No. 23-1293

In The
Supreme Court of the United States

UNITED STATES ET AL., EX REL. ADAM HART,
Petitioners,

v.

MCKESSON CORPORATION, ET AL.,
Respondents.

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

BRIEF FOR THE RESPONDENTS IN OPPOSITION

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QUESTION PRESENTED

"As a general matter, when used in the criminal context, a 'willful' act is one undertaken with a bad purpose," meaning that "the defendant acted with knowledge that his conduct was unlawful." *Bryan v. United States*, 524 U.S. 184, 191 (1998) (quotation marks omitted). Consistent with this general rule and with the decisions of virtually every other court of appeals, the Second Circuit held that the Anti-Kickback Statute—which criminalizes "knowingly and willfully" offering or paying remuneration to induce certain healthcare purchases, 42 U.S.C. § 1320a-7b(b)(2)—is violated only when the defendant knows that its conduct is unlawful. App. 16a. The sole outlier is a single Fifth Circuit decision that conflicts with at least seven other Fifth Circuit decisions, all of which follow the "general" rule applied by the Second Circuit below.

The question presented is: Whether a defendant can act "willfully" under the Anti-Kickback Statute without knowing that its conduct was unlawful.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of the Rules of this Court, Respondents state as follows: Respondent McKesson Corporation is a publicly held corporation that has no parent corporation, and no publicly held corporation owns 10% or more of its stock. Respondent McKesson Specialty Care Distribution Corporation was converted to a limited liability company, McKesson Specialty Care Distribution LLC, on or about November 1, 2018. McKesson Specialty Care Distribution LLC is a wholly owned subsidiary of US Oncology, Inc., which is a wholly owned subsidiary of US Oncology Holdings, Inc., which is a wholly owned subsidiary of McKesson Corporation. Respondent McKesson Specialty Distribution LLC is a wholly owned subsidiary of McKesson Corporation.

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

INTRODUCTION

This Court has held that, "as a general matter," a defendant has committed a "willful act" under federal criminal law only if "the defendant acted with knowledge that his conduct was unlawful." *Bryan v. United States*, 524 U.S. 184, 191-92 (1998) (cleaned up). A different rule applies when Congress enacts "highly technical statutes." *Id.* at 194. In that context, "willfully" requires more than just a general knowledge that the defendant's conduct is unlawful; the defendant must have knowledge of the specific law he allegedly violated. *Id.* at 194-95.

The Second Circuit applied this precedent to hold that Congress used "willfully" in the Anti-Kickback Statute in its "general" sense. App. 8a-21a. The court of appeals held that the Anti-Kickback Statute is not the sort of "highly technical" statute that requires proof that the defendant specifically knew it was violating a particular law. App. 10a n.5. Instead, a defendant acts "willfully" under this statute if it has knowledge that its conduct was unlawful, even if it does not know the specific law it violated. App. 16a. In so holding, the Second Circuit interpreted "willfully" under the Anti-Kickback Statute the same way that every other court of appeals interprets that term.

Petitioner urges the Court to reject the typical interpretation of "willfully" and interpret the Anti-Kickback Statute to dispose of any requirement that the defendant know its conduct is unlawful. Pet. 18-19. In Petitioner's view, a defendant acts "willfully" under the statute so long as it intentionally engages in the conduct that Petitioner alleges is unlawful. *Id.* But that interpretation would render "willfully" superfluous, because the statute's

"knowingly" requirement already ensures that the defendant knows it has engaged in the challenged conduct.

The sole appellate decision that adopts Petitioner's interpretation is *United States v. St. Junius*, 739 F.3d 193 (5th Cir. 2013). There, the Fifth Circuit stated—without citing any authority—that a showing of willfulness under the Anti-Kickback Statute required only that "the defendant willfully committed an act that violated the Anti-Kickback Statute." *Id.* at 210. The panel's failure to cite any authority was significant because circuit precedent had already required a showing that the defendant knew it was violating the law. *See* Part I.B *infra*. In any event, the Fifth Circuit does not treat *St. Junius* as establishing the law of the circuit. Earlier this year, a Fifth Circuit panel clearly and unequivocally treated the general rule as controlling: "A violation of the [Anti-Kickback Statute] requires that the defendant know that his actions were unlawful." *United States v. Marchetti*, 96 F.4th 818, 828 (5th Cir. 2024).

This Court does not typically grant certiorari to resolve intra-circuit splits, and this Fifth Circuit division of authority is no exception. Just last year, the Court denied a pair of petitions that also invoked *St. Junius* to argue that "[t]he Fifth Circuit is split within itself." *See* Petition for Writ of Certiorari at 4, *Wilkerson v. United States,* No. 22-685, *cert. denied*, 143 S. Ct. 2581 (2023).[1] In the year since that petition was denied, the intra-circuit split has only become more lopsided. *See, e.g.*, *Marchetti*, 96 F.4th at 828.

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[1] *See also* Petition for Writ of Certiorari at 2-3, *Montgomery v. United States*, No. 22-6653, *cert. denied*, 143 S. Ct. 2581 (2023).

Petitioner attempts to portray the split as more substantial by arguing that the Eighth Circuit also follows the *St. Junius* approach. But the Eighth Circuit has never held that willfulness under the Anti-Kickback Statute can be proven without evidence that the defendant knew its conduct was unlawful. To the contrary, the Eighth Circuit has expressly rejected Petitioner's (and *St. Junius*'s) view that willful in this context requires only a showing that the defendant's actions were intentional. *See United States v. Jain*, 93 F.3d 436, 440 (8th Cir. 1996). The Eighth Circuit instead held—like the Second Circuit held in this case—that a "heightened *mens rea*" applies to the Anti-Kickback Statute. *Id.*

Petitioner has not identified a circuit split. Nor has he offered any reason why Congress would have included "willfully" in the Anti-Kickback Statute had it not wanted the general understanding of that term to apply here. And there are good reasons why Congress would want the statute to have a meaningful mens rea requirement. The statute includes broad language that could be read to turn common business practices into federal felonies. A meaningful mens rea requirement is thus vitally important to distinguish between culpable and innocent conduct. The petition should be denied.

STATEMENT

A. Statutory Framework

Petitioner brought this suit as a *qui tam* action under the False Claims Act, 31 U.S.C. §§ 3729-33. He attempted to plead that claims were "false or fraudulent" in violation of the False Claims Act by proving that Respondents violated a federal criminal

statute, the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b).

The False Claims Act prohibits "knowingly present[ing], or caus[ing] to be presented, a false or fraudulent claim for payment" to the government. 31 U.S.C. § 3729(a)(1)(A). That prohibition can be enforced by the government or by private plaintiffs ("relators") in *qui tam* actions. *Id.* § 3730(a), (b). And it is backed up by an "essentially punitive" regime of remedies, which include civil penalties, treble damages, and fees for relators' attorneys. *Id.* §§ 3729(a), 3730(d)(1); *Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 784 (2000).

One way a claim can be "false or fraudulent" is if it "includes items or services resulting from a violation of" the federal Anti-Kickback Statute. *See* 42 U.S.C. § 1320a-7b(g). That Statute prohibits (among other things) "knowingly and willfully offer[ing] or pay[ing] any remuneration … to any person to induce such person" to purchase products or services "for which payment may be made … under a Federal health care program." *Id.* § 1320a-7b(b)(2). Violations of this law are felonies punishable by up to 10 years' imprisonment and fines of up to $100,000. *Id.* § 1320a-7b(b). Violators also may be subject to exclusion from participation in federal health care programs. *Id.* § 1320a-7(a), (b).

The question presented concerns the proper interpretation of the Anti-Kickback Statute's "knowingly and willfully" mens rea requirement. Violations of the statute were originally misdemeanors, and the statute did not expressly require any mens rea. Pub. L. No. 92-603, § 242(b), (c), 86 Stat. 1329, 1419-20 (1972) (originally codified at 42 U.S.C. §§ 1395nn, 1396h). In 1977, Congress

stiffened the penalties for violations of the Statute, which it made felonies. Pub. L. No. 95-142, § 4(a), (b), 91 Stat. 1175, 1179-82. Congress became "concerned that criminal penalties may be imposed … [on] an individual whose conduct, while improper, was inadvertent." H.R. Rep. No. 96-1167, at 59 (1980), *reprinted in* 1980 U.S.C.C.A.N. 5526, 5572 (quoted in App. 14a). It therefore added a mens rea requirement, which limits liability to only "knowing[] and willful[]" violations of the Statute. Pub. L. No. 96-499, § 917, 94 Stat. 2599, 2625 (1980) (codified as amended at 42 U.S.C. § 1320a-7b(b)).

Courts of appeals adopted different interpretations of that mens rea requirement. Most courts interpreted the term based on its typical meaning, holding that to act "willfully," a defendant needed to know that its conduct was "unlawful" or "wrongful," but did not need to specifically intend to violate the Anti-Kickback Statute. *See, e.g.*, *United States v. Bay State Ambulance & Hosp. Rental Serv.*, 874 F.2d 20, 33 (1st Cir. 1989); *United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998); *Jain*, 93 F.3d at 440; *United States v. Starks*, 157 F.3d 833, 837-38 (11th Cir. 1998). The Ninth Circuit, however, read the Anti-Kickback Statute as a highly technical statute, holding that a willful violation requires a specific intent to violate that particular statute, *Hanlester Network v. Shalala*, 51 F.3d 1390, 1400 (9th Cir. 1995), as this Court has interpreted similar mens rea requirements in tax and currency-structuring offenses, *see Ratzlaf v. United States*, 510 U.S. 135, 146-48 (1994); *Cheek v. United States*, 498 U.S. 192, 201 (1991).

Congress resolved that split in 2010, specifying in Section 6402(f)(2) of the Affordable Care Act that the

Anti-Kickback Statute does not require the defendant to "have actual knowledge of this section [*i.e.*, the Anti-Kickback Statute] or specific intent to commit a violation of this section [*i.e.*, the Statute]." Pub. L. No. 111-148, 124 Stat. 119, 759 (codified at 42 U.S.C. § 1320a-7b(h)). That amendment abrogated the Ninth Circuit's "read[ing] the term to require proof that the defendant not only intended to engage in unlawful conduct, but also knew of the particular law in question and intended to violate that particular law." 155 Cong. Rec. 25920, 25921 (Oct. 28, 2009) (Sen. Kaufman); *see* App. 14a-15a & n.7. In abrogating *Hanlester*, Congress did not question the courts of appeals' otherwise-uniform consensus that the Anti-Kickback Statute imposed liability only where the defendant "intended to engage in unlawful conduct." 155 Cong. Rec. at 25921.

B. Factual Background

Some prescription drugs are purchased at pharmacies and taken at home. Others are administered to patients by providers in doctors' offices or outpatient clinics. App. 33a.[2] For physician-administered drugs, providers often purchase the specialty drugs from wholesale pharmaceutical distributors, then bill patients' insurers for the cost of those drugs. App. 3a, 33a.

When a patient is covered by Medicare, that insurer is the federal government. Medicare reimburses providers at standard, publicly disclosed rates that are set based on the average price at which drugmakers sell those drugs. *See* 42 U.S.C.

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[2] Because this case arises from the grant of a motion to dismiss, this statement draws on the allegations of Petitioner's complaint. *See* App. 3a n.1.

§ 1395w-3a; App. 3a. A provider can thus profit by purchasing drugs for less than the Medicare reimbursement rate, but also "bears the risk that the reimbursement rate for a given drug will fall below [the provider's] costs." App. 3a.

Respondent McKesson Corporation is a wholesale pharmaceutical distributor that provides prescription drugs to pharmacies and to healthcare providers, including the oncology clinics that are at issue in this case. *Id.* Petitioner alleges that McKesson has two business lines that serve oncology clinics: the U.S. Oncology Network, which provides member healthcare practices with management tools and services in exchange for a fee, and the Open Market division, which sells drugs to providers. *Id.*

Petitioner alleges that McKesson gave some oncology clinics that were Open Market division customers access to two spreadsheet-based tools that informed those clinics of the financial consequences of prescribing different drugs. App. 4a. The first of those tools, the Margin Analyzer, compares McKesson's prices with publicly available Medicare reimbursement rates for therapeutically equivalent drugs (*e.g.*, various iron supplements), and thus shows the financial consequences of prescribing particular drugs. *Id.* The second, the Regimen Profiler, is similar but allows practices to compare costs for entire courses of treatment (*e.g.*, reflecting how an injected drug might require more of a nurse's time than an equivalent oral medicine). *Id.*

Contrary to Petitioner's unsupported assertions (Pet. 25-26), neither tool purported to advise doctors on which drug was most appropriate to prescribe, which is of course a matter of medical judgment. Nor did the tools consistently suggest that providers

should purchase drugs that were more expensive for Medicare to reimburse, as Petitioner incorrectly suggests. *Cf.* Pet. 5. Instead, the tools pointed out where the margin between McKesson's price and the standard Medicare reimbursement rate was greatest. As materials attached to Petitioner's complaint made clear, the tools often showed providers that the margin was greater on drugs that cost Medicare less. McKesson Br. 11-12, ECF No. 77 (2d Cir.) (collecting examples).

C. Procedural History

Petitioner, a former McKesson employee, brought this *qui tam* action under the False Claims Act in 2015. He alleges that these spreadsheets were valuable to the practices that received them, App. 5a, even though equivalent tools comparing publicly available Medicare reimbursement rates with drug prices are available from other distributors, from online healthcare entities, and from trade associations, *cf.* App. 87(a) (declining to take judicial notice of those tools). He also alleges that McKesson offered them to practices that agreed to purchase most of their drugs from McKesson. App. 5a. He therefore claims that McKesson's provision of (or offer to provide) the tools to practices constituted a prohibited kickback in violation of the Anti-Kickback Statute.

Petitioner asserts that once a practice was offered or received access to the tools, *every claim* it thereafter submitted to Medicare or Medicaid violated the False Claims Act, making McKesson liable for treble damages for those claims. 2d Am. Compl. ¶ 116, 2d Cir. App'x JA296, ECF No. 55. Petitioner also asserted claims under the laws of 27 States and the District of Columbia.

The United States declined to intervene in the action. App. 6a; *see* 31 U.S.C. § 3730(b)(4)(B). McKesson then moved to dismiss Petitioner's first amended complaint on the grounds that he had not adequately alleged either that providing these spreadsheet-based tools constituted "remuneration" under the Anti-Kickback Statute *or* that McKesson had "willfully" violated that Statute by acting in a manner it knew to be unlawful. App. 77a. The District Court (Abrams, J.) held that Petitioner had adequately alleged that the provision of the tools could be "remuneration," though it acknowledged that this presented "a somewhat closer question." App. 84a. It concluded, however, that Petitioner's complaint "lacked any … non-conclusory allegations as to scienter." App. 100a.

In an attempt to cure that deficiency, Petitioner filed a second amended complaint adding scattered allegations about McKesson's supposed mens rea. For example, Petitioner alleged that while he was at McKesson, he and his coworkers had raised concerns about the propriety of McKesson's "sales practices," though he stopped short of alleging that he or anyone else at McKesson believed that offering the tools was unlawful. *See* App. 49a. The District Court determined that Petitioner's new allegations were insufficient to raise a plausible inference of willfulness. App. 48a-61a.

The Second Circuit unanimously affirmed in relevant part.[3] The court held that the Anti-Kickback Statute uses the term "willfully" in its general sense.

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[3] The court vacated the dismissal of state-law claims and remanded the claims for the district court to determine whether to exercise supplemental jurisdiction over them. App. 28a & n.17.

App. 12a. Under that common meaning, "a defendant must act with a bad purpose," *i.e.*, "with knowledge that his conduct was unlawful." App. 16a (quotation marks omitted). The defendant is not, however, required to know that its conduct violated, or have any specific intent to violate, the Anti-Kickback Statute in particular. *Id.*

The Second Circuit observed that Petitioner's broader rule not only was unsupported by the statutory text and case law, but also "would risk creating a trap for the unwary and deter socially beneficial conduct." App. 12a. The court refused to follow the Fifth Circuit's decision in *St. Junius*, noting that it is an "outlier" and "unpersuasive," and "[p]erhaps for that reason, the Fifth Circuit has failed to follow [its] reasoning … in several subsequent published decisions." App. 20a-21a.

The Second Circuit then applied this interpretation and held that Petitioner had not plausibly alleged that McKesson had acted "willfully" by providing spreadsheet tools to some oncology practices. App. 21a. The court of appeals concluded: "[N]one of Hart's allegations, alone or in combination with each other, plausibly suggests that when McKesson offered its Business Management Tools to encourage customers to commit to purchasing from McKesson, it believed that its conduct was unlawful under the [Anti-Kickback Statute] or any other law." App. 26a.

REASONS FOR DENYING THE PETITION

Petitioner contends that this Court should grant certiorari to reconcile a shallow split about how to read the term "willfully" in the Anti-Kickback Statute. But the split is illusory. The sole decision that adopts

Petitioner's interpretation—the Fifth Circuit's decision in *St. Junius*—is not even followed in the Fifth Circuit. Petitioner contends that the Eighth Circuit has adopted his interpretation of "willfully," but he is incorrect: That court has expressly rejected his interpretation. Moreover, the decision below correctly concluded that the Anti-Kickback Statute uses "willfully" the same way that criminal statutes generally use the term. The question presented does not warrant this Court's review, especially in this case.

I. The Circuits Are Not Split on the Meaning of "Willfully" in the Anti-Kickback Statute.

Petitioner asserts that the circuits are evenly divided on the question presented here. By Petitioner's count, two circuits—the Second and Eleventh—hold that, to act "willfully" under the Anti-Kickback Statute, a defendant must know that its conduct is unlawful. And two circuits—the Fifth and Eighth—hold that a defendant can act "willfully" without knowing its conduct is unlawful.

Petitioner's accounting falls apart upon closer inspection. At least seven circuits—the First, Second, Third, Fourth, Sixth, Seventh, and Eleventh—interpret "willfully" under the Anti-Kickback Statute to require that a defendant know its conduct is unlawful. Moreover, the overwhelming majority of Fifth Circuit decisions also follow the majority approach, which means that, at most, Petitioner has a lopsided split *within* the Fifth Circuit. And the Eighth Circuit has never held that a defendant can violate the Anti-Kickback Statute without evidence that it knew its conduct was unlawful. Because there is no circuit split, this Court should deny the petition.

A. The Second Circuit's Decision Is Consistent with Decisions of Six Other Courts of Appeals.

The Second Circuit held "that the term 'willfully' in the [Anti-Kickback Statute] means what it typically means in federal criminal law." App. 16a. "To act willfully under the [Statute], a defendant must act with a bad purpose. In other words, the defendant must act with knowledge that his conduct was unlawful." *Id.* (cleaned up). In so holding, the Second Circuit joined at least six other circuits that have interpreted "willfully" the same way.

As Petitioner concedes (Pet. 12-13), the Eleventh Circuit has repeatedly and consistently held that, to violate the Anti-Kickback Statute, a defendant must act "with the specific intent to do something the law forbids, that is with a bad purpose, either to disobey or disregard the law." *United States v. Sosa*, 777 F.3d 1279, 1293 (11th Cir. 2015) (quoting *United States v. Vernon*, 723 F.3d 1234, 1256 (11th Cir. 2013)); *see also Starks*, 157 F.3d at 837-38.

The Second and Eleventh Circuits are not alone in adopting this interpretation of the Anti-Kickback Statute. At least five other circuits have also interpreted "willfully" in the Anti-Kickback Statute to require a defendant to know its conduct was unlawful.

- **First Circuit.** *See Bay State*, 874 F.2d at 33 (affirming use in prosecution under Anti-Kickback Statute of jury instruction stating that "[w]illfully means to do something purposely, with the intent to violate the law, to do something purposely that law forbids").

- **Third Circuit.** *See United States v. Goldman*, 607 F. App'x 171, 174-75 (3d Cir. 2015) (approving jury instruction requiring that defendant "knew his conduct was unlawful and intended to do something the law forbids"); *United States v. Shvets*, 631 F. App'x 91, 95-96 (3d Cir. 2015) (similar).

- **Fourth Circuit.** *See United States v. Mallory*, 988 F.3d 730, 736-37 (4th Cir. 2021) (not irrational for jury to find that provider acted "willfully" by making commission payments while turning a "continued blind eye to illegal activity").

- **Sixth Circuit.** *See United States v. Montgomery*, No. 20-5891, 2022 WL 2284387, at *12 (6th Cir. June 23, 2022) (affirming conviction where evidence sufficient to show that defendant "knew his conduct was unlawful, and therefore … had the requisite mens rea in that he knowingly and willfully received unlawful kickbacks"), *cert. denied*, 143 S. Ct. 2581 (2023) (No. 22-6653); *United States v. Trumbo*, 849 F. App'x 147, 150 (6th Cir. 2021) (government "had to prove that [defendant] knew that he was receiving kickbacks unlawfully.").

- **Seventh Circuit.** *See Stop Ill. Health Care Fraud, LLC v. Sayeed*, 100 F.4th 899, 905 (7th Cir. 2024) (affirming judgment of liability under False Claims Act where defendant "knew full well that it was illegal to buy protected health information" (quotation marks omitted)); *United States v. Nagelvoort*, 856 F.3d

> 1117, 1126 (7th Cir. 2017) (evidence sufficient for jury to conclude that defendants who paid doctors for referrals "knew the contracts were illegal"); *United States v. Moshiri*, 858 F.3d 1077, 1082 (7th Cir. 2017) (similar).

Petitioner does not address the decisions from the First, Fourth, and Sixth Circuits. Despite acknowledging some of the decisions from the Third and Seventh Circuits, he dismisses them as irrelevant to the alleged circuit split. Pet. 14. In his view, those courts showed only "apparent approval" of the majority approach; they did not "directly h[o]ld" that "willfully" under the Anti-Kickback Statute to require that a defendant have known its conduct was unlawful. *Id.*

Those decisions cannot be disregarded so easily. In *Goldman*, for example, the Third Circuit clearly held that "[t]he District Court correctly instructed the jury on willfulness." 607 F. App'x at 174. That instruction stated that defendant's "conduct was willful if he knew his conduct was unlawful and intended to do something the law forbids." *Id.* (cleaned up). And the Seventh Circuit has held there was sufficient evidence of willfulness to support a conviction under the Anti-Kickback Statute by pointing to evidence that the defendant "knew" his conduct was "illegal." *See Nagelvoort*, 856 F.3d at 1127; *see also Stop Illinois Health Care Fraud*, 100 F.4th at 905 (similar).

In sum, Petitioner understates the consensus on interpreting "willfully" under the Anti-Kickback Statute to require that the defendant know its conduct is unlawful. At least seven circuits follow that approach.

B. The *St. Junius* Decision Does Not Establish a Contrary Rule in the Fifth Circuit.

In attempting to manufacture a circuit split, Petitioner focuses on *St. Junius*, 739 F.3d 193. Pet. 8, 15-16. In *St. Junius*, the Fifth Circuit stated that willfulness under the Anti-Kickback Statute does not require that a defendant knows its conduct is unlawful, but instead requires only that the defendant deliberately engaged in conduct that violated the statute. 739 F.3d at 210 & n.19.

As the Second Circuit explained, *St. Junius* is not only "unpersuasive," but also an "outlier" in the Fifth Circuit. App. 20a. Indeed, at least seven Fifth Circuit rulings—issued both before and after *St. Junius*—have required proof that the defendant knew its conduct was unlawful.

- *Davis*, 132 F.3d at 1094 (defendant must act "with the specific intent to do something the law forbids; that is to say, with bad purpose either to disobey or disregard the law" (cleaned up).
- *United States v. Njoku*, 737 F.3d 55, 64 (5th Cir. 2013) (defendant must act "with the specific intent to do something the law forbids" (cleaned up)).
- *United States v. Ricard*, 922 F.3d 639, 648 (5th Cir. 2019) (affirming conviction where the evidence was sufficient to prove "that [the defendant] knew the payments were unlawful").
- *United States v. Nora*, 988 F.3d 823, 830 & n.3 (5th Cir. 2021) (*reversing* a conviction where

government failed to present sufficient evidence that defendant "acted with knowledge that his conduct was unlawful").

- *United States v. Hagen*, 60 F.4th 932, 943 n.3 (5th Cir. 2023) (defendant must act "with the specific intent to do something the law forbids, meaning a bad purpose either to disobey or disregard the law" (cleaned up)).
- *United States v. Shah*, 95 F.4th 328, 350 (5th Cir. 2023) (defendant must act "with the specific intent to do something the law forbids or with bad purpose either to disobey or disregard the law" (cleaned up)).
- *Marchetti*, 96 F.4th at 828 ("A violation of the [Anti-Kickback Statute] requires that the defendant know that his actions were unlawful.").

Despite all of these decisions, Petitioner contends that *St. Junius* should be treated as establishing the law of the Fifth Circuit because "the Fifth Circuit follows the rule that, when panel decisions conflict, 'the earlier panel decision controls.'" Pet. 16 (quoting *Austin v. Davis*, 876 F.3d 757, 778 (5th Cir. 2017)). But, under that rule, *St. Junius* is properly disregarded because two earlier decisions held that willfulness under the Anti-Kickback Statute required a defendant to act "with the specific intent to do something the law forbids; that is to say, with bad purpose either to disobey or disregard the law." *Davis*, 132 F.3d at 1094; *accord Njoku*, 737 F.3d at 64. Perhaps for this reason, all of the Fifth Circuit decisions after *St. Junius* have followed *Davis* and *Njoku*, not *St. Junius*.

At most, Petitioner has identified an intra-circuit split. But "[i]t is primarily the task of a Court of Appeals to reconcile its internal difficulties." *Wisniewski v. United States*, 353 U.S. 901, 902 (1957) (per curiam); *see also Joseph v. United States*, 574 U.S. 1038, 1040 (2014) (Kagan, J., respecting the denial of certiorari) (this Court "usually allow[s] the courts of appeals to clean up intra-circuit divisions on their own"). The Fifth Circuit has done that, by consistently disregarding *St. Junius* and following the general rule that willfulness requires a defendant to know its conduct is unlawful.

Consistent with this longstanding practice, the Court recently denied a pair of petitions presenting the same intra-circuit split. *See* Petition, *Wilkerson*, No. 22-685, *supra*, at 4 (citing *Nora* and *St. Junius*, and arguing that "[t]he Fifth Circuit is split within itself"); Petition, *Montgomery*, No. 22-6683, *supra*, at 2-3 ("The Fifth Circuit … seems to be at odds with itself …."); *see also* 143 S. Ct. 2581 (denying the petitions). In the 14 months since the petitions were denied, the intra-circuit split has only become more lopsided. *See Marchetti*, 96 F.4th at 828; *Shah*, 95 F.4th at 350.[4]

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[4] Petitioner cites several district-court decisions applying *St. Junius*, Pet. 16 & n.5, but omits other district-court decisions that have applied the ordinary definition of "willfully" in this context. *See, e.g.*, *United States v. Medoc Health Servs. LLC*, 470 F. Supp. 3d 638, 656 (N.D. Tex. 2020) ("To act willfully is to act with the specific intent to do something the law forbids." (quotation marks omitted)); *United States ex rel. Emerson Park v. Legacy Heart Care, LLC*, No. 3:16-CV-0803, 2019 WL 4450371, at *11 (N.D. Tex. Sept. 17, 2019) ("For a defendant to act 'knowingly and willfully' under the Anti-Kickback Statute], the defendant must have acted 'voluntarily[,] intentionally, ... and purposely with the specific intent to do something the law

C. The Eighth Circuit Has Not Departed from the Consensus View.

That leaves only Petitioner's alleged split between the decision below and the Eighth Circuit. Pet. 17-18. But the Eighth Circuit has never adopted the rule that Petitioner ascribes to it.

To the contrary, the Eighth Circuit's leading case explicitly *rejected* Petitioner's construction of the Anti-Kickback Statute. *See Jain*, 93 F.3d at 440. In that case, the government and defendants proposed "radically different" interpretations of the Anti-Kickback Statute. *Id.* The government contended—as *St. Junius* later held and Petitioner argues here—that it needed to prove that the defendant was "conscious[] of the act but not … conscious[] that the act [wa]s unlawful." *Id.* (quotation marks omitted). Conversely, the defendants asked the court to incorporate into the Anti-Kickback Statute the strongest willfulness requirement, which this Court has applied in criminal-tax and currency-structuring cases. *Id.*; *see supra* pp. 5-6.

The Eighth Circuit rejected both parties' arguments and instead adopted a "middle ground" approach. *Jain*, 93 F.3d at 440. Because the statute's broad language reached conduct that was not "inevitably nefarious," the court held that the government needed to meet a "heightened mens rea burden," not just show that the defendants acted deliberately. *Id.* The Eighth Circuit thus rejected the government's argument that the government did not

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forbids; that is to say, with bad purpose either to disobey or disregard the law.'" (quoting *Davis*, 132 F.3d at 1094)); *United States ex rel. Patel v. Cath. Health Initiatives*, 312 F. Supp. 3d 584, 595 (S.D. Tex. 2018) (similar), *aff'd*, 792 F. App'x 296 (5th Cir. 2019).

have to prove that the defendant was "conscious[] that [his] act is unlawful." But the Eighth Circuit also rejected the defendants' argument that—as in *Ratzlaf*, *Cheek*, and *Hanlester*—the government needed to prove that they violated a "known legal duty," *i.e.*, that they knew about and intended to violate the law they were charged with violating. *Id.* (quoting *Cheek*, 498 U.S. at 201, and citing *Ratzlaf*, 510 U.S. at 148). Instead, it was sufficient that the defendants knew that their conduct was "wrongful."

In defining "willfully" that way, the Eighth Circuit aligned itself with the courts of appeals (other than the Ninth Circuit) that had considered the issue. Those other courts likewise found a "middle ground" between efforts to equate willfulness with deliberate action, on the one hand, and the especially demanding mens rea requirement of *Cheek* and *Ratzlaf*, on the other. While *Jain* described that "middle ground" in slightly different terms than other courts—*i.e.*, as "unjustifiably and wrongfully, known to be such by the defendant," *id.*, rather than as done "with bad purpose either to disobey or disregard the law," *e.g.*, *Davis*, 132 F.3d at 1094—nothing in the decision suggested that the Eighth Circuit intended to chart a substantively different course.

Nor have subsequent Eighth Circuit decisions attempted to differentiate between knowledge of *unlawful* conduct and knowledge of *lawful but wrongful* conduct. In *United States v. Yielding*, that court concluded that it was not error to instruct the jury that it could convict if it found "that the defendant knew his conduct was wrongful or unlawful," reasoning simply that the instruction "was consistent with *Jain*." 657 F.3d 688, 708 (8th Cir. 2011). Nothing in that decision suggests that the

Eighth Circuit understood "wrongful" to mean something other (and less demanding) than "unlawful." To the contrary, the court held that it was not plain error for the district court to have instructed the jury that it could convict if it concluded that the defendant's conduct was "wrongful *or* unlawful," suggesting there was no meaningful distinction between these two terms.

The more recent decision in *United States v. Goodwin*, 974 F.3d 872 (8th Cir. 2020), further suggests that the Eighth Circuit's interpretation of the Anti-Kickback Statute's mens rea requirements is aligned with that of the other courts of appeals. There, the Eighth Circuit held that the government had proved mens rea because there was evidence that the defendant was "on notice" that a particular payment "arrangement … was *unlawful*." *Id.* at 875 (emphasis added). That analysis would have made little sense if the Eighth Circuit had in fact adopted a more relaxed mens rea requirement, as Petitioner contends.

Petitioner cites *no* other case from the Eighth Circuit supporting any supposed distinction between "wrongful" and "unlawful." It is therefore unclear whether there is *any* daylight between the Eighth Circuit's definition of "willfully" and how every other court of appeals defines that term. And it is clear that even if there is, that distinction is irrelevant in practice. This Court should not grant review to consider an alleged split that appears to be illusory or at worst academic.

II. The Second Circuit's Decision Is Correct.

This Court should also deny the petition because the well-reasoned decision below is correct. The court

of appeals simply concluded that Congress used "willfully" in the Anti-Kickback Statute to mean what it usually means in a federal criminal statute: that the defendant must know that its conduct was unlawful. App. 9a-10a (quoting *Bryan,* 524 U.S. at 191); *see also* App. 16a.

A. When Congress uses a term of art in a statute, courts should presume that Congress intended for the term to be given its established meaning. "[W]illfully" is "a word of many meanings whose construction is often dependent on the context." *Bryan,* 524 U.S. at 191 (quotation marks omitted). But "when used in the criminal context," that word typically describes an act "undertaken with a bad purpose," or, "[i]n other words," that "the defendant acted with knowledge that his conduct was unlawful." *Id.* at 191-92 (quotation marks omitted).[5]

The Second Circuit correctly applied this general understanding of "willfully" to the Anti-Kickback Statute. Because it is a criminal statute, creating felonies punishable by up to 10 years' imprisonment, 42 U.S.C. § 1320a-7b(b), the Anti-Kickback Statute should be read as incorporating that ordinary meaning of willfulness. That interpretation does not change simply because the issue arises, as here, in a False Claims Act case, rather than in a criminal prosecution. *See Leocal v. Ashcroft*, 543 U.S. 1, 11 n.8

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[5] *See also Dixon v. United States*, 548 U.S. 1, 5 (2006) (for mens rea of "willfully," defendant must "have acted with knowledge that his conduct was unlawful" (quotation marks omitted)); *Wooden v. United States*, 595 U.S. 360, 378 (2022) (Kavanaugh, J., concurring) ("[W]ith respect to federal crimes requiring 'willfulness,' the Court generally requires the Government to prove that the defendant was aware that his conduct was unlawful.").

(2004) ("[W]e must interpret the statute consistently, whether we encounter its application in a criminal or noncriminal context ….").

Congress's repeated amendments of the Anti-Kickback Statute confirm that Congress intended for "willfully" to carry its common meaning and require that the defendant acted with knowledge that its conduct was unlawful. The original version of the statute did not have an express mens rea requirement, and violations of the statute were punishable only as misdemeanors. *See* 86 Stat. at 1418-19 (originally codified at 42 U.S.C. §§ 1395nn, 1396h). Shortly after amending the law to treat violations as a felony, Congress added the "knowingly and willfully" mens rea requirement. 91 Stat. at 1179-82 (amending 42 U.S.C. §§ 1395nn, 1396h); 94 Stat. at 2625 (same). Congress imposed a heightened mens rea requirement out of "concern[] that criminal penalties may be imposed … [on] an individual whose conduct, while improper, was inadvertent." H.R. Rep. No. 96-1167, at 59. Interpreting the statute as allowing for liability when a defendant merely acted deliberately—regardless of his knowledge that doing so was unlawful—flouts Congress's choice to add a robust mens rea requirement to the statute.

The 2010 amendment to the Anti-Kickback Statute confirms that reading. By the late 1990s, a split had emerged among several courts of appeals over how to interpret "willfully" in the Anti-Kickback Statute. Most courts gave the term its usual meaning, holding that a defendant must know that its conduct was "unlawful" or "wrongful," but need not have specifically intended to violate the Anti-Kickback Statute. *See, e.g.*, *Bay State,* 874 F.2d at 33; *Jain*, 93

F.3d at 440; *Starks*, 157 F.3d at 837-38. But the Ninth Circuit had adopted the more stringent mens rea requirement applicable to highly technical statutes, and held that a willful violation required a specific intent to violate the Anti-Kickback Statute. *Hanlester*, 51 F.3d at 1400.

Congress resolved the disagreement in favor of the usual interpretation of "willfully." Congress added a provision to the Anti-Kickback Statute to clarify that the law does not require a defendant to "have actual knowledge of this section [*i.e.*, the Anti-Kickback Statute] or specific intent to commit a violation of this section [*i.e.*, the Statute]." 124 Stat. at 759 (codified at 42 U.S.C. § 1320a-7b(h)). This provision thus rejected the Ninth Circuit's interpretation as "requir[ing] proof that the defendant not only intended to engage in unlawful conduct, but also knew of the particular law in question and intended to violate that particular law." *See* 155 Cong. Rec. at 25921.

The Second Circuit's interpretation also comports with the statute's purpose. The statutory language is extraordinarily "expansive" and threatens to punish what would be standard operating procedure in many other industries with prison time, exclusion from participation in federal healthcare programs, and possibly even treble-damages, statutory penalties, and attorney's fees under the False Claims Act. App. 11a-12a; *see* 42 U.S.C. §§ 1320a-7(a)(1), 1320a-7b(b). The bounds of the Statute's prohibitions are ill-defined and turn on the meaning of nebulous terms like "remuneration." 42 U.S.C. § 1320a-7b(b); *see* App. 17a-18a. "As a result, even a well-counseled defendant who has taken every effort to comply with the [Statute] and all other relevant laws could still

find herself accidentally in violation of the statute." App. 13a. Given the Anti-Kickback Statute's expansive language, which makes its precise "reach … is far from settled," *id.*, a robust mens rea requirement is "necessary to separate wrongful conduct from otherwise innocent conduct." *Ruan v. United States*, 597 U.S. 450, 458 (2022) (quotation marks omitted).

Interpreting "willfully" to require knowledge of unlawfulness is also important to avoid discouraging healthcare businesses and providers from offering beneficial services. The government has cautioned that "[s]ince the statute on its face is so broad, concern has arisen among a number of health care providers that many relatively innocuous, or even beneficial, commercial arrangements are technically covered by the statute and are, therefore, subject to criminal prosecution." Dep't of Health & Hum. Servs., Off. of Inspector Gen., Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,952 (July 29, 1991). On its face, the Anti-Kickback Statute could be read to reach a variety of socially beneficial arrangements that pose no threat to the integrity of federal healthcare programs—for example, services by which manufactures educate patients about how to take their medicines.[6]

The statute's mens rea requirement helps ensure that healthcare industry participants who operate in good faith cannot be held liable if they inadvertently engage in a practice later deemed to constitute a

[6] Reflecting the Anti-Kickback Statute's potential to reach innocent conduct, Congress and federal regulators have promulgated lengthy lists of particular arrangements that do not (or will be deemed not to) violate the Statute. 42 U.S.C. §§ 1320a-7b(b)(3), 1320a-7d; 42 C.F.R. § 1001.952 (2023).

prohibited kickback. Diminishing the statute's mens rea requirement, as Petitioner urges, would mean that these participants could be subject to criminal prosecution and—through the False Claims Act—ruinous liability for Medicare and Medicaid claims "resulting from" violations of the Statute. *See* 42 U.S.C. § 1320a-7b(g). And it would deprive defendants of a tool for dismissing suits where relators have not plausibly alleged that the defendants did not act in good faith. Either way, that prospect will make for more mercenary lawsuits, greater settlement pressure, and a powerful disincentive to offering beneficial services that a relator might later allege to have been prohibited kickbacks.[7]

B. Petitioner's contrary arguments lack merit. Petitioner incorrectly contends that the statutory text supports his interpretation. To violate the Anti-Kickback Statute, a defendant must "knowingly *and* willfully offer[] or pay[] any remuneration" for prohibited purposes. 42 U.S.C. § 1320a-7b(b)(2) (emphasis added). But if Petitioner (and *St. Junius*) were correct that "willfully" requires only deliberate action, then the statute's separate requirement that the defendant act "knowingly" would render "willfully" surplusage. That is not how statutes are

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[7] Petitioner amplifies his already-tendentious allegations by contending that Respondents did not act in such good faith. Pet. 24. But his assertions that the business tools "massively increas[ed] costs to Medicare" or that he warned that they "did not square with [Respondents'] own Anti-Kickback Statute compliance programs" lack a basis in his complaint, let alone in the truth. The Second Circuit explained at length why his allegations were insufficient to plead that Respondents acted willfully, App. 21a-26a, and that factbound (and correct) determination does not warrant this Court's review.

supposed to be interpreted. The Second Circuit's reading, by contrast, gives effect to "every clause and word of [the] statute." *United States ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419, 432 (2023).

Petitioner fares no better in arguing that the way the Anti-Kickback Statute is drafted—with "knowingly and willfully" purportedly modifying only the proscribed conduct—makes the statute more like laws subject to a lower mens rea. Pet. 21-22 (citing *Browder v. United States*, 312 U.S. 335 (1941), and *Morissette v. United States*, 342 U.S. 246 (1952)). But this Court has repeatedly rejected similar attempts to limit the reach of mens rea elements. *See, e.g.*, *Ruan*, 597 U.S. at 458 ("We have … held that a word such as 'knowingly' modifies not only the words directly following it, but also those other statutory terms that 'separate wrongful from innocent acts.'" (quoting *United States v. Rehaif*, 588 U.S. 225, 232 (2019))).[8] The Second Circuit correctly refused to follow a different approach here.

Petitioner's interpretation also depends on an implausible reading of the 2010 amendments. By Petitioner's telling, Congress added the new provision

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[8] The comparison between the Anti-Kickback Statute and the statutes in *Browder* and *Morrissette* also fails. Those statutes prohibited knowingly and willfully engaging in conduct that was *itself* inherently wrongful (*i.e.*, use of a passport obtained with false statements and conversion of government property, respectively). By contrast, the general prohibitions of the Anti-Kickback Statute arguably reach a wide range of healthcare-industry payment arrangements, some of which would be uncontroversial in other industries—a point underscored by the fact that Congress and the Executive Branch have promulgated a litany of exceptions to those general prohibitions through statutory and regulatory safe harbors and through advisory opinions. *See supra* pp. 25-26 & n.6.

not merely to reject the Ninth Circuit's interpretation in *Hanlester*, but to reject *both sides of the split*—thereby disagreeing with every court of appeals to have interpreted the statute. No legislative history suggests that any member of Congress thought that was the provision they were enacting. Had Congress really intended to make that change, it could have simply removed "willfully" from the statute and imposed only a "knowingly" mens rea requirement.[9] But Congress did not do so. It left "willfully" in the statute while clarifying that the term did not require an intent to violate the Anti-Kickback Statute in particular.

Petitioner also errs in arguing that interpreting the Anti-Kickback Statute to have a heightened mens rea requirement is in tension with Congress's decision to establish safe harbors for specific conduct. *Cf.* Pet. 20-21. The statutory safe harbors describe conduct—namely, particular financial arrangements—and lack distinct mens rea requirements. Thus, even if the safe harbors create affirmative defenses, *id.* at 20, there is no inconsistency in concluding that mens rea is an element of an Anti-Kickback Statute violation while

[9] Petitioner seizes on the Second Circuit's statement that a defendant must violate a "known legal duty," arguing that the 2010 amendment was specifically intended to "wr[i]te [that interpretation] out of the Anti-Kickback Statute." Pet. 20 (citing App. 10a; *Pfizer, Inc. v. Dep't of Health & Hum. Servs.*, 42 F.4th 67, 77 (2d Cir. 2022)). As the Second Circuit explained, however, the Statute requires only that a defendant violate some legal duty of which it is aware, not the Anti-Kickback Statute in particular. *See* App. 10a-11a. In this way, the Second and Eighth Circuits are aligned in rejecting the heightened willfulness requirement that applies to technical statutes, consistent with the 2010 amendment. *Cf.* Part I.C *supra* (discussing Eighth Circuit caselaw).

also concluding that, regardless of its mental state, a defendant whose conduct falls within a safe harbor cannot be liable under that Statute. If the fact that a defendant is operating in a safe harbor means that the defendant *also* lacks the requisite mens rea, that is not an inconsistency, but just another reason why the defendant cannot be liable under the Statute.

III. This Case Is a Poor Vehicle for Resolving the Purported Circuit Split.

Petitioner contends that resolving the alleged circuit split here is important because "[t]he conduct alleged here would violate the Anti-Kickback Statute applying the standards adopted by the Fifth and Eighth Circuits." Pet. 26. Petitioner is incorrect as to each circuit.

Petitioner argues that his claims would have survived a motion to dismiss in the Fifth Circuit, but every decision that court has issued in the past decade—at least five of them—applied the same willfulness requirement as the Second Circuit. *See* Part I.B *supra*. Those panels would have dismissed Petitioner's claims just as the Second Circuit did.

Nor is there any reason to think that Petitioner's claims would have survived a motion to dismiss in the Eighth Circuit. That court has not held that a defendant can violate the Anti-Kickback Statute even if it does not know that its conduct is unlawful. *See* Part I.C *supra*. The Eighth Circuit has held that "wrongful" conduct can violate the Anti-Kickback Statute, but it has never explained whether that term is synonymous with "unlawful," or whether it encompasses conduct that is lawful, yet wrong. This Court should wait until the Eighth Circuit decides

that question to see whether a circuit split actually develops.

In any event, this is not the case to explore whether "wrongful" is different from "unlawful." This issue has been raised for the first time in this Court, and thus has not been properly preserved. Petitioner did not advocate for a "knowingly wrongful" standard below and apparently does not do so before this Court.

In the Second Circuit, he never argued that the Eighth Circuit imposed a different, more lenient standard of "willfulness" than that imposed by the other courts. *Cf.* Hart Br. 7, 32-34, ECF No. 51 (arguing that Eighth Circuit applied mens rea requirement in same manner as other courts); *id.* at 37-41 (arguing for *St. Junius* rule). Petitioner now relies chiefly on *Yielding*, 657 F.3d 688, but he did not even cite that case below, and the Second Circuit cited the case only to explain why its approach "aligns with the approach … taken by several of [its] sister circuits." App. 11a; *see also* App. 19a-20a.

Even now, while Petitioner argues that the Anti-Kickback Statute "does not require knowledge of unlawful conduct," Pet. 18 (capitalization adapted), he never argues that it requires knowledge of "wrongful" conduct. He instead suggests that *no* culpable mental state is required. *Id.* at 21-22. This Court should not grant certiorari to address a hypothetical conflict between the decision below and a position Petitioner has not asserted and is unwilling to defend.

Finally, there is a reason Petitioner does not want a "wrongful or unlawful" standard: He has not plausibly alleged either. As the courts below noted, Petitioner relied on "peculiarly indirect" and "artful[ly] ple[d]" allegations to try to plead

Respondents' supposed knowledge that providing spreadsheet-based tools with publicly available information to oncology clients was supposedly unlawful. App. 24a n.11, 49a. The Second Circuit held that Petitioner's allegations were insufficient to plead Respondents' mental state. And its reasoning demonstrates that Petitioner's allegations would also be insufficient if he needed to plead that Respondents knew that their conduct was "wrongful."

For example, Petitioner alleged that he told his supervisor that Respondents' sales practices violated the company's compliance policies and that he "discussed concerns" with the creator of one of the tools. App. 24a-25a. As the Second Circuit explained, however, those allegations not only fell short of alleging that *anyone* thought the conduct might be unlawful, but also were insufficient to allege that those views could be imputed to *Respondents*, such that *Respondents* ever allegedly formed the required mens rea. *Id.* That logic dooms Petitioner's claim regardless of the precise definition of "willfully."[10]

This Court should not grant review to decide an issue that will thus have no bearing on this case.

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[10] Nor is there any reason for this Court to review the Second Circuit's fact-bound conclusion that Petitioner's other allegations—including that Respondents purportedly destroyed evidence or that one executive sent another a single email attaching a lengthy set of documents that referenced the tools a handful of times in passing—did not adequately allege willfulness. *See* App. 22a-23a (alleged destruction of evidence does not suggest that Respondents thought they were doing anything wrong "*concurrently* with the [alleged] violation"); App. 25a-26a (Petitioner did not plausibly allege that the sender of the email was even referring to the tools, much less that the sender's "sentiment" could be imputed to Respondents).

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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