless. *Id.*

2. Understanding this, every other circuit to address the issue—six in all—has rigorously enforced the scienter requirement when statutory ambiguity is involved. These courts hold that when a relator's claim rests on one interpretation of an ambiguous regulatory provision, a relator must allege more than mere knowledge of facts that, after the defendant has acted, are deemed to be a violation of that provision.[6]

This interpretation follows directly from the plain text of the FCA, which requires the *knowing* submission of a *false* claim; that is, a defendant must have knowledge *of the falsity*. *See, e.g.*, *United States ex rel. Phalp* v. *Lincare Holdings, Inc.*, 857 F.3d 1148, 1156 (11th Cir. 2017) (allegations must show that defendants "believed or had reason to believe they were violating Medicare regulations"); *United States ex rel. Harper* v. *Muskingum Watershed Conservancy Dist.*, 842 F.3d 430, 437–438 (6th Cir. 2016) (allegations must show more than the "theoretical possibility" that defendant knew its actions were illegal); *United States ex rel. Davis* v. *District of Columbia*, 793 F.3d 120, 125 (D.C. Cir. 2015) ("Davis has not met his burden to show that the District was in

[6] Courts have also reached this conclusion in the context of contractual ambiguity. *See, e.g.*, *United States ex rel. K & R Ltd. P'ship* v. *Massachusetts Hous. Fin. Agency*, 530 F.3d 980, 983 (D.C. Cir. 2008); *Commercial Contractors, Inc.* v. *United States*, 154 F.3d 1357, 1366 (Fed. Cir. 1998).

knowing violation of these regulations when DCPS submitted the FY 1998 Transportation Cost Report."); *United States ex rel. Hochman* v. *Nackman*, 145 F.3d 1069, 1074 (9th Cir. 1998) ("Absent evidence that the defendants knew that the VHA Guidelines on which they relied did not apply, or that the defendants were deliberately indifferent to or recklessly disregardful of the alleged inapplicability of those provisions, no False Claims Act liability can be found.").

In the Eighth Circuit and D.C. Circuit, a defendant who acts in line with a reasonable interpretation of an ambiguous regulatory provision does not have the requisite FCA scienter, unless some authoritative interpretation of the provision warned it away from its actions.

The Eighth Circuit reached this holding in *Hixson*. There, the relators alleged that the defendants submitted false claims to Medicare by seeking reimbursement without first seeking reimbursement for those expenses caused by medical negligence. *See United States ex rel. Hixson* v. *Health Mgmt. Sys., Inc.*, 613 F.3d 1186, 1189 (8th Cir. 2010). The defendants moved to dismiss, arguing the relators had not alleged scienter. They pointed to a state statute that, they argued, prevented them from seeking reimbursement. *See id.* at 1190. The Eighth Circuit agreed that the relators had not pled scienter. The falsity allegation rested "on a legal conclusion," but "there [wa]s a reasonable interpretation of the law that d[id] not" require "the defendants to seek reimbursement." *Id.* at 1190–91. The Eighth Circuit held that a claim submitted "based on a reasonable interpretation of a statute cannot support a claim

under the FCA if there is no authoritative contrary interpretation of that statute * * * because the defendant in such a case could not have acted with the knowledge that the FCA requires." *Id.* at 1190. It thus affirmed the dismissal of the complaint. *See id.* at 1191; *see also Olson* v. *Fairview Health Servs. of Minnesota*, 831 F.3d 1063, 1070–71 (8th Cir. 2016) (applying *Hixson* to affirm the dismissal of a relator's complaint); *United States ex rel. Ketroser* v. *Mayo Found.*, 729 F.3d 825, 832 (8th Cir. 2013) (same).

In *Purcell*, the D.C. Circuit reached the same conclusion as the Eighth Circuit. The United States alleged that the defendant falsely certified that the only payments to its sales agents were "regular commissions" when it secured loans from the Export-Import Bank. *Purcell*, 807 F.3d at 283. The parties disagreed over whether "regular" referred to an industry standard, or to a defendant's own past payments. *See id.* at 288–289. "Absent evidence that" a "government entity[] had officially warned [the defendant] away from its otherwise facially reasonable interpretation of that undefined and ambiguous term, the FCA's objective knowledge standard" was not met. *Id.* at 284. As a result, the D.C. Circuit reversed the verdict "with instructions to enter judgment" in the defendant's favor. *See id.* at 291.

The Sixth, Ninth, Tenth, and Eleventh Circuits treat additional allegations as relevant to scienter, but in these jurisdictions there must still be some allegation that suggests a defendant was *knowingly* violating an ambiguous regulatory provision.

In *Harper*, the Sixth Circuit considered allegations that a defendant improperly retained government

property—in violation of FCA provisions that require a defendant to have acted "knowingly." 842 F.3d at 433 (discussing 31 U.S.C. § 3729(a)(1)(G), (a)(1)(D)). It held that to plead scienter, a relator must allege that the defendant had knowledge of "the fact that he is involved in conduct that violates a legal obligation to the United States." *Id.* at 437. The relators argued—mirroring the Third Circuit's holding—that all they had to allege was that the defendant "ha[d] notice of a legal obligation." *Id.* The Sixth Circuit disagreed. The relators' argument collapsed the falsity and scienter requirements, making the FCA's punitive remedies "interchangeable" with those for ordinary breach of contract. *Id.* (internal quotation marks omitted). Because the relators merely recounted restrictions in a deed and the defendant's actions but did not allege that the defendant "knew about the deed restrictions when it signed the leases," they had not alleged scienter. *Id.* at 438. The allegations showed only "a possibility that [the defendant] acted unlawfully." *Id.* The Sixth Circuit thus affirmed the district court's dismissal of the complaint. *See Harper*, 842 F.3d at 438; *see also United States ex rel. Harper* v. *Muskingum Watershed Conservancy Dist.*, 739 F. App'x 330, 334 (6th Cir. 2018) (reaching same conclusion after relator amended), *cert. denied* 139 S. Ct. 798 (2019).

The Ninth Circuit similarly requires additional allegations when a relator's falsity claim is based on a violation of an ambiguous regulatory provision. In *Oliver*, it held that "[a] contractor relying on a good faith interpretation of a regulation is not subject to liability * * * because the good faith nature of his or her action forecloses the possibility that the scienter requirement is met." *United States ex rel. Oliver* v.

Parsons Co., 195 F.3d 457, 464 (9th Cir. 1999). And it later relied on *Oliver* to affirm the dismissal of a relator's complaint where the relators did not "clearly allege sufficient facts to support an inference or render plausible that [the defendant] acted while knowing that its Compensation Program fell outside of the Safe Harbor Provision on which it was entitled to rely." *United States* v. *Corinthian Colls.*, 655 F.3d 984, 997 (9th Cir. 2011).

In *Boeing*, the Tenth Circuit considered a claim that Boeing had falsely impliedly certified compliance with Federal Aviation Administration regulations. *See United States ex rel. Smith* v. *Boeing Co.*, 825 F.3d 1138, 1148 (10th Cir. 2016). But relators offered "no evidence that anyone at Boeing knew the * * * parts didn't comply with FAA regulations * * * yet submitted a claim to the government for payment anyway." *Id.* at 1149. "*Even if*" Boeing had violated the regulations, nothing suggested it "*knew* about the nonconformities." *Id.* (first emphasis added). That was not enough to support scienter. *See id.* at 1151 (affirming the grant of summary judgment); *see also Pack* v. *Hickey*, 776 F. App'x 549, 557 (10th Cir. 2019) (applying *Boeing*); *United States ex rel. Simpson* v. *Leprino Foods Dairy Prods. Co.*, No. 16-cv-00268-CMA-NYW, 2018 WL 1375792, at *5 (D. Colo. Mar. 19, 2018) (applying this standard at the motion-to-dismiss stage).

And in *Lincare Holdings*, the Eleventh Circuit held that the FCA requires courts to ask if "the defendant actually knew or should have known that its conduct violated a regulation in light of any ambiguity at the time of the alleged violation." 857 F.3d at 1155. It reasoned that "[a]lthough ambiguity may be relevant

to the scienter analysis, it does not foreclose a finding of scienter." *Id.* Applying that standard, the relators had not shown scienter because their "best evidence" was two emails, one of which dealt with a different compliance issue and the other of which post-dated the actions at issue. *Id.* at 1156. And there was "nothing in the plain language of [the relevant regulations] that would put Defendants on notice" that they were in violation. *Id.* The Eleventh Circuit thus affirmed summary judgment in the defendants' favor. *See id.*; *see also Thornton* v. *Nat'l Compounding Co.*, No. 8:15-cv-2647-T-36JSS, 2019 WL 2744623, at *22 (M.D. Fla. July 1, 2019) (denying a motion to dismiss where United States alleged, among other things, that a pharmacy's statements had put the defendant "on notice that its commission structure ran afoul of the Anti-Kickback Statute").

In any of these jurisdictions, Relators' complaint would have been dismissed because there is no dispute that the Stark Act provisions at issue here are deeply ambiguous, and Relators did not allege *any* facts that spoke to Petitioners' knowledge of a Stark Act violation. *See United States ex rel. Williams* v. *Renal Care Grp., Inc.*, 696 F.3d 518, 531 (6th Cir. 2012) (holding United States failed to prove the defendant knowingly violated Medicare regulations where the defendant had "sought legal counsel," counsel had sought CMS's guidance, "industry publications openly encouraged" the defendant's actions, and CMS was aware of the defendant's actions).

II. The Question Presented Is Important And Recurring.

1. The issue of how to enforce the FCA's scienter requirement when a relator claims that a defendant

violated an ambiguous obligation and thus submitted false claims is not going away.

The issue of regulatory ambiguity is particularly important to hospital systems, which are highly regulated. As the Stark Act itself shows, hospital systems face an ever-shifting sea of regulations. CMS has added to and amended these regulations numerous times. *See* Proposed Rule, 84 Fed. Reg. at 55,767 (discussing nine prior rulemakings under the Stark Act). But the question this petition presents is relevant to *every* potential FCA defendant.

Federal contractors, suppliers, and grantees are subject to a host of regulatory requirements. Science and research grant recipients often must "certify compliance with the accounting regulations found at 45 C.F.R. Part 74." *Siebert* v. *Gene Sec. Network, Inc.*, 75 F. Supp. 3d 1108, 1120 (N.D. Cal. 2014). Companies that "contract[] with the federal government for the manufacture and sale or lease of" aircraft must certify compliance with the FAA's "design type" regulations, among others. *Boeing Co.*, 825 F.3d at 1141 n.1, 1142. Higher education institutions that receive federal funding similarly enter agreements that "incorporate[] by reference thousands of pages" of federal regulations, including civil rights and disability rights laws. *United States* v. *Sanford-Brown, Ltd.*, 788 F.3d 696, 707 (7th Cir. 2015), *reinstated in part and superseded in part*, 840 F.3d 445 (2016). Defense contractors often agree to comply with "environmental laws and regulations including the Clean Water Act, the Clean Air Act and the Resource Conservation and Recovery Act." *United States ex. rel. Fallon* v. *Accudyne Corp.*, 880 F. Supp. 636, 638 (W.D. Wis. 1995). And developers

that receive block grants must follow "HUD regulations and guidelines" about, among other things, the "bidding process." *Mack* v. *Augusta-Richmond County*, 148 F. App'x 894, 895 (11th Cir. 2005) (per curiam). The list goes on. And after *Escobar*, even *impliedly* certifying compliance with regulatory requirements can lead to FCA liability.

These statutory and regulatory obligations are often ambiguous. "[R]egulations (like any legal text) will inevitably contain ambiguities." John F. Manning, *Constitutional Structure and Judicial Deference to Agency Interpretation of Agency Rules*, 96 Colum. L. Rev. 612, 687 (1996). The problem of regulatory ambiguity can be exacerbated if agency deference "encourages agencies to be vague in framing regulations." *Decker* v. *Nw. Envtl. Def. Ctr.*, 568 U.S. 597, 620 (2013) (Scalia, J., concurring in part and dissenting in part) (internal quotation marks omitted). And even if an agency strives to promulgate clear rules, "[c]hanged and unforeseen circumstances" can generate ambiguity. Kevin M. Stack, *Interpreting Regulations*, 111 Mich. L. Rev. 355, 366 (2012).

The problem is getting bigger, not smaller. The number of regulations potentially applicable to any given claim is enormous. In 2017 alone, federal agencies promulgated 61,950 pages of federal rules in the Federal Register. *See* Brookings Inst., Vital Statistics on Congress, at tbl. 6-5 (updated Mar. 2019), https://brook.gs/38QHJg0. That number is growing—and has been. *City of Arlington*, 569 U.S. at 313 (Roberts, C.J., dissenting) ("And the federal bureaucracy continues to grow."). Between 1950 and 2017, the total pages of the C.F.R. grew 1,812 per-

cent. *See* C.F.R. Total Pages and Volumes, *supra* note 1 (from 9,745 pages in 1950 to 186,374 pages in 2017). Regulatory accumulation is, to put it mildly, "a central feature of modern American government." *City of Arlington*, 569 U.S. at 313 (Roberts, C.J., dissenting).

2. A relaxed approach to what it takes to plausibly plead FCA scienter imposes real burdens on persons and entities that interact with the government. The government relies on contractors and other claimants for national defense, software development, telecommunications, education, disaster relief, and administration of housing and mortgage lending programs—to just name a few. Under the Third Circuit's scienter holding, these providers face discovery, the pressure to settle, and potential FCA liability, based only on allegations that they violated ambiguous regulations, without allegations that they *knew* about that interpretation, or that they were violating it. Even the threat of that type of liability will disrupt broad sectors of the economy and touch upon every facet of the federal government.

"[T]he costs of litigation, including the expense of discovery and experts, may push cost-conscious defendants to settle even anemic cases." *Texas Dep't of Hous. & Cmty. Affairs* v. *Inclusive Cmtys. Project, Inc.*, 135 S. Ct. 2507, 2550 (2015) (internal quotation marks omitted). That general truth applies to FCA actions, where discovery burdens are "particularly vitriolic." Mathew Andrews, Note, *The Growth of Litigation Finance in DOJ Whistleblower Suits: Implications and Recommendations*, 123 Yale L.J. 2422, 2434 (2014); Todd J. Canni, *Who's Making False Claims, the Qui Tam Plaintiff or the Govern-*

ment Contractor? A Proposal to Amend the FCA to Require That All Qui Tam Plaintiffs Possess Direct Knowledge, 37 Pub. Cont. L.J. 1, 11 & n.66 (2007) (Discovery and litigation expenses require FCA defendants to spend "hundreds of thousands of dollars, if not millions," to defend themselves.).

Defendants are even more likely to settle frivolous FCA claims because the remedies are "punitive in nature," imposing "treble damages and a civil penalty of up to [$22,363] per claim." *Vermont Agency of Nat. Res.* v. *United States ex rel. Stevens*, 529 U.S. 765, 784–785 (2000); *see supra* p. 6 (statutory penalties adjusted for inflation). Relators often seek to maximize these already-punitive penalties, seeking damages as the entire amount billed or the full value of a contract and arguing that every invoice a contractor submits is "false." *See, e.g.*, *United States ex rel. Vosika* v. *Starkey Labs., Inc.*, No. 01-cv-709(DWF/SRN), 2004 WL 2065127, at *1 (D. Minn. Sept. 8, 2004); *United States ex rel. Tran* v. *Computer Scis. Corp.*, 53 F. Supp. 3d 104, 122 (D.D.C. 2014). This exerts overwhelming pressure on defendants to settle even meritless suits. *See* Robert Salcido, *DOJ Must Reevaluate Use of False Claims Act in Medicare Disputes*, Wash. Legal Found. Legal Backgrounder 4 (Jan. 7, 2000) (The "dirty little secret" of FCA litigation is that "given the civil penalty provision and the costs and risks associated with litigation, the rational move * * * is to settle the action even if the [plaintiff's] likelihood of success is incredibly small.").

And Relators have every incentive to litigate even meritless suits, given the share of the penalties that awaits if they succeed. *See* 31 U.S.C. § 3730(d)(1). Unsurprisingly, the number of suits has exploded.

In 1987, 30 relators filed suit. *See* Civil Div., U.S. Dep't of Justice, Fraud Statistics – Overview, October 1, 1986 – September 30, 2019, http://bit.ly/2019quitam (last visited Mar. 19, 2020). By 2000, the number of suits had increased tenfold, to 363, and in 2018, the number nearly doubled again, to 646. *See id.* Recoveries in relator-led FCA litigation have increased too, from $33,750 in 1988 to $293,170,997 in 2019. *See id.* (qui tam recoveries where the United States declined to intervene).

* * *

This Court should step in now to correct the Third Circuit's dangerous scienter holding. The FCA contains a broad venue provision that permits a realtor to sue where a defendant "can be found, resides, transacts business, or in which any act proscribed by [31 U.S.C. §] 3729 occurred." 31 U.S.C. § 3732(a). Seventy-four Fortune 100 companies—many of which submit claims to the United States—are headquartered or incorporated in the Third Circuit. Countless other smaller companies that submit claims are too.[7]

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[7] This is not the first time the Third Circuit has split with other circuits in order to adopt an expansive view of FCA liability. *See, e.g.*, *United States ex rel. Druding* v. *Care Alternatives*, No. 18-3298, 2020 WL 1038083, at *7 (3d Cir. Mar. 4, 2020) (holding that "medical opinions may be 'false' and an expert's testimony challenging a physician's medical opinion can be appropriate evidence for the jury to consider on the question of falsity"); Petition for Writ of Certiorari i-ii, *PharMerica Corp.* v. *United States ex rel. Silver*, 140 S. Ct. 202 (2019) (No. 18-1044) (cert. denied) (seeking review of "the Third Circuit's new, heightened standard" for the FCA's public-disclosure bar); Petition for Writ of Certiorari i, *Victaulic Co.* v. *United States ex*

III. This Case Is An Ideal Vehicle To Resolve The Question Presented.

1. The relevant statutory and regulatory terms are undeniably ambiguous. The Stark Act "is infamous * * * for being complicated, confusing, and counter-intuitive." Charles B. Oppenheim et al., The Stark Law: Comprehensive Analysis + Practical Guide 1 (AHLA 6th ed. 2019). The panel acknowledged that the provisions underlying Relators' claims are just that. The panel stated that its interpretation "may not be obvious on the face of the statute and regulations." Pet. App. 17a. The relevant agency has said so as well. *See* Proposed Rule, 84 Fed. Reg. at 55,789 ("Over the years, stakeholders have approached CMS with requests for clarification * * * under what circumstances compensation is considered to take into account the volume or value of referrals * * * and how to determine the fair market value of compensation"); *see also id.* at 55,792–93 (stating that "commenters shared their concerns that * * * parties can never be sure that their determination of the compensation to be paid under an arrangement with a referring physician will be insulated from scrutiny"). And CMS has proposed rules to clarify that the Stark Act means the opposite of what the panel majority held it does. *See id.* at 55,793 (explaining that compensation takes into account referrals "only when the mathematical formula used to calculate the

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rel. Customs Fraud Investigations, LLC, 138 S. Ct. 107 (2017) (No. 16-1398) (cert. denied) (seeking review of "[w]hether a qui tam relator's complaint under the False Claims Act satisfies Rule 9(b) by alleging nothing more than the opportunity for fraud, as held by the Third Circuit").

amount of the compensation includes as a variable referrals * * * and the amount of the compensation correlates with the number or value of the physician's referrals"); *id.* at 55,797 ("[A] careful reading of the statute shows that the fair market value requirement is separate and distinct from the volume or value standard * * * ."). If regulatory ambiguity is ever to be a relevant consideration for FCA scienter, it must be here.

2. The scope of the dispute is narrow, and the question presented is dispositive. The case arises on a motion to dismiss, so there are no factual disputes. Relators' scienter allegations are bare-bones and conclusory. They alleged only that Petitioners knew "of the compensation arrangements" and "had actual knowledge of, or acted in reckless disregard or deliberate ignorance of,"—paraphrasing 31 U.S.C. § 3729(b)(1)(A)—"the fact that the Physicians received aggregate compensation that varied with, or took into account, the volume or value of referrals or other business generated by the Physicians for the hospitals"—paraphrasing 42 C.F.R. § 411.354(c)(2). C.A. J.A. 193 (Second Am. Compl. ¶ 232). The Third Circuit found that sufficient. Pet. App. 25a ("They had all the data right in front of them.").

Relators did not allege, nor did the panel identify, any of the traditional facts that could suggest scienter. They did not allege that UPMC was on notice of a potential violation. *Compare Minnesota Ass'n of Nurse Anesthetists* v. *Allina Health Sys. Corp.*, 276 F.3d 1032, 1053–54 (8th Cir. 2002) (agency had sent memo to providers discussing criteria for proper billing). They did not allege that UPMC communicated internally about a potential Stark Act viola-

tion. *Compare United States ex rel. Harrison* v. *Westinghouse Savannah River Co.*, 352 F.3d 908, 919 (4th Cir. 2003) (employee had warned defendant of a potential conflict of interest). They did not allege that UPMC concealed the compensation contract. *Compare United States ex rel. Hendow* v. *Univ. of Phoenix*, 461 F.3d 1166, 1175 (9th Cir. 2006) (defendant changed its policies to avoid detection). They did not, in short, offer any factual basis to infer UPMC knew that the standard contracts were suspect under the Stark Act, much less in violation.

Petitioners raised this scienter argument at every turn. Before the District Court, Petitioners argued that wRVU-based compensation was an accepted method for rewarding "physician productivity," and that Relators failed to "ple[ad] facts" that Petitioners should have known their contracts violated the Stark Act. Pet. App. 140a; *see also id.* at 110a (scienter "is particular[ly] pertinent when, in a case like this, the law is ambiguous and the relator's view of it is unprecedented"). Before the Third Circuit, Petitioners explained that in light of the regulatory "ambiguity," Relators' allegations do "not permit an inference that [Petitioners] knew" their compensation contracts violated the Stark Act. C.A. Response Br. 50. And on rehearing, Petitioners emphasized that "before this case was filed, no hospital system was on notice that the industry standard compensation structure used here even raised a Stark Act concern, much less triggered the FCA." C.A. Rehearing Pet. 15.

3. The Third Circuit's decision was incorrect. The FCA's scienter requirement requires more than mere knowledge of facts that a court concludes—after the

fact—add up to a violation of an ambiguous statute or regulation. The FCA applies to "fraud." *Escobar*, 136 S. Ct. at 2004. And fraud involves more than "regulatory or contractual violations," it requires a *knowing* violation. *Id.*; *accord Sanford-Brown, Ltd.*, 788 F.3d at 712 ("The FCA is simply not the proper mechanism for government to enforce violations of" those regulations.); *United States ex rel. Steury* v. *Cardinal Health, Inc.*, 625 F.3d 262, 268 (5th Cir. 2010) ("The FCA is not a general enforcement device for federal statutes, regulations, and contracts." (internal quotation marks omitted)); *Mikes* v. *Straus*, 274 F.3d 687, 699 (2d Cir. 2001) (The FCA is "not designed for use as a blunt instrument to enforce compliance."); *United States ex rel. Hopper* v. *Anton*, 91 F.3d 1261, 1267 (9th Cir. 1996) ("Mere regulatory violations do not give rise to a viable FCA action.").

"[D]ifferences in interpretations," the most that Relators alleged here, do not demonstrate that a defendant *knew* its submissions were false. *Corinthian Colls.,* 655 F.3d at 996 (internal quotation marks omitted). Relators must instead plead that the defendant knew its claims were false. *Purcell,* 807 F.3d at 286–287 (government or relator must prove "that the claim was false" *and* "that the defendant knew that the claim was false" (quoting *Davis*, 793 F.3d at 124); *see also Corinthian Colls.*, 655 F.3d at 997. They did not do that. The Third Circuit should not have revived their third complaint.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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MARCH 2020