No. 23-_____

IN THE
Supreme Court of the United States

UNITED STATES OF AMERICA 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

PETITION FOR A WRIT OF CERTIORARI

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June 7, 2024

QUESTION PRESENTED

The Anti-Kickback Statute prohibits, among other things, "knowingly and willfully offer[ing] or pay[ing] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person . . . to purchase . . . any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2)(B). To violate the Anti-Kickback Statute, a "person need not have actual knowledge of [the Statute] or specific intent to commit a violation of" it. *Id.* § 1320a-7b(h).

The question presented is:

> To act "willfully" within the meaning of the Anti-Kickback Statute, must a defendant know that its conduct violates the law?

PARTIES TO THE PROCEEDINGS

Petitioner Adam Hart was the *qui tam* plaintiff and relator on behalf of the United States of America, and the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Washington, and the District of Columbia, in the district court proceedings, and the appellant in the court of appeals proceedings.

Respondents McKesson Corporation, McKesson Specialty Distribution LLC, and McKesson Specialty Care Distribution Corporation were the defendants in the district court proceedings and the appellees in the court of appeals proceedings.

RELATED CASES

United States ex rel. Hart v. McKesson Corp., 602 F. Supp. 3d 575 (S.D.N.Y. May 5, 2022) (No. 15-CV-0903 (RA))

United States ex rel. Hart v. McKesson Corp., 2022 WL 2286950 (S.D.N.Y. June 22, 2022) (No. 15-CV-0903 (RA))

United States ex rel. Hart v. McKesson Corp., 2023 WL 2663528 (S.D.N.Y. Mar. 28, 2023) (No. 15-CV-0903 (RA))

United States ex rel. Hart v. McKesson Corp., 96 F.4th 145 (2d Cir. Mar. 12, 2024) (No. 23-726-cv)

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Petitioner Adam Hart, as the *qui tam* plaintiff and relator on behalf of the United States of America, and the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Washington, and the District of Columbia, petitions for a writ of certiorari to review the Second Circuit's judgment in this case.

OPINIONS BELOW

The Second Circuit's opinion (App. 1a-29a) is reported at 96 F.4th 145. The opinion and order of the district court granting the motion to dismiss the Second Amended Complaint (App. 30a-63a) is not reported but is available at 2023 WL 2663528. The opinion and order of the district court granting the motion to dismiss the First Amended Complaint (App. 64a-105a) is reported at 602 F. Supp. 3d 575.

JURISDICTION

The Second Circuit entered judgment on March 12, 2024. This Court has jurisdiction to review that judgment under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

The Anti-Kickback Statute (or "Statute"), 42 U.S.C. § 1320a-7b(b), and relevant provisions of the False Claims Act, 31 U.S.C. § 3729 *et seq.*, are reproduced at App. 106a-123a.

INTRODUCTION

Federal health programs such as Medicare and Medicaid account for more than $1.5 trillion a year in federal spending. Those programs are constantly beset by waste, fraud, and abuse. As a protective measure, Congress has enacted the Anti-Kickback Statute, which prohibits the offer, payment, solicitation, or receipt of "remuneration" – including, but not limited to, bribes and kickbacks – to induce the purchase of goods and services paid for by a federal health program. To violate the Statute, the payor or recipient of a kickback must act "knowingly and willfully." Congress has specified that this scienter requirement does not mean that the violator must know of the Statute itself. Nevertheless, the circuits are divided on what constitutes knowing and willful action.

The Second Circuit has adopted a rule that a bribe or kickback violates the Anti-Kickback Statute only if the payor or recipient intends to violate a known legal duty – a duty imposed either by the Statute itself or by some other provision of law such as the federal wire and mail fraud statutes. In adopting its rule, the Second Circuit joined at least the Eleventh Circuit, but split with the Fifth and Eighth Circuits. The Fifth Circuit has construed the Statute to require only that the prohibited acts be performed knowingly and willfully, as opposed to by mistake or accident. The Eighth Circuit has construed it to require intent to commit an act known to be wrongful, but not necessarily one known to be unlawful.

This case illustrates the difference and shows why it matters. Respondent McKesson Corporation is a pharmaceutical wholesaler: among other things, it sells anti-cancer drugs to oncology practices. To bolster its sales, it designed software tools that show medical practices which prescriptions and treatment plans will maximize their revenue – with no basis in medical efficacy and with no regard for costs imposed on patients or their insurers. It then used those valuable software tools (worth as much as $150,000 to some practices, by its own calculations) as an inducement for practices to buy from McKesson. The district court found that McKesson's practice was prohibited remuneration under the Anti-Kickback Statute.

Petitioner and relator Hart, a former McKesson employee, observed during compliance training that McKesson was paying prohibited (and unethical) remuneration to medical practices. He warned his supervisor and colleagues. McKesson nevertheless continued to give out its software tools to induce purchasers. During the course of a Department of Justice investigation, it even destroyed documents about its practices. In the Fifth and Eighth Circuits, McKesson's conduct would have violated the Anti-Kickback Statute: it was committed intentionally and was wrongful on its face. But the Second Circuit rejected Hart's allegations, holding that his allegations did not support an inference that McKesson believed his warnings or otherwise knew that its conduct was unlawful.

This Court should now grant review to resolve the circuit courts' ongoing and important disagreement about the mental state needed to violate the Anti-Kickback Statute. It should then hold that knowledge of illegality is not required. The contrary rule adopted by the Second and Eleventh Circuits contravenes the text of the statute, departs from Congress's goals of preventing waste, fraud, and abuse, and shows too much solicitude for a company that deliberately profiteered off cancer patients but (erroneously) contended that it had followed the letter of the Statute.

STATEMENT

1. The Anti-Kickback Statute is a criminal statute that prohibits "knowingly and willfully" offering or providing any remuneration to induce the purchase of goods or services that may be reimbursed by a federal health program, such as Medicare. 42 U.S.C. § 1320a-7b(b). It is the only federal statute that explicitly prohibits the provision of kickbacks. Through amendments passed in 2010, Congress clarified that the term "knowingly and willfully" in the Statute does not require "actual knowledge of this section or specific intent to commit a violation of this section." *Id.* § 1320a-7b(h) (added by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6402(f)(2), 124 Stat. 119, 759 (2010)). Any claim for payment made to a government agency resulting from an Anti-Kickback Statute violation is "false or fraudulent" under the False Claims Act, 31 U.S.C. § 3729(a). *See* 42 U.S.C. § 1320a-7b(g).

2. Respondent McKesson is a large wholesale pharmaceutical distributor that purchases drugs from manufacturers and then resells them at a markup to physician practice groups, including oncology practices. App. 3a. Unlike ordinary drugs that are typically dispensed to individual patients through pharmacies, oncology drugs are frequently purchased by oncology practices and administered by the practices to their patients. *Id.* The practices that purchase pharmaceuticals from McKesson then bill the patient's insurer – including Medicare and Medicaid – for the costs of the drugs. *Id.*

This case concerns whether McKesson violated the Anti-Kickback Statute by giving business management tools called the Margin Analyzer and Regimen

Profiler to practices for no monetary cost, but in exchange for commitments by those practices to buy most of their drugs from McKesson. App. 4a-5a.

Because oncology practices buy drugs from wholesalers like McKesson and then "sell" them to patients, they can earn profits (or losses) on each dose they administer depending on the drug's purchase price and reimbursement rate. App. 4a. The Margin Analyzer evaluates categories of "therapeutically interchangeable" drugs – *i.e.*, drugs that, according to McKesson, can be substituted for one another – and recommends which drugs from each category a given oncology practice should prescribe to its patients based on their insurance provider. *Id.* The recommendation has nothing to do with patient welfare. Its sole basis for the recommendation is the drug that will yield the highest profit margins to the oncology practice. *Id.* The Margin Analyzer does not take into account medical efficacy, side effects, cost to the government or other insurers, or out-of-pocket cost to patients. *Id.*

Based on the current utilization rates of the practice's patient pool, the Margin Analyzer calculates the additional profit margin that the physician group could generate by switching its patients' prescriptions to other "therapeutically interchangeable" drugs. *Id.* McKesson even created individualized Margin Analyzers for oncology practices on a quarterly basis to capture the quarterly changes in reimbursement rates by Medicare and other insurers. App. 35a-36a.

The Regimen Profiler is a similar tool that informs practices about the profitability of an entire course of treatment for a patient. App. 4a. Many oncology drugs are administered in physician offices by medical staff. Medicare and Medicaid typically reimburse practices for the efforts in administering those drugs as well as for the costs of the drugs themselves. Like the Margin Analyzer, the Regimen Profiler considers reimbursement for drug administration and other courses of treatment and identifies the most profitable treatment course. *Id.*

McKesson knew that the Margin Analyzer and Regimen Profiler were worth a great deal of money to medical practices. App. 4a-5a. In internal documents, it estimated the "Market Value" of the two business tools at more than $150,000 per year to a "larger representative practice." App. 42a; C.A. App. 309. Providing these tools in exchange for purchase commitments formed the centerpiece of McKesson's nationwide sales strategy. App. 5a. Rather than compete on price, McKesson used the tools to induce drug purchases and to win business. *Id.* Indeed, McKesson considered the tools so important a business-generation device that it "refused to offer them on a standalone basis, even when providers expressly requested as much and offered to pay." *Id.*

McKesson's tactics worked. By 2014, it credited its free business tools as the "[s]ecret sauce" that made it the "#1 [wholesaler] in Oncology." C.A. App. 299. At least 113 practices nationwide that received the Margin Analyzer and/or Regimen Profiler as an inducement to purchase drugs from McKesson thereafter submitted claims for reimbursement to government health agencies. App. 34a.

3. McKesson knew about the Anti-Kickback Statute and knew what it prohibited. Every customer-facing employee and sales executive at McKesson was required to undergo annual compliance training on the Statute, which emphasized that providing anything of value to induce the sale of drugs was unlawful. App. 5a-6a, 24a. It further knew that the Margin Analyzer and Regimen Profiler were valued at $150,000 and that these tools were given to practices for free to induce purchase commitments. App. 42a.

McKesson's employees contemporaneously expressed concern that its sales practices were unlawful. For instance, during an Anti-Kickback Statute training session, petitioner Hart advised his supervisor, who was then McKesson's South Region Vice President of Sales and Account Management, that the company's sales practices violated the instructions employees were given in the training session. App. 24a. That supervisor dismissed these concerns. App. 42a-43a. Hart and other McKesson sales employees also discussed that McKesson's kickback scheme was "unethical and wrongful" because it encouraged physician practices to purchase the highest-margin drugs, which led cancer patients to make far higher co-payments and the government and private insurers to pay far higher reimbursements rates. App. 50a-51a. Hart also alleges that McKesson improperly destroyed documents after the start of this case, including all files on Hart's laptop. McKesson did so even though the Department of Justice had already served McKesson with a civil investigative demand for documents about Hart's allegations. App. 22a.

4. On February 6, 2015, Hart filed his initial Complaint on behalf of the United States, 27 States, and the District of Columbia, asserting claims under the False Claims Act based on McKesson's violation of the Anti-Kickback Statute and analogous state laws. On May 29, 2020, the Complaint was unsealed. On June 3, 2020, Hart filed a First Amended Complaint. McKesson moved to dismiss, arguing that Hart failed to allege that the Margin Analyzer and Regimen Profiler constitute prohibited remuneration under the

Anti-Kickback Statute; failed to allege that McKesson acted "knowingly and willfully"; and failed to plead with sufficient particularity that false claims were submitted to the government.

The district court rejected McKesson's first argument, ruling that Hart adequately alleged that the business tools were prohibited remuneration. App. 78a-87a; *see* App. 82a (quoting McKesson's "internal assessment of the Margin Analyzer as 'the single most important, and most valuable, tool for McKesson to win new business and maintain its existing customers'"; C.A. App. 231). It also rejected the third argument, ruling that Hart had alleged with particularity that McKesson had caused the submission of false or fraudulent claims. App. 100a-103a; *see* App. 101a-102a (finding that Hart's "allegations support a 'strong inference' that the practices named in the complaint which were provided the Margin Analyzer and Regimen Profiler actually submitted claims for reimbursement to federal health care programs").

But the district court accepted McKesson's second argument, ruling that the First Amended Complaint did not adequately plead scienter. App. 90a. The court acknowledged that the circuit courts were split on what the term "willfully" means under the Anti-Kickback Statute. App. 94a-97a. The Fifth Circuit, for instance, held in *United States v. St. Junius*, 739 F.3d 193 (5th Cir. 2013), that "willfully" requires only that the "defendant willfully committed an act that violated the . . . Statute." *Id.* at 210. It does not recognize any requirement that a defendant know that its conduct was unlawful. But the Eleventh Circuit held in *United States v. Sosa*, 777 F.3d 1279 (11th Cir. 2015), that willfulness under the Statute requires a defendant to have acted with knowledge that its conduct was unlawful. *Id.* at 1293.[1] And the Eighth Circuit, in *United States v. Jain*, 93 F.3d 436 (8th Cir. 1996), staked out the intermediate position that "willfully" requires only knowledge that the defendant's conduct "was *wrongful*, rather than proof that he knew it violated 'a known *legal* duty.'" *Id.* at 441 (emphases added).[2]

The district court concluded that Hart was required to plead that McKesson had acted with knowledge that its conduct was unlawful. App. 97a. It further concluded that Hart could not do so by alleging (1) that McKesson knew that the Anti-Kickback Statute prohibited giving anything of value as an inducement, but (2) nonetheless intentionally gave away business tools that it knew were worth hundreds of thousands of dollars. App. 99a-100a. Instead, the court suggested that Hart had to plead special facts that would show heightened intent, "such as actions taken to conceal the fraudulent scheme; notice from counsel that the program may be unlawful; cancellation of the program

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[1] The district court also attributed this view to the First Circuit based on *United States v. Bay State Ambulance & Hospital Rental Service, Inc.*, 874 F.2d 20, 33 (1st Cir. 1989), to the Third Circuit based on *United States v. Goldman*, 607 F. App'x 171, 174-75 (3d Cir. 2015), and to the Seventh Circuit based on *United States v. Nagelvoort*, 856 F.3d 1117, 1126 (7th Cir. 2017).

[2] The district court incorrectly cited *Jain* as supporting a conclusion that "the term 'willfully' requires knowledge that the relevant conduct is unlawful," while simultaneously quoting *Jain*'s statement that the Anti-Kickback Statute requires only "kn[owledge] that . . . conduct was wrongful." App. 92a-93a (quoting *Jain*, 93 F.3d at 441). Both *Jain* and *United States v. Yielding*, 657 F.3d 688 (8th Cir. 2011), reject any equation of willfulness with knowledge of unlawful conduct. *Infra* pp. 16-17.

due to concerns over its lawfulness; or a service without legitimate value that was a pretext to provide remuneration." App. 98a-99a (citations omitted). The court dismissed with leave to amend. App. 103a-104a.

5. On June 7, 2022, Hart filed a Second Amended Complaint. He added allegations identifying particular individuals who received training stating that providing anything of value to induce purchases was unlawful under the Anti-Kickback Statute (absent an applicable safe harbor) and nevertheless went on to craft and participate in McKesson's sales strategy of inducing purchases with "value-added services," C.A. App. 317-19; *see also id.* at 299-309; about McKesson's knowledge that the Margin Analyzer and Regimen Profiler had substantial value (calculated at approximately $150,000 per year or more for a representative practice), *id.* at 308-11; about conversations in which McKesson employees discussed concerns about the legality of its sales strategy, *id.* at 319-20; and about McKesson's destruction of documents relating to the Margin Analyzer and Regimen Profiler, *id.* at 320-22.

McKesson again moved to dismiss, arguing that Hart had not alleged that McKesson acted with the requisite scienter and had not pleaded nationwide, continuing violations with particularity. App. 45a. On March 28, 2023, the district court granted the motion, ruling that the additional allegations did not show McKesson knew its conduct was unlawful. *Id.* Among other things, the court concluded that Hart's allegations about his conversations with other McKesson executives and employees identifying McKesson's kickback practices as improper "d[id] not establish what *McKesson* believed." App. 51a. It also declined to infer from Hart's document-destruction allegations that McKesson meant "to conceal evidence." App. 55a-56a.

The district court also dismissed Hart's state-law claims, holding that the Second Amended Complaint "d[id] not allege a violation of the states' [False Claims Act] analogues by way of kickbacks under each of those state law regimes," but only under the federal Anti-Kickback Statute. App. 48a.

Hart appealed to the Second Circuit.

6. On March 12, 2024, the Second Circuit affirmed the dismissal of Hart's federal claims. App. 2a. It acknowledged that the circuit courts were split as to the meaning of "willfully" in the Anti-Kickback Statute. App. 19a-20a. It then agreed with the Eleventh Circuit that the term is best read to require that the "defendant act understanding that his conduct is unlawful," though "not necessarily" unlawful under that particular Statute. App. 12a.

Applying that standard, the Second Circuit held that the Second Amended Complaint's allegations of scienter were inadequate. *First*, it concluded that the allegations of document destruction showed only that, at some point during the litigation, "McKesson determined that its use of the Business Management Tools may have been improper." App. 22a-23a. *Second*, it concluded that Hart's allegations that he informed his supervisor during compliance training that the company's conduct violated those compliance policies "suggest[] only that *Hart* believed that McKesson's use of the Business Management Tools violated" the Anti-Kickback Statute, not that "*McKesson* believed" it did. App. 24a. *Third*, the Court concluded that Hart's allegations that he frequently discussed with employees that McKesson was inappropriately exploiting the business tools did not support an inference that the other employees, or McKesson, shared Hart's concerns. App. 25a.[3]

REASONS FOR GRANTING THE PETITION

I. THE CIRCUITS ARE SPLIT ON WHETHER A DEFENDANT CAN VIOLATE THE ANTI-KICKBACK STATUTE ONLY WITH KNOWLEDGE THAT ITS CONDUCT IS UNLAWFUL

A. The Second and Eleventh Circuits Require That a Defendant Know That Its Conduct Violates the Law

1. The Second Circuit held in this case that a defendant does not act "willfully" within the meaning of the Anti-Kickback Statute unless that defendant "act[s] 'with knowledge that his conduct was unlawful.'" App. 16a (quoting *United States v. Kukushkin*, 61 F.4th 327, 332 (2d Cir. 2023)). It further equated that state of mind with "a voluntary, intentional violation of a known legal duty." App. 10a (quoting *Pfizer, Inc. v. U.S. Dep't of Health & Hum. Servs.*, 42 F.4th 67, 77 (2d Cir. 2022)). In adopting that standard, the court of appeals acknowledged Congress's direction in § 1320a-7b(h) that "actual knowledge" of the Statute itself, or "specific intent" to violate it, is not required. Nevertheless, the court read § 1320a-7b(h) to "le[ave] intact . . . [a] require[ment]" that "a defendant . . . know that her conduct was in some way unlawful." App. 14a. As examples of other relevant

[3] The Second Circuit, however, overturned the dismissal of relator's state False Claims Act claims based on violations of state anti-kickback statutes, and remanded to the district court for further proceedings. App. 27a-28a.

types of unlawfulness, the court suggested that a violation could "implicate other crimes including, among others, wire fraud, health care fraud, and bribery." App. 20a-21a n.8.

Further, the court of appeals construed the statute to require – even at the pleading stage – that the defendant not only know of a legal duty and purposefully violate that duty, but also hold the subjective belief that its conduct was a violation. That is shown by its rejection of Hart's allegations that he told both his supervisor and the creator of the Margin Analyzer of his concerns that McKesson's actions "violated [McKesson's] policies" for compliance with the Anti-Kickback Statute and were "inappropriate[]." App. 24a-25a. The court instead pointed to the lack of further allegations that the "supervisor agreed," that the "tool's creator *shared* Hart's concerns," or that "McKesson as a whole" believed its conduct to be unlawful. *Id.* It further rejected Hart's document-destruction allegations as showing only McKesson's beliefs "at some point during this litigation," rather than at the time of the relevant conduct. App. 22a-23a. That standard is extremely demanding.

2. The Eleventh Circuit has also held that a defendant must know that its conduct is unlawful in order to violate the Anti-Kickback Statute. It first announced that requirement in *United States v. Starks*, 157 F.3d 833 (11th Cir. 1998). *Starks* affirmed a conviction based on a jury instruction that required an "act . . . with the specific intent to do something the law forbids, that is with a bad purpose, either to disobey or disregard the law." *Id.* at 838 (quoting pattern jury instructions). Since then, the Eleventh Circuit has several times endorsed the use of the same instruction in Anti-Kickback Statute cases. *See United*

States v. Sosa, 777 F.3d 1279, 1293 (11th Cir. 2015) ("[T]o find that a person acted willfully in violation of § 1320a-7b, the person must have acted '"voluntarily and purposely, with the specific intent to do something the law forbids, that is with a bad purpose, either to disobey or disregard the law."'") (quoting *United States v. Vernon*, 723 F.3d 1234, 1256 (11th Cir. 2013), in turn quoting *Starks*, 157 F.3d at 838). Although both *Sosa* and *Vernon* were decided after Congress enacted § 1320a-7b(h), neither addresses that statute. Indeed, our research has found no case in which the Eleventh Circuit has cited § 1320a-7b(h) at all.

3. Other circuits have cited similar generalized-knowledge instructions with apparent approval, though have not directly held that a defendant must know its conduct was unlawful. The Seventh Circuit has twice suggested that knowledge of unlawful conduct is required. *See United States v. Moshiri*, 858 F.3d 1077, 1083 (7th Cir. 2017) (relying on a defendant's "knowledge of the statute's prohibitions," among other facts, to reject his argument that he had "a good fa[i]th belief in the lawfulness of his contract"); *United States v. Nagelvoort*, 856 F.3d 1117, 1127 (7th Cir. 2017) (affirming conviction based on evidence that the defendants "knew the[ir] arrangements were illegal and that they were attempting to cover their tracks"). The Third Circuit has stated that a district court "correctly instructed [a] jury" to convict only if the defendant "knew his conduct was unlawful and intended to do something the law forbids." *United States v. Goldman*, 607 F. App'x 171, 174 (3d Cir. 2015).

B. The Fifth and Eighth Circuits Do Not Require That a Defendant Know That Its Conduct Violates the Law

1. The Fifth Circuit has held that a defendant's conduct is willful under the Anti-Kickback Statute if the defendant "willfully committed an act that violated [that] Statute" and has rejected a requirement that a "defendant act with knowledge that her conduct was unlawful." *United States v. St. Junius*, 739 F.3d 193, 210 & n.19 (5th Cir. 2013). The relevant defendant in that case had signed an agreement to provide "marketing services" to a Medicare provider and in exchange receive a "10% commission on the price of items purchased for patients [she] referred." *Id.* at 199. She then received commission payments in cash or by check. *Id.* She argued that a "conviction under the Anti-Kickback Statute require[d] proof beyond a reasonable doubt that she knew that being paid on commission was illegal." *Id.* at 210. The Fifth Circuit rejected that argument, holding that "the Government was only required to prove that she willfully solicited or received money for referring Medicare patients to" the provider. *Id.*[4]

The Second Circuit recognized that its decision in this case conflicts with *St. Junius*. App. 20a-21a (describing *St. Junius* as an "outlier" and declining to follow it as "unpersuasive"). It pointed to later decisions in which panels of the Fifth Circuit have "failed to follow the reasoning of *St. Junius*." App. 21a (citing, *e.g.*,

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[4] The Fifth Circuit further pointed out that, "as part of [her] employment," the relevant defendant had "signed documents that explained that receiving commission payments in this context was illegal." *St. Junius*, 739 F.3d at 211. In doing so, the court made clear that "such proof was not required" and was "unnecessary to sustain a conviction." *Id.*

United States v. Shah, 84 F.4th 190 (2023), *withdrawn and superseded*, 95 F.4th 328 (5th Cir. 2024), and *United States v. Nora*, 988 F.3d 823, 830 (5th Cir. 2021)). But the Fifth Circuit follows the rule that, when panel decisions conflict, "the earlier panel decision controls." *Austin v. Davis*, 876 F.3d 757, 778 (5th Cir. 2017). Accordingly, *St. Junius* remains the law of the Fifth Circuit on the question presented.

District courts in the Fifth Circuit have continued to apply *St. Junius* as binding precedent, including as recently as 2022 and 2023. *See*, *e.g.*, *United States ex rel. Hueseman v. Professional Compounding Ctrs. of Am., Inc.*, 664 F. Supp. 3d 722, 740-41 (W.D. Tex. 2023) (applying *St. Junius* to hold that "it is sufficient for the Government to plead 'that the defendant willfully committed an act that violated the'" Anti-Kickback Statute) (quoting 739 F.3d at 210); *United States v. Marlin Med. Sols. LLC*, 579 F. Supp. 3d 876, 885 (W.D. Tex. 2022) (same).[5] Further, *Marlin Medical Solutions* specifically addressed and distinguished *Nora* – one of the decisions the Second Circuit cited as conflicting with *St. Junius* – commenting that *St. Junius* "is squarely consistent with the statute's language." 579 F. Supp. 3d at 885 & n.2.

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[5] *See also United States ex rel. Est. of Turner v. Gardens Pharmacy, LLC*, 2022 WL 17824009, at *7 (S.D. Miss. Dec. 20, 2022) ("The necessary intent applies to the act that violates the [Anti-Kickback Statute] . . . ."); *United States v. Catholic Health Initiatives*, 2022 WL 2657131, at *9 & n.12 (S.D. Tex. Mar. 31, 2022) (citing and following *St. Junius*), *report and recommendation adopted sub nom. Chihi v. Catholic Health Initiatives*, 2022 WL 2652135 (S.D. Tex. July 8, 2022); *United States v. Waller*, 2017 WL 2559092, at *5 (S.D. Tex. June 13, 2017) (denying motion for new trial after giving jury instructions based on *St. Junius*), *aff'd*, 741 F. App'x 267 (5th Cir. 2018) (per curiam).

2. The Eighth Circuit has held that a defendant's conduct is willful under the Anti-Kickback Statute if the defendant "knew that his conduct was wrongful," but has not "require[d] proof that [the defendant] . . . knew it violated 'a known legal duty.'" *United States v. Jain*, 93 F.3d 436, 441 (8th Cir. 1996) (quoting and distinguishing *Ratzlaf v. United States*, 510 U.S. 135, 140-42 (1994)). Indeed, *Jain* reached that conclusion even without the benefit of § 1320a-7b(h). The Eighth Circuit thus approved a jury instruction defining "the word 'willfully' [to] mean[] unjustifiably and wrongfully, known to be such by the defendant," and affirmed the district court's rejection of a "known legal duty" instruction. *Id.* at 440.[6]

The Eighth Circuit applied the same rule in *United States v. Yielding*, 657 F.3d 688 (8th Cir. 2011). In that case, the district court had instructed a jury that, under the Anti-Kickback Statute, a "defendant acts willfully if he knew his conduct was wrongful *or* unlawful." *Id.* at 708 (emphasis added). Thus, the instruction permitted a conviction based on knowingly "wrongful" conduct, regardless of whether that conduct also knowingly violated the law. The court of appeals affirmed, reasoning that the "instruction . . . was consistent with *Jain*." *Id.*; *see id.* at 709 (stating that

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[6] The Eighth Circuit also observed in the "[a]lternative[]" that the defendant had testified that it would be "illegal" to accept "payments for patient referrals," making any error "harmless." *Jain*, 93 F.3d at 441. That does not detract from the force of its primary holding that knowledge of illegality is not required. *See Sutton v. Addressograph-Multigraph Corp.*, 627 F.2d 115, 117 n.2 (8th Cir. 1980) (per curiam) ("When two independent reasons support a decision, . . . each represents a valid holding of the court."). Also, the Eighth Circuit's later *Yielding* decision (discussed in text) had no similar alternative holding. It thus confirms that Eighth Circuit law requires no knowledge of illegality.

the defendant's request for a "known legal duty" instruction was "an inaccurate description of the law as established in *Jain*"); *see also In re EpiPen Direct Purchaser Litig.*, 2021 WL 147166, at *13-14 (D. Minn. Jan. 15, 2021) (applying *Jain* and *Yielding* in private litigation against drug manufacturers).

The Second Circuit did not acknowledge that its holding in this case conflicted with the Eighth Circuit's holdings in *Jain* and *Yielding*. To the contrary, it incorrectly asserted that *Yielding* "aligns" with its own previous opinion in *Pfizer*. App. 11a. But *Pfizer* endorsed a "known legal duty" standard for willfulness under the Anti-Kickback Statute and further stated that "the [Statute] does not apply to those who are unaware that such payments are prohibited by law." 42 F.4th at 77. As shown above, *Jain* and *Yielding* rejected that approach in plain terms.

II. THE COURT OF APPEALS ERRED IN REQUIRING HART TO PLEAD THAT McKESSON KNEW IT WAS VIOLATING THE LAW

A. The Language and Structure of the Anti-Kickback Statute Show That It Does Not Require Knowledge of Unlawful Conduct

The term "willfully" in a statute can have several meanings. A "willful" act can be one performed "deliberately." *Browder v. United States*, 312 U.S. 335, 341 (1941) ("Read in its context the phrase 'willfully and knowingly,' as the trial court charged the jury, can be taken only as meaning 'deliberately and with knowledge and not something which is merely careless or negligent or inadvertent.'"). Or "willful" conduct can be conduct undertaken with a particular purpose, often "a 'bad purpose.'" *Bryan v. United States*, 524 U.S. 184, 191 (1998). Or a person can act "willfully" by intentionally breaking a known rule. *Cheek v. United States*, 498 U.S. 192, 201 (1991) ("Willfulness, as construed by our prior decisions in criminal tax cases, requires the Government to prove that the law imposed a duty on the defendant, that the defendant knew of this duty, and that he voluntarily and intentionally violated that duty."). To determine which meaning the term "willful" has in a statute, courts look to the "context in which it appears." *Taggart v. Lorenzen*, 139 S. Ct. 1795, 1804 (2019). In the Anti-Kickback Statute, context shows that the term "willfully" does not create a requirement that a defendant know its actions violated the law.

As relevant here, that Statute affirmatively prohibits "knowingly and willfully offer[ing] or pay[ing] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person . . . to purchase . . . any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2)(B). The phrase "knowingly and willfully" modifies the other elements of the offense: (1) an offer or payment, (2) of remuneration, (3) to induce a purchase, (4) of a good, facility, service, or item, (5) for which the federal government wholly or partially pays under certain programs. Nothing in that language suggests that the term "willfully" creates a requirement that the person offering or paying prohibited remuneration must know or intend that the offer or payment violates the law.

The lack of any such requirement is underscored by § 1320a-7b(h), which states that "a person need not have actual knowledge of this section" – that is,

§ 1320a-7b – or "specific intent to commit a violation of this section." That provision is strong evidence that the terms "knowingly" and "willfully" do not stand for a requirement that the person making a prohibited offer or payment intend to act unlawfully. In particular, § 1320a-7b(h) rules out any requirement of "a voluntary, intentional violation of a known legal duty," App. 10a (quoting *Pfizer*, 42 F.4th at 77), the standard the Second Circuit applied here. This Court has construed the "known legal duty" standard to require knowledge "of the duty purportedly imposed by the provision of the statute or regulation [a defendant] is accused of violating." *Cheek*, 498 U.S. at 201; *see also Ratzlaf*, 510 U.S. at 141-42 (collecting cases applying a "known legal duty" standard for violations of regulatory reporting requirements). That is the actual knowledge and specific intent that Congress specifically wrote out of the Anti-Kickback Statute.

The structure of § 1320a-7b(b) provides additional support for that conclusion. Paragraph (3) provides a list of conditions under which paragraphs (1) and (2) "shall not apply." 42 U.S.C. § 1320a-7b(b)(3); *see also* 42 C.F.R. § 1001.952. Conditions under which a criminal prohibition shall not apply create affirmative defenses, as to which a defendant presumptively "ha[s] the burden of production and persuasion." *Ruan v. United States*, 597 U.S. 450, 475-76 (2022) (Alito, J., concurring) (citing *Smith v. United States*, 568 U.S. 106, 112 (2013)). The phrase "knowingly and willfully" does not appear in § 1320a-7b(b)(3). Yet the court of appeals' rule would allocate to the government (or, in a *qui tam* case like this one, the relator) the burden of pleading and proving that a defendant knew and intended that its conduct would *not* fit within an exception. App. 13a (explaining that the court's rule would avoid "sweeping in . . . innocent conduct" such as a defendant who "rel[ied] on a published [Department of Health and Human Services] advisory opinion").[7] Whatever the merits of such a rule, it is not in the statute Congress enacted.

B. Nothing Requires Departure from the Statute's Text and Structure

The Second Circuit contended that the Anti-Kickback Statute includes a requirement that "a defendant act understanding that his conduct is unlawful (if not necessarily under the [Anti-Kickback Statute])" because that reading best "accords with the general goal of criminal law to punish only those who act with a 'vicious will.'" App. 12a (quoting *Ruan*, 597 U.S. at 457). But the general goals of criminal law do not support the court's holding.

First, the "presumption . . . that Congress intends to require a defendant to possess a culpable mental state," *Ruan*, 597 U.S. at 457-58 (quoting *Rehaif v. United States*, 588 U.S. 225, 229 (2019)), is a guide to the interpretation of statutes, not a license to rewrite them. In the line of cases on which the court of appeals relied, Congress framed a criminal prohibition in terms of a knowing or willful violation of an identified legal rule. This Court then held that the defendant had to know it was violating or intend to violate

[7] In addition, the statutory authorization for advisory opinions states that "[e]ach advisory opinion issued by the Secretary shall be binding as to the Secretary and the party or parties requesting the opinion." 42 U.S.C. § 1320a-7d(b)(4)(A). But under the court of appeals' approach, advisory opinions would benefit entities that did not request them and bind the government in all § 1320a-7b(b) cases, because even arguable reliance on an advisory opinion would make it effectively impossible to commit a knowing and willful violation of the statute.

that rule. *See id.* at 457 (applying phrase "knowingly or intentionally" to prohibition on distribution of controlled substance "[e]xcept as authorized by" law, 21 U.S.C. § 841(a)); *Rehaif*, 588 U.S. at 225 (construing phrase "knowingly violates [certain] subsection[s]," 18 U.S.C. § 924(a)(2)); *Bryan*, 524 U.S. at 188-89 & n.6 (applying term "willfully" to prohibition on "violat[ing] any other provision of this chapter," 18 U.S.C. § 924(a)(1)(D)).

Section 1320a-7b is not like those statutes. It does not impose a criminal or otherwise more severe penalty for the willful "violation" of a separate legal prohibition, as in *Rehaif* and *Bryan*, or for the willful commission of an act that is not "authorized" by another law, as in *Ruan*. Instead, it directly prohibits the willful and knowing commission of certain acts. It is more like the statute in *Browder*, which prohibited "willfully and knowingly us[ing] . . . [a] passport . . . secured . . . by reason of any false statement," and which the Court construed to require only knowledge that the passport had been secured by such a statement, 312 U.S. at 336 (quoting Act of June 15, 1917, ch. 30, tit. IX, § 2, 40 Stat. 217, 227) (first ellipsis in *Browder*); or the statute in *Morissette v. United States*, 342 U.S. 246 (1952), which prohibited "knowingly convert[ing] . . . any record, voucher, money, or thing of value of the United States," and which the Court construed to require "knowledge of the facts, though not necessarily the law, that made the taking a conversion," *id.* at 248 n.2, 271 (quoting 18 U.S.C. § 641); *see generally United States v. George*, 386 F.3d 383, 392 (2d Cir. 2004) (Sotomayor, J.) (describing "*Cheek, Ratzlaf,* and *Bryan* . . . [as] atypical[]" departures from "the Supreme Court's seemingly principal approach to interpreting the term 'willful' in criminal statutes").

Second, the conduct prohibited by the Anti-Kickback Statute is not innocent in nature. This Court has described "[t]he general rule that ignorance of the law or a mistake of law is no defense to criminal prosecution [as] deeply rooted in the American legal system." *Cheek*, 498 U.S. at 199. That rule does not cease to apply merely because a statute penalizes "willful" conduct. *See American Sur. Co. of N.Y. v. Sullivan*, 7 F.2d 605, 606 (2d Cir. 1925) (L. Hand, J.) ("The word 'willful,' even in criminal statutes, means no more than that the person charged with the duty knows what he is doing. It does not mean that, in addition, he must suppose that he is breaking the law."). Where the Court has carved out an exception, it has done so because of a felt need to "separate the purposeful . . . violator from the well-meaning, but easily confused, mass" who may inadvertently violate an unusually "complex" system of laws such as the Tax Code. *United States v. Bishop*, 412 U.S. 346, 361 (1973).

Such concerns have little force here. Even the Eleventh Circuit – on the Second Circuit's side of the split – has recognized that "the giving or taking of kickbacks for medical referrals is hardly the sort of activity a person might expect to be legal" and that "such kickbacks are more clearly *malum in se*, rather than *malum prohibitum*." *Starks*, 157 F.3d at 838. To be sure, there may be cases in which a defendant has a reasonable argument that a particular payment was not prohibited remuneration. For example, before *Abramski v. United States*, 573 U.S. 169 (2014), reasonable minds could have differed (as the members of this Court did differ, 5 to 4) on whether a straw purchase of a gun was unlawful if "the true buyer could have purchased the gun without the straw." *Id.* at 172. Abramski was convicted for it anyway, and his conviction was upheld. It was no defense that the criminality of his conduct was a close legal question.

The facts of this case illustrate the extraordinary (and unwarranted) solicitude that the Second Circuit's rule shows for unethical practices in the medical industry. McKesson was fully aware of the Anti-Kickback Statute. It had compliance programs that explicitly advised all relevant personnel that the Anti-Kickback Statute made it unlawful to provide anything of value to induce purchases. With full knowledge of that prohibition, McKesson created business tools that could, and in specific instances did, massively increase costs to Medicare without in any way benefiting patients. It valued those software programs at more than $150,000 to some medical practices yet gave them away to induce those practices to purchase Medicare-covered drugs. Hart, observing this conduct, warned his supervisor that it did not square with its own Anti-Kickback Statute compliance programs.

Yet under the court of appeals' approach, none of this stated a claim. That court not only held that the Anti-Kickback Statute required knowledge of unlawful conduct; it further held that such knowledge could not be established even by showing that the defendant both knew of a legal prohibition (here, the prohibition against providing anything of value to induce purchases) and knew that its conduct satisfied each element of that prohibition (here, that McKesson was providing something of value to induce purchases). App. 17a-18a. That rule goes far beyond anything required to separate the culpable from the innocent. This Court's review is warranted to clarify the statutory state-of-mind element and to direct the courts of appeals to apply the Statute as Congress wrote it.

III. THE REQUIRED MENTAL STATE FOR A VIOLATION OF THE ANTI-KICKBACK STATUTE IS IMPORTANT AND WARRANTS REVIEW

Federal spending on Medicare and Medicaid alone will exceed $1.56 trillion in 2024 – an amount that is on par with the federal government's entire discretionary budget.[8] The Anti-Kickback Statute is a key measure for protecting those important government programs "from increased costs and abusive practices resulting from provider decisions that are based on self-interest rather than cost, quality of care or necessity of services." *United States v. Patel*, 778 F.3d 607, 612 (7th Cir. 2015) (quoting Health Res. & Servs. Admin., *Guidance on the Federal Anti-Kickback Law*, Program Assistance Letter 1995-10 (also stating that the "law seeks to prevent overutilization, limit cost, preserve freedom of choice and preserve competition"), http://www.lb7.uscourts.gov/documents/14-26071.pdf).

Nor is the Anti-Kickback Statute limited purely to fiscal concerns. It also protects "patients from doctors whose medical judgments might be clouded by improper financial considerations." *Id.* This case is an excellent example: the purpose and effect of McKesson's Margin Analyzer and Regime Profiler is to set aside doctors' medical judgment entirely and treat patents based on what is good for the practice's bottom line – and, by inducing purchases from McKesson, for McKesson's own. A rule that enables a

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[8] *See* House Budget Comm., *Government's Mandatory Health Care Spending Now Exceeds Entire Discretionary Budget* (Jan. 26, 2024), https://budget.house.gov/press-release/governments-mandatory-health-care-spending-now-exceeds-entire-discretionary-budget.

pharmaceutical wholesaler to engage in such conduct absent a showing that it deliberately violated a known legal duty does not serve the goals of protecting patients.

In addition, the nature of the medical industry supports the need for a nationally uniform scienter standard for the Anti-Kickback Statute. Health care companies, such as McKesson, operate nationwide and rely on these federal programs for much of their earnings. The conduct alleged here would violate the Anti-Kickback Statute applying the standards adopted by the Fifth and Eighth Circuits. The Second Circuit reached a different result here, applying the standard adopted by the Second and Eleventh Circuits. That split is important, and this Court should resolve it. This case, which presents the question squarely, is an excellent vehicle for doing so.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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