

Petition for Certiorari Filed in Supreme Court in False Claims Act Case Seeking Review of Whether “Willful” Under the Anti-Kickback Statute Requires Knowledge that the Conduct is Unlawful

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The Supreme Court now has the opportunity to define “willfulness” under the federal criminal Anti-Kickback Statute (AKS). In a declined *qui tam* case filed against McKesson Corporation, a pharmaceutical wholesaler, the relator, Adam Hart, a former McKesson employee, [filed a petition for certiorari seeking Supreme Court review of a Second Circuit decision](#) that upheld the dismissal of relator’s complaint asserting claims under the civil False Claims Act (FCA) premised on alleged violations of the AKS. *U.S. ex rel. Hart v. McKesson Corp.*, 96 F.4th 145 (2d Cir. 2024). A violation of the AKS requires as the scienter element that the defendant “knowingly and willfully” offered or paid remuneration to induce the recipient of the remuneration to purchase goods or items for which payment may be made under a federal health care program. 42 U.S.C. § 1320a-7b(b)(2). [The Second Circuit held](#) that a defendant does not act “willfully” within the meaning of the AKS unless that defendant “act[s] knowing that his conduct is unlawful.” *United States ex rel. Hart*, 96 F.4th at 154.

The AKS is enforced both as a criminal statute and, as in this case, is frequently used by the government or relators as a predicate violation to support an alleged violation of the civil FCA. Since 2010, Congress has specified that a claim that includes items or services “resulting from” an AKS violation is a false or fraudulent claim under the FCA. 42 U.S.C. § 1320a-7b(g). Though the evidentiary standard in criminal and civil cases differs, the government or relator in civil cases must adequately plead the “knowingly and willfully” scienter element of the AKS.

Hart alleged in his Second Amended Complaint that McKesson offered physician oncology practices two valuable business tools, the Margin Analyzer and the Regimen Profiler, to induce those practices to purchase oncology pharmaceuticals from McKesson. Hart alleged that these business tools were prohibited remuneration, and that McKesson acted “knowingly and willfully” in offering these two tools to its customers in violation of the AKS. Hart’s basis for alleging “willfulness” included: (1) alleged document destruction during the litigation; (2) Hart informed his supervisor during compliance training about the potential AKS violation, yet McKesson continued to provide these tools, worth

about \$150,000, to medical practices free of charge in exchange for commitments to purchase drugs from McKesson; and (3) Hart's discussions with other employees that McKesson was inappropriately exploiting the business tools.

After the government declined to intervene, the District Court dismissed the FCA claims in a Second Amended Complaint (after dismissing the prior complaint as well) by ruling that Hart failed to plausibly allege sufficient facts to suggest McKesson acted "willfully". The Second Circuit upheld the dismissal and agreed that a defendant acts "willfully" under the AKS only if the defendant knows "that its conduct is, in some way, unlawful."

The Second Circuit rejected the relator's proposed approach, a looser standard that would meet the "willfully" standard of the scienter element if (a) the company provided something of value in connection with the sale of pharmaceuticals reimbursed by the government, and (b) knew, even through general compliance training, that it is illegal to provide things of value to induce sales. Hart filed a petition for a *writ of certiorari*, presenting the question: "[t]o act 'willfully' within the meaning of the [AKS], must a defendant know that its conduct violates the law?"

There is no dispute, under the law, that a defendant does not need "specific intent" to violate the AKS. 42 U.S.C. § 1320a-7b(h). However, the petition raises questions about how certain sister Circuits interpret "willfully" when addressing violations of the AKS:

- The Second Circuit held in this case that a defendant does not act "willfully" within the meaning of the AKS unless that defendant "act[s] knowing that his conduct is unlawful, even if the defendant is not aware that his conduct is unlawful under the AKS specifically." *United States ex rel. Hart v. McKesson Corp.*, 96 F.4th 145,154 (2d Cir. 2024).
- The Eleventh Circuit, in accord with the Second, has also held that a defendant must know that its conduct is unlawful in order to violate the AKS. *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.") (internal quotations omitted).
- The relator argues in the petition that the Fifth and Eighth Circuits are split with the Second Circuit. Relator relies on a Fifth Circuit case holding that "willfully" requires that a "defendant willfully committed an act that violated the . . . Statute" without a requirement that a defendant know its conduct is unlawful. *United States v. St. Junius*, 739 F.3d 193, 210 & n.19 (5th Cir. 2013). However, a more recent Fifth Circuit case, which was cited by the Second Circuit, defines "willfully" to mean "the act was committed voluntarily or purposely, with the specific intent to do something the law forbids; that is to say, with bad purpose either to disobey or disregard the law." *United States v. Nora*, 988 F.3d 823, 830 (5th Cir. 2021) (citation omitted).
- The relator cites an Eighth Circuit case holding a defendant's conduct is willful if a defendant "knew that his conduct was wrongful," but asserts the Eighth Circuit 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). However, a more recent Eighth Circuit relied on *Jain* to uphold a jury instruction stating, "[a] defendant acts willfully if he knew his conduct was wrongful or unlawful." *United States v. Yielding*, 657 F.3d 688, 708 (8th Cir. 2011).
- The Second Circuit did recognize a circuit split, but described its view as in "align[ment] with the approach to the AKS taken by several of our sister courts [including the Third, Fifth, Sixth, Seventh, Eighth, and Eleventh Circuits], which have held or implied that to be liable under the AKS, defendants must know that their particular conduct was wrongful." *United States ex rel.*

Hart, 96 F.4th at 154-55.

It is important to remember that the AKS is a felony statute subject to criminal fines and up to 10 years of imprisonment. It also criminalizes conduct that, in other industries, is not illegal. Further, due to the breadth of the statute and its complexity, Congress and the U.S. Department of Health and Human Services' Office of Inspector General (OIG) have developed a complicated set of guidance to help attorneys and compliance professionals understand and provide counsel with respect to AKS compliance, including statutory exceptions, regulatory safe harbors, advisory opinions, and an enormous body of sub-regulatory guidance. The Second Circuit understood this and noted that its "interpretation of the AKS's willfulness requirement thus protects those (and only those) who innocently and inadvertently engage in prohibited conduct." *Id.* at 155-56.

If the Supreme Court takes an interest in this case, it likely will invite the view of the Solicitor General. Any Supreme Court interest in granting this petition will likely attract a wide range of *amici* participation at the *certiorari* stage by health care industry groups and associations, pharmaceutical company associations, other business groups, as well as associations of whistleblower counsel and other supporters of the private action *qui tam* provisions of the FCA. Though the range of holdings by the Courts of Appeal are often nuanced, Supreme Court consideration of the issue would be viewed as very significant, and a decision that creates a rigorous standard for "willfulness," or alternatively, a lenient one, could considerably impact the Department of Justice (DOJ) and relators' ability to successfully plead, and prove, an AKS violation as a predicate to an alleged FCA violation.

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National Law Review, Volume XIV, Number 190

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