No. 23-1293

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**

## REPLY BRIEF FOR PETITIONERS


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September 4, 2024

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This Court should grant certiorari to define the willfulness element of a violation of the Anti-Kickback Statute. The circuits have adopted a range of conflicting positions on that issue. At McKesson's urging, the Second Circuit applied an exacting requirement under which willfulness is the "voluntary and intentional violation of a known legal duty." App. 17a. That requirement departs from the language of the Statute both as Congress originally enacted it and as Congress amended it in 2010 to loosen the scienter standard. Indeed, the brief in opposition now barely defends the court of appeals' "known legal duty" standard.

McKesson cannot avoid review by denying the circuit split. The Second Circuit in this case directly disagreed with the Fifth Circuit's *St. Junius* decision. McKesson fails to show that *St. Junius* (which the Fifth Circuit has never overruled) is not good law. McKesson likewise fails to harmonize the Second and Eleventh Circuits' position with the Eighth – relying (at 19) on the strained contention that knowingly unlawful conduct is not "substantively different" from knowingly wrongful conduct. There is all the difference in the world between an act known to be wrong and an act known to violate a legal duty.

The question presented is important and recurs frequently. The number of cases both Hart and McKesson cite only underscores that point. If Hart is correct, an important federal law is being systematically underenforced in the circuits that follow McKesson's rule. If McKesson is correct, defendants in the circuits that follow Hart's rule are being charged with civil and criminal liability despite Congress's (purported) intent to spare them. This Court should settle the matter.

## ARGUMENT

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

Hart showed in his petition (at 12-18) that the circuits disagree on whether a violation of the Anti-Kickback Statute requires that the defendant know its conduct violates the law. Neither the Fifth Circuit, under *United States v. St. Junius*, 739 F.3d 193 (5th Cir. 2013), nor the Eighth Circuit, under *United States v. Jain*, 93 F.3d 436 (8th Cir. 1996), and *United States v. Yielding*, 657 F.3d 688 (8th Cir. 2011), applies such a requirement. But the Second Circuit held that an Anti-Kickback defendant must believe it is violating a "known legal duty," App. 10a, and declined to follow *St. Junius*. At least the Eleventh Circuit is in accord with that holding. McKesson's attempts to deny a live, entrenched circuit conflict fall short.

#### A. *St. Junius* Is Good Law in the Fifth Circuit and Conflicts with the Second Circuit's Decision in This Case

McKesson erroneously contends (at 2) that Hart seeks resolution of an "intra-circuit split" within the Fifth Circuit. Hart seeks review of the Second Circuit's decision finding the Fifth Circuit's decision in *St. Junius* "unpersuasive" and "declin[ing] to apply" it. App. 20a-21a. That is an inter-circuit split, not an intra-circuit one. The real substance of McKesson's objection is that the split does not warrant review because *St. Junius* is supposedly not good law. That is wrong for three reasons.

*First*, McKesson erroneously claims (at 15-16) that *St. Junius* itself conflicts with prior circuit precedent:

*United States v. Davis*, 132 F.3d 1092 (5th Cir. 1998), which rejected a defendant's challenge to jury instructions that required a "specific intent to do something the law forbids." *Id.* at 1094. *Davis* found that such an instruction "amply protected [the defendant's] interests," *id.*, not that no less protective instruction would have done so. And *Davis* also predated 42 U.S.C. § 1320a-7b(h), the special scienter provision on which the Fifth Circuit relied in *St. Junius* and on which Hart relies in this case. *Davis* could not have bound the *St. Junius* panel in construing a provision not even enacted when *Davis* was decided.

*Second*, McKesson misplaces reliance (at 15-16) on Fifth Circuit cases that affirm convictions based on evidence that defendants actually knew their conduct was unlawful or even that it violated the Anti-Kickback Statute in particular.[1] No one disputes that a violation of a known legal duty is *sufficient* for willfulness under the Statute. The dispute concerns whether that mental state is *necessary*. Cases upholding the liability or guilt of defendants who actually knew they were breaking the law do not contradict *St. Junius*.

The only Fifth Circuit decision that should have come out differently because of *St. Junius* is *United*

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[1] *See United States v. Marchetti*, 96 F.4th 818, 828 (5th Cir. 2024) (affirming conviction based on knowledge of unlawfulness); *United States v. Shah*, 95 F.4th 328, 350-51, 355-56 (5th Cir. 2024) (same), *petitions for cert. pending*, Nos. 24-23, 24-25 & 24-5032; *United States v. Ricard*, 922 F.3d 639, 648 (5th Cir. 2019) (same); *see also United States v. Hagen*, 60 F.4th 932, 942-46 (5th Cir. 2023) (affirming conviction and rejecting challenge to exclusion of testimony allegedly relevant to knowledge of unlawfulness). *United States v. Njoku*, 737 F.3d 55 (5th Cir. 2013), also fits in this category, *see id.* at 64, although decided shortly before *St. Junius* rather than shortly after it.

*States v. Nora*, 988 F.3d 823 (5th Cir. 2021), which reversed the conviction of a low-level health services employee who knew his company was making referral payments, but did not know they were unlawful. As shown in the petition (at 16), *Nora* does not change the Fifth Circuit's law because, when panel decisions conflict, the earlier decision controls.

*Third*, McKesson has no persuasive response to the petition's showing (at 16 & n.5) that district courts in the Fifth Circuit have applied *St. Junius* as recently as 2022 and 2023 – that is, after *Nora*. McKesson points (at 17-18 n.4) to a smaller number of cases that recite a knowing-violation standard.[2] None endorses McKesson's argument that *St. Junius* is not good law. That a few district courts may have misapplied their own circuit's law does not weaken the case for review.

### B. The Eighth Circuit's Decisions in *Jain* and *Yielding* Conflict with the Second Circuit's Decision in This Case

McKesson also fails to overcome the petition's showing (at 17-18) that the Second Circuit's decision conflicts with the Eighth Circuit's decisions in *Jain* and *Yielding*. In attempting to harmonize those cases, McKesson abandons not only the Second Circuit's reasoning but also its own arguments to that court.

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[2] *United States v. Medoc Health Services LLC*, 470 F. Supp. 3d 638 (N.D. Tex. 2020), does not conflict with *St. Junius*. Like the circuit decisions cited in footnote 1, it ruled a complaint sufficiently pleaded a knowing violation of law. *See id.* at 656-58. The other decisions McKesson cites departed from *St. Junius* without addressing it. *See United States ex rel. Emerson Park v. Legacy Heart Care, LLC*, 2019 WL 4450371, at *11 (N.D. Tex. Sept. 17, 2019); *United States ex rel. Patel v. Catholic Health Initiatives*, 312 F. Supp. 3d 584, 594-96 (S.D. Tex. 2018), *aff'd*, 792 F. App'x 296 (5th Cir. 2019) (per curiam).

The Second Circuit's decision defines willfulness "as '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), *cert. denied*, 143 S. Ct. 626 (2023)). The district court similarly wrote: "[B]eliefs about the 'inappropriate' or 'unethical' nature of providing the business tools [are], without more, insufficient to adequately plead purported knowledge of *unlawfulness* – let alone an 'intentional violation of a known legal duty.'" App. 51a (quoting *Pfizer*); *see also* App. 46a, 55a. McKesson itself urged both courts to apply a "known legal duty" standard. Resp. C.A. Br. 26; Dist. Ct. ECF #184, at 2.

McKesson concedes (at 18-19) that *Jain* "rejected the defendants' argument that . . . the government needed to prove that they violated a 'known legal duty.'"[3] It also concedes (at 18-19) that the "known legal duty" standard is the one that applies in "criminal-tax and currency-structuring cases" such as *Ratzlaf v. United States*, 510 U.S. 135 (1994), and *Cheek v. United States*, 498 U.S. 192 (1991), and that the Ninth Circuit applied in *Hanlester Network v. Shalala*, 51 F.3d 1390 (9th Cir. 1995), which everyone agrees § 1320a-7b(h) overruled. But McKesson buries in a footnote its acknowledgement that it persuaded the Second Circuit to apply a "known legal duty" standard in this very case.

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[3] McKesson observes (at 18-20) that, by requiring knowingly wrongful conduct, *Jain* and *Yielding* also rejected the approach the Fifth Circuit adopted in *St. Junius*, under which deliberate payment of kickbacks is willful whether or not known to be wrongful. That observation shows only that the circuit split runs three ways rather than two, which is no less reason to grant certiorari.

In that footnote (at 27 n.9), McKesson presses a makeweight distinction between knowing the legal duty imposed by the Anti-Kickback Statute itself and knowing a legal duty imposed by some other law. It is implausible that Congress meant Anti-Kickback liability to turn on a kickback-payer's knowledge of (for example) the wire fraud statute. Certainly *Jain* and *Yielding* adopted no such rule.

McKesson also errs in contending (at 19) that there is no "substantive[] differen[ce]" between conduct done "unjustifiably and wrongfully," *Jain*, 93 F.3d at 440, and conduct with a "bad purpose either to disobey or disregard the law," *Davis*, 132 F.3d at 1094. Even "indisputably abhorrent" acts are not unlawful unless prohibited by the "criminal laws as written." *Fischer v. United States*, 144 S. Ct. 2176, 2190 (2024) (Jackson, J., concurring). Here, McKesson obtained business by giving medical practices tools to increase their profit margins by sending larger bills to the federal government, private insurers, and cancer patients, with no basis in medical efficacy or patient welfare. *See* Pet. 5-6. Whether or not McKesson knew it was violating a legal duty, it plausibly knew it was doing something wrong.[4]

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[4] *United States v. Goodwin*, 974 F.3d 872 (8th Cir. 2020), does not help McKesson. *Goodwin* applied the same standard as *Jain* and *Yielding*, then found that a defendant's actual knowledge about the Anti-Kickback Statute satisfied that standard. *Id.* at 875-76. McKesson's argument reflects the same confusion between a necessary and a sufficient showing that muddles its analysis of the Fifth Circuit's cases. *Supra* p. 3 & n.1.

### C. McKesson's Claims That Other Circuits Have Adopted Its Preferred Rule Are Irrelevant and Incorrect

The petition notes (at 14) that the Third and Seventh Circuits have affirmed convictions based on jury instructions that followed the Second and Eleventh Circuit standards. McKesson contends (at 12-14) that the First, Fourth, and Sixth Circuits are on its side of the split. Even if the count is seven (rather than four) to two, that does not matter. If anything, a greater number of circuits passing on the question presented shows that the issue recurs frequently and shows more percolation and development of the arguments on both sides.

In any event, McKesson overstates its support. Its First Circuit case, *United States v. Bay State Ambulance & Hospital Rental Service*, 874 F.2d 20 (1st Cir. 1989), long predated § 1320a-7b(h). Its Fourth Circuit case, *United States ex rel. Lutz v. Mallory*, 988 F.3d 730, 736-37 (4th Cir. 2021), found knowledge of unlawfulness sufficient to support a conviction, but did not address whether such knowledge was necessary in all cases. And its Sixth Circuit cases, *United States v. Montgomery*, 2022 WL 2284387, at *12 (6th Cir. June 23, 2022), *cert. denied*, 143 S. Ct. 2581 (2023), and *United States v. Trumbo*, 849 F. App'x 147, 150 (6th Cir. 2021), are unpublished and do not bind future panels. *See* 6th Cir. R. 32.1(b). Taken as a whole, McKesson's cases confirm that the question presented is important, but do not show the supposed "consensus" it asserts (at 14).

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

As the petition shows (at 18-24), the language, structure, and context of the Anti-Kickback Statute show that the phrase "knowingly and willfully" requires deliberate action, but not knowledge that one is violating the law. McKesson's contrary arguments lack force – and, in any event, all that is now before the Court is whether (not how) to decide the merits.

The phrase "knowingly and willfully" in § 1320a-7b(b)(2)(B) modifies the conduct of "offer[ing] or pay[ing] remuneration" to induce purchases. That distinguishes the Anti-Kickback Statute from other statutes that punish the willful violation of a separate legal rule. McKesson responds (at 26) with the principle 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.'" *Ruan v. United States*, 597 U.S. 450, 458 (2022) (emphasis added). But even if making payments to obtain medical business were itself innocent (which it is not, *see* Pet. 23-24), there is no relevant "other statutory term" to modify. McKesson seeks to read in language such as "knowingly and willfully violates," which the Statute does not contain.

Nor is McKesson's construction necessary, as it contends (at 25-26), to give "willfully" independent meaning. By requiring deliberate action, "willfully" ensures that prohibited "remuneration" must be meant "to induce . . . [a] purchase" of federally insured goods or services, 42 U.S.C. § 1320a-7b(b)(2)(B), rather than inducing a purchase as an unintended byproduct. A doctor who sends a get-well card and flowers to a sick

patient need not fear liability if she intends to cheer the patient up rather than to ensure he comes back for his next appointment. In contrast, McKesson's construction makes "knowingly" surplusage. A person cannot violate a known legal duty without knowing the facts that trigger that duty.

Section 1320a-7b(h) removes any doubt that the "known legal duty" standard does not apply. McKesson responds (at 27 n.9) that § 1320a-7b(h) means only that a defendant need not know of the duty imposed by the Anti-Kickback Statute specifically, if it knows it is violating some other law. If so, knowledge of the Statute *is* required in cases where the prohibited conduct violates no other law. But § 1320a-7b(h) does not say that "actual knowledge of this section" is required sometimes but not always. It says categorically that a person "need not have actual knowledge of this section . . . to commit a violation." McKesson fails to reconcile its rule with that mandate.

McKesson also misplaces reliance (at 22-23) on legislative history and (purported) purpose. "Even those [members of this Court] who sometimes consult legislative history will never allow it to be used to 'muddy' the meaning of 'clear statutory language.'" *Food Mktg. Inst. v. Argus Leader Media*, 588 U.S. 427, 436 (2019) (quoting *Milner v. Department of Navy*, 562 U.S. 562, 572 (2011)). Regardless, the legislative history on which McKesson relies suggests only that some legislators did not want to punish "inadvertent" conduct, H.R. Rep. No. 96-1197, at 59 (1980), and wanted to overrule *Hanlester*, *see* 155 Cong. Rec. 25,920, 25,921 (2009). It says nothing about those who deliberately pay kickbacks but assert ignorance of the law.

Finally, McKesson's policy argument (at 24) that "socially beneficial arrangements" should not be deterred is answered by its own citations (at 24 n.6, 26 n.8) to the Statute's safe-harbor and advisory-opinion provisions. Those provisions help industry participants to resolve good-faith doubts about the law to obtain comfort. In contrast, under McKesson's construction, companies engaging in prohibited socially harmful conduct can avoid liability by simply never asking what the law says.

## III. THIS CASE IS A GOOD VEHICLE TO ANSWER THE QUESTION PRESENTED

Aside from its weak argument that the circuits are not split, McKesson does not contest that the question presented is important enough to review. It contends, however, that this case is a poor vehicle. That contention lacks substance. The decisions here turned on the point in contention: whether, to act "willfully" under the Anti-Kickback Statute, a defendant must know its conduct violates the law. The district court dismissed Hart's complaint for lack of allegations showing such knowledge, and the Second Circuit endorsed that ruling. If this Court holds that no such knowledge is required, those decisions cannot stand.

McKesson complains (at 29) that Hart did not argue the Eighth Circuit's intermediate position (knowledge of wrongful, but not necessarily illegal, conduct) to the court of appeals. It cites no authority, and we know of none, that a petitioner must press two sides of a three-way conflict to preserve its chance at review. Nor would such a rule serve any practical purpose. Further, contrary to McKesson's suggestion (at 29), the petition invokes (at 26) "the standard[] adopted by . . . the Eighth Circuit[]" as well as the one adopted by the Fifth Circuit. There is no bar to Hart arguing both alternatively in his merits brief.

Finally, McKesson also fails to show (at 28-29) that it would prevail under the Eighth Circuit's standard. The conduct here was "unjustifiabl[e] and wrongful[]," *Jain*, 93 F.3d at 440, on its face: McKesson purposefully inflated bills to patients, government payers, and insurance companies in order to direct more business to itself. Further, as the petition sets out (at 7), Hart alleged that he told a company vice president that the company was violating its own compliance policies, that he discussed the "unethical and wrongful" nature of McKesson's conduct with other employees, and that the company destroyed documents after receiving an investigative demand from the government. Those allegations plausibly show that, regardless of whether McKesson knew it was breaching a legal duty, it knew it was doing wrong. At a minimum, were this Court to agree with either the Fifth or the Eighth Circuit, remand would be warranted – which is all that a vehicle requires.[5]

## CONCLUSION

The petition for a writ of certiorari should be granted.

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[5] By contrast, the certiorari petitions in *Wilkerson v. United States*, No. 22-685, and *Montgomery v. United States*, No. 22-6653, which McKesson cites (at 2 & n.1), sought review of factual determinations that those defendants actually knew their conduct was unlawful. *See Montgomery*, 2022 WL 2284387, at *12 (Sixth Circuit decision for both petitions). That made *Wilkerson* and *Montgomery* poor vehicles for the question presented here.

Respectfully submitted,

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