

## United States ex rel. Hart v. McKesson Corp.

96 F.4th 145 (2d Cir. 2024)  
Decided Mar 12, 2024

Docket No. 23-726-cv August Term, 2023  
03-12-2024

UNITED STATES of America, et al., EX REL.  
Adam HART, Plaintiffs-Appellants, v.  
MCKESSON CORPORATION, McKesson Specialty Distribution LLC, McKesson Specialty Care Distribution Corporation, Defendants-Appellees.

Andrew C. Shen, Kellogg, Hansen, Todd, Figel & Frederick, P.L.L.C. Washington, DC (James M. Webster, David L. Schwarz, Bradley E. Oppenheimer, Grace W. Knofczynski, Kellogg, Hansen, Todd, Figel & Frederick, P.L.L.C., Washington, DC; Stephen S. Hasegawa, Phillips & Cohen LLP, San Francisco, CA; Ari Yampolsky, Constantine Cannon LLP, San Francisco, CA, on the brief), for Plaintiffs-Appellants. Mark Mosier, Covington & Burling LLP, Washington, DC (Krysten L. Rosen Moller, Ethan M. Posner, Nicholas Pastan, Covington & Burling LLP, Washington, DC; S. Conrad Scott, Covington & Burling, New York, NY, on the brief), for Defendants-Appellees.

Gerard E. Lynch, Circuit Judge

- 149 \*149 Appeal from the United States District Court for the Southern District of New York (Ronnie Abrams, J.) Andrew C. Shen, Kellogg, Hansen, Todd, Figel & Frederick, P.L.L.C. Washington, DC (James M. Webster, David L. Schwarz, 150 Bradley E. Oppenheimer, Grace \*150 W. Knofczynski, Kellogg, Hansen, Todd, Figel & Frederick, P.L.L.C., Washington, DC; Stephen S.

Hasegawa, Phillips & Cohen LLP, San Francisco, CA; Ari Yampolsky, Constantine Cannon LLP, San Francisco, CA, on the brief), for Plaintiffs-Appellants. Mark Mosier, Covington & Burling LLP, Washington, DC (Krysten L. Rosen Moller, Ethan M. Posner, Nicholas Pastan, Covington & Burling LLP, Washington, DC; S. Conrad Scott, Covington & Burling, New York, NY, on the brief), for Defendants-Appellees. Before: Lynch and Park, Circuit Judges, and Williams, District Judge. \*\* Gerard E. Lynch, Circuit Judge:

\*\* Judge Omar A. Williams of the United States District Court for the District of Connecticut, sitting by designation.

In this *qui tam* action, Adam Hart sued McKesson Corporation, McKesson Specialty Distribution LLC, and McKesson Specialty Care Distribution Corporation (together, "McKesson") under the federal False Claims Act (the "FCA"), [31 U.S.C. § 3729 et seq.](#), and the FCA analogues of 27 states and the District of Columbia. Hart, a former McKesson Business Development Executive, alleges that McKesson, a pharmaceutical wholesaler, offered its customers free access to two valuable business management tools to induce those customers to purchase drugs from McKesson. He argues that McKesson's use of the tools operated as a kickback under the federal Anti-Kickback Statute (the "AKS"), [42 U.S.C. § 1320a-7b](#), and similar anti-kickback laws of various states and the District of Columbia.

The United States District Court for the Southern District of New York (Ronnie Abrams, *J.*) dismissed Hart's federal claim, concluding that Hart had failed to allege that McKesson acted with the requisite scienter under the AKS. It dismissed his remaining claims on the ground that they were all premised on a violation of the federal AKS.

As explained below, we agree with the district court that to violate the federal AKS, a defendant must act knowing that its conduct is, in some way, unlawful, and that Hart failed to allege facts sufficient to satisfy that standard. We disagree, however, with the district court's conclusion that Hart's claims under the FCA analogues of several states and the District of Columbia were premised solely on a violation of the federal AKS. Accordingly, we AFFIRM the district court's dismissal of Hart's federal claim, VACATE the dismissal of Hart's remaining claims, and REMAND for further proceedings consistent with this opinion.

## BACKGROUND

### I. Factual Background <sup>1</sup>

<sup>1</sup> When reviewing the district court's grant of a motion to dismiss, we - like the district court - take the plaintiff's well-pleaded allegations as true and draw all reasonable inferences in his favor. *United States ex rel. Foreman v. AECOM*, 19 F.4th 85, 104 (2d Cir. 2021).

McKesson is a large wholesale pharmaceutical distributor that sells products across the United States. It provides drugs and other medical supplies to various health care providers, including oncology providers. McKesson includes two divisions that serve oncology customers - the U.S. Oncology Network ("USON"), which offers tools and services to member health care practices in exchange for management fees, and the Open Market Division, which operates as a traditional

151 drug wholesaler that purchases drugs from \*151 manufacturers and sells them at a markup to health care practices.

Oncology practices often obtain specialty drugs from wholesalers like McKesson. When an oncology practice buys a specialty drug from a wholesaler, it bills its patient's insurer for the cost of the drug. Medicare and Medicaid are federally funded health insurance programs that are major payors for oncology drugs procured in that fashion. Those programs reimburse health care providers for such drugs at standardized rates set by Medicare. Because the reimbursement rates do not change based on what a given provider paid for the drugs, each provider bears the risk that the reimbursement rate for a given drug will fall below its costs. If the reimbursement rate exceeds a provider's costs, however, the provider can profit from the difference.

McKesson offers two tools (the "Business Management Tools") to help providers maximize their profits and mitigate the risk that the reimbursement rate will fall below the actual cost they paid for drugs. The first tool, the Margin Analyzer, evaluates sets of "therapeutically interchangeable" drugs by comparing McKesson's price for each drug to publicly available Medicare reimbursement rates for that drug. App'x 277-78, ¶¶ 63, 65. Using the Margin Analyzer, a medical provider can thus compare drugs that McKesson categorizes as interchangeable to determine which treatment option provides the highest profit margin based on how each drug's reimbursement rate measures up to McKesson's prices. The Margin Analyzer does not evaluate the comparative medical benefits of the drugs that it analyzes, nor does it evaluate which drug would provide the least expensive option for a given patient. Instead, according to Hart, the tool's "sole function is to identify which among several purportedly equivalent drugs will earn a physician practice - and, not coincidentally, McKesson - the most money." *Id.* at 279, ¶ 67. The second tool, the Regimen Profiler, is similar to the Margin

Analyzer, but it provides profit-margin information for an entire course of treatment, as opposed to information only for specific drugs. Several of McKesson's Open Market Division customers who had received the Business Management Tools submitted millions of dollars in Medicare reimbursement claims from 2012 to late 2017.

But according to Hart, while the Business Management Tools led to increased costs for insurers, they were hugely valuable tools for McKesson and for health care providers, and McKesson understood as much. Hart alleges, for example, that multiple internal and external analyses determined that the Margin Analyzer and Regimen Profiler possessed significant value. Further, the Business Management Tools formed a central component of McKesson's national marketing and sales strategy, and McKesson often won new business by touting the benefits of the tools to health care providers.

Hart's objection to the Business Management Tools is that McKesson's Open Market Division offered them for free to induce providers to buy drugs from McKesson.<sup>2</sup> The Open Market Division offered providers two basic purchase arrangements. Under one arrangement, providers could purchase individual drugs without making any additional commitments to McKesson, leaving those providers free to purchase other drugs from McKesson competitors. Under the  
 152 other <sup>152</sup>arrangement, providers promised to use McKesson as their primary wholesale supplier of branded and generic drugs. In exchange for that promise, McKesson granted providers free access to the Business Management Tools. Only providers enrolled in the second type of purchase arrangement could access those tools; McKesson refused to offer them on a standalone basis, even when providers expressly requested as much and offered to pay. Thus, according to Hart, McKesson provided the valuable Business Management Tools as an unlawful kickback to induce customers to buy from McKesson.

<sup>2</sup> Unlike McKesson's Open Market Division, USON provides customers with the Business Management Tools, along with other tools and services, in exchange for a management fee.

Hart further contends that McKesson acted willfully. He points out that sales executives and other customer-facing employees at McKesson received regular training on the AKS and that those training sessions emphasized that providing anything of value to induce a sale of pharmaceuticals violates federal law. Hart also alleges that he and other McKesson employees often discussed concerns that McKesson's sales practices (including its use of the Business Management Tools) were improper. He further alleges that McKesson destroyed several documents after this litigation began to conceal its wrongful conduct.

## II. Procedural History

Hart filed his complaint on February 6, 2015. Because Hart asserted a *qui tam* action under the FCA,<sup>3</sup> the United States was given an opportunity to intervene in the case. *See* 31 U.S.C. § 3730(b)(2), (b)(4). After the government declined to intervene, Hart filed his first amended complaint (the "FAC") on June 3, 2020. The defendants moved to dismiss the FAC, and the district court granted that motion on May 5, 2022. The district court reasoned that the plaintiff failed to plausibly plead that the defendants acted with the requisite scienter under the AKS. Nonetheless, the court gave the plaintiff leave to amend his complaint a second time to add more allegations regarding McKesson's scienter, and Hart filed his second amended complaint (the "SAC") roughly one month later. McKesson moved to dismiss the SAC, and on March 28, 2023, the district court again granted the motion. *United States ex rel. Hart v. McKesson Corp.*, No. 15-CV-0903 (RA), 2023 WL 2663528, at \*13 (S.D.N.Y. Mar. 28, 2023).

3 A private individual may bring a *qui tam* action under the FCA for violations of the AKS. The FCA prohibits, as relevant here, "knowingly present[ing], or caus[ing] to be presented, a false or fraudulent claim for payment or approval" to the federal government. 31 U.S.C. § 3729(a)(1)(A). The AKS, in turn, provides that "a claim that includes items or services resulting from a violation" of the AKS "constitutes a false or fraudulent claim for purposes of" the FCA. 42 U.S.C. § 1320a-7b(g).

In its opinion on the motion to dismiss the SAC, the district court concluded that to act "willfully," as required for liability under the AKS, a defendant must act knowing that its conduct was unlawful. *Id.* at \*7. The court then concluded that Hart's allegations, including the new allegations that he added to the SAC, did not plausibly plead that McKesson acted willfully under that standard. *Id.* at \*8-12. The district court also dismissed Hart's claims under the FCA analogues of several states and the District of Columbia, reasoning that those claims were premised only on "a violation of the *federal AKS*," which Hart had not plausibly alleged. *Id.* at \*8 (emphasis in original). The court again granted Hart leave to amend his complaint because it was "conceivable" that Hart could state a claim under the anti-kickback laws of one or more states, which may have a lower scienter requirement than the federal AKS. *Id.* at \*13.<sup>4</sup>

<sup>4</sup> The court noted, however, that it was "skeptical that it would retain jurisdiction" over a third amended complaint that raised exclusively state-law claims. *Id.*

On April 7, 2023, Hart filed a notice of intent not to amend his complaint and requested that the court enter a final judgment. The district court did so on April 17. This appeal followed.

## DISCUSSION

Hart argues on appeal that the district court erred in dismissing his federal FCA claim because he alleged sufficient facts to show that McKesson

acted with the requisite scienter under the federal AKS. He also argues that the district court erred in dismissing his remaining claims because, contrary to the district court's conclusion, they were not premised solely on a violation of the federal AKS. As explained below, we agree with the district court's dismissal of Hart's federal FCA claim but disagree with its dismissal of the remaining claims.

### I. Standard of Review

We review *de novo* a district court's grant of a motion to dismiss. *Meyer v. Seidel*, 89 F.4th 117, 128 (2d Cir. 2023). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009), quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007).

"Claims under the FCA are subject to the particularity requirement of *Federal Rule of Civil Procedure 9(b)*." *United States v. Strock*, 982 F.3d 51, 66 (2d Cir. 2020). Accordingly, a plaintiff bringing an FCA claim "must state with particularity the circumstances constituting fraud." *Fed. R. Civ. P. 9(b)*. To do so, plaintiffs must "plead the factual basis which gives rise to a strong inference of fraudulent intent." *Strock*, 982 F.3d at 66 (internal quotation marks omitted), quoting *O'Brien v. Nat'l Prop. Analysts Partners*, 936 F.2d 674, 676 (2d Cir. 1991).

### II. The Federal AKS Claim

#### A. Willfulness

The primary issue on appeal is whether the SAC plausibly alleges that McKesson acted with the *mens rea* applicable under the federal AKS. That statute provides, in pertinent part, that

[w]hoever knowingly and willfully offers or pays 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, shall be guilty of a felony . . . .

42 U.S.C. § 1320a-7b(b)(2)(B). A defendant convicted under the AKS may be subject to significant penalties, including ten years' imprisonment and fines of up to \$100,000. *See id.*

When interpreting a statute, "[w]e begin with the text." *Facebook, Inc. v. Duguid*, 592 U.S. 395, 402, 141 S.Ct. 1163, 209 L.Ed.2d 272 (2021). The statute here requires, *inter alia*, that a defendant act "willfully" to be liable, but it does not define that term.

Interpreting the term "willfully" has long "bedeviled" courts, *United States v. George*, 386 F.3d 383, 389 (2d Cir. 2004), because it is " 'a word of many meanings' whose construction is often dependent on the context," *Bryan v. United States*, 524 U.S. 184, 191, 118 S.Ct. 1939, 141 L.Ed.2d 197 (1998), quoting *Spies v. United States*, 317 U.S. 492, 497, 63 S.Ct. 364, 87 L.Ed. 418 (1943). "Most obviously it differentiates between deliberate and unwitting conduct, but in the criminal law it also typically refers to a culpable state of mind." *Bryan*, 524 U.S. at 191, 118 S.Ct. 1939. Thus, "[a]s a general matter, when used in the criminal context, a willful act is one undertaken with a bad purpose." *United States v. Kosinski*, 976 F.3d 135, 154 (2d Cir. 2020) (alterations in original) (internal quotation marks omitted), quoting *Bryan*, 524 U.S. at 191, 118 S.Ct. 1939. "In other words, in order to establish a willful violation of a [criminal] statute, the Government must prove that the defendant acted with knowledge that his conduct was unlawful." *United States v. Kukushkin*, 61 F.4th 327, 332 (2d

Cir. 2023) (internal quotation marks omitted), quoting *Bryan*, 524 U.S. at 191-92, 118 S.Ct. 1939.

At the same time, it is well settled that "ignorance of the law or a mistake of law is no defense to criminal prosecution." *Cheek v. United States*, 498 U.S. 192, 199, 111 S.Ct. 604, 112 L.Ed.2d 617 (1991). Accordingly, with few exceptions, "a person who acts willfully need not be aware of the *specific* law that his conduct may be violating." *United States v. Henry*, 888 F.3d 589, 599 (2d Cir. 2018) (emphasis added). "Rather, 'knowledge that the conduct is unlawful is all that is required.'" *Id.*, quoting *Bryan*, 524 U.S. at 196, 118 S.Ct. 1939.<sup>5</sup>

<sup>5</sup> The Supreme Court has applied a heightened standard of willfulness to certain "highly technical statutes," requiring not only that a defendant understand that her conduct is unlawful but also that she "have knowledge of the law" that she is alleged to have violated. *Bryan*, 524 U.S. at 194-95, 118 S.Ct. 1939, citing *Cheek*, 498 U.S. at 201, 111 S.Ct. 604, and *Ratzlaf v. United States*, 510 U.S. 135, 138, 149, 114 S.Ct. 655, 126 L.Ed.2d 615 (1994). McKesson does not argue for such a standard here. Nor could it. The AKS expressly provides that "a person need not have actual knowledge of [the AKS] or specific intent to commit a violation of [the AKS]" to be criminally liable. 42 U.S.C. § 1320a-7b(h).

Drawing on that background understanding of willfulness, our only opinion to address the AKS's *mens rea* requirement suggested that to violate the AKS, a defendant must act knowing that his conduct is unlawful, even if the defendant is not aware that his conduct is unlawful under the AKS specifically. *Pfizer, Inc. v. U.S. Dep't of Health & Hum. Servs.*, 42 F.4th 67, 77 (2d Cir. 2022). In that case, we explained that the "bad purpose" required for willful violations of criminal statutes is best "understood as 'a voluntary, intentional violation



of a known legal duty.' " *Id.*, quoting *United States v. Bishop*, 412 U.S. 346, 360, 93 S.Ct. 2008, 36 L.Ed.2d 941 (1973). Thus, we reasoned that an individual who "accidentally violate[s] the statute" because he is "unaware" that a given payment arrangement is prohibited by law cannot be held criminally liable under the AKS. *Id.* But a person can "willfully" violate a criminal statute like the AKS, "as long as he knows that his conduct is illegal, even if he is not aware of the exact statutory provision that his conduct violates." *Id.* at 77 n.8.

Although *Pfizer* addressed a slightly different issue than the one we now face, its discussion of the term "willfully" in the AKS is evidence that we have understood that term as it is typically interpreted in federal criminal law. Moreover, the interpretation suggested in *Pfizer* aligns with the approach to the AKS taken by several of our sister circuits, which have held or implied that to be liable under the AKS, defendants must know that their particular conduct was wrongful. *See, e.g., United States v. Montgomery*, No. 20-5891, 2022 WL 2284387, at \*12 (6th Cir. June 23, \*155 2022); *United States v. Nora*, 988 F.3d 823, 830 (5th Cir. 2021); *United States v. Hill*, 745 F. App'x 806, 815-16 (11th Cir. 2018); *United States v. Nagelvoort*, 856 F.3d 1117, 1126 (7th Cir. 2017); *United States v. Goldman*, 607 F. App'x 171, 174-75 (3d Cir. 2015); *United States v. Yielding*, 657 F.3d 688, 708 (8th Cir. 2011).

*Pfizer's* interpretation also makes sense given the text and structure of the statute. The AKS forbids "offer[ing] or pay[ing] any remuneration . . . directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person" to make certain purchases. 42 U.S.C. § 1320a-7b(b)(2)(B). Thus, the statute's plain language is expansive. To cabin the statute's broad reach, Congress defined twelve exceptions to the AKS's criminal penalties, some of which are themselves quite broad. *See, e.g., id.* § 1320a-7b(b)(3)(A) (criminal penalties shall not apply to "a discount or other reduction in price obtained by a provider

of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program"). Moreover, Congress created a robust regime through which the Department of Health and Human Services ("HHS") can establish safe harbors that exempt certain arrangements from the AKS and issue advisory opinions explaining whether the AKS reaches particular arrangements. *Id.* §§ 1320a-7c(a)(1)(D), 1320a-7d.

All of that suggests that Congress understood that the precise contours of the AKS would evolve over time. Thus, interpreting "willfully" to require that a defendant act understanding that his conduct is unlawful (if not necessarily under the AKS) accords with the general goal of criminal law to punish only those who act with a "vicious will." *Ruan v. United States*, 597 U.S. 450, 457, 142 S.Ct. 2370, 213 L.Ed.2d 706 (2022) (internal quotation marks omitted), quoting *Morissette v. United States*, 342 U.S. 246, 251, 72 S.Ct. 240, 96 L.Ed. 288 (1952). A more expansive interpretation would risk creating a trap for the unwary and deter socially beneficial conduct. *See id.* at 459, 142 S.Ct. 2370; *United States v. Pineda*, 847 F.2d 64, 65 (2d Cir. 1988) (rejecting challenge to sentencing enhancement "because the statute requires proof that a defendant knowingly and intentionally possessed a controlled substance").

The legal landscape that has emerged through HHS's safe harbors and advisory opinions only strengthens that conclusion. HHS has codified over 35 safe harbor provisions and continues to add new safe harbors and modify existing ones. *See* 42 C.F.R. § 1001.952(a)-(kk). Thus, the reach of the AKS is far from settled. In addition, HHS has acknowledged that the existence of its safe harbor provisions may not resolve whether a particular arrangement is permissible under the AKS. *See* Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,954 (July 29,

1991). Specifically, it has explained that a business arrangement that does not satisfy a safe harbor could be (1) outside the ambit of the AKS altogether, (2) a clear violation of the AKS that also fails to satisfy a safe harbor, or (3) an arrangement that "violate[s] the statute in a less serious manner" but that is also not "in compliance with a safe harbor provision," in which case "there is no way to predict the degree of risk" of prosecution. *Id.* As a result, even a well-counseled defendant who has taken every effort to comply with the AKS and all other relevant laws could still find herself accidentally in violation of the statute. The same is true for HHS's advisory  
 156 opinions. A defendant could innocently rely \*156 on a published advisory opinion to conclude that her conduct is lawful, even if she is ultimately incorrect. Again, defining "willfully" to require that a defendant act knowing that her conduct is in some way unlawful avoids sweeping in such innocent conduct.<sup>6</sup>

<sup>6</sup> We do not suggest that the defendants in this case relied on an advisory opinion or safe harbor to conclude that their conduct was lawful. Rather, our discussion of the legal landscape that has arisen from HHS's advisory opinions and safe harbors merely illustrates that understanding the reach of the AKS is a difficult endeavor. A defendant could innocently conclude in light of a safe harbor provision or advisory opinion that its conduct is lawful under the AKS and all other applicable laws. The possibility that such a defendant would draw that conclusion and turn out to be incorrect supports interpreting willfulness to require knowledge of wrongdoing.

The historical evolution of the AKS also supports that interpretation. Congress amended the AKS to add the term "knowingly and willfully" in 1980. Medicare and Medicaid Amendments of 1980, Pub L. No. 96-499, tit. IX, § 917, 94 Stat. 2599, 2625 (1980). The drafters of the amendment added the term "knowingly and willfully" out of a "concern[ ] that criminal penalties may be

imposed under current law to an individual *whose conduct, while improper, was inadvertent.*" H.R. Rep. No. 96-1167, at 59 (1980), as *reprinted in* 1980 U.S.C.C.A.N. 5526, 5572 (emphasis added).

Several years later, the Ninth Circuit held that "knowingly and willfully" required not only that a defendant act knowing that her conduct was unlawful in general, but also that she act with specific knowledge of the AKS. *Hanlester Network v. Shalala*, 51 F.3d 1390, 1400 (9th Cir. 1995). Other circuits rejected that interpretation, concluding that "ignorance of the law is no excuse" and that "knowledge that conduct is unlawful is all that is required." *E.g., United States v. Starks*, 157 F.3d 833, 838 (11th Cir. 1998) (internal quotation mark omitted), quoting *Bryan*, 524 U.S. at 196, 118 S.Ct. 1939.

In 2010, Congress resolved the conflict. It amended the statute to provide that, to violate the AKS, "a person need not have actual knowledge of [the AKS] or specific intent to commit a violation of [the AKS]." Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6402(f)(2), 124 Stat. 119, 759 (2010) (codified at 42 U.S.C. § 1320a-7b(h)). Thus, Congress rejected the Ninth Circuit's heightened standard of willfulness, but it left intact the AKS's willfulness requirement, even as other circuits interpreted that term to require a defendant to know that her conduct was in some way unlawful. *See also* 155 Cong. Rec. S10,852, S10,853 (2009) (statement of Sen. Edward Kaufman) (explaining that "the Ninth Circuit Court of Appeals has read 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"). The retention of the willfulness requirement in that context suggests that Congress still intended the term to protect against criminal liability for unwitting defendants by requiring that a defendant act with knowledge that her conduct is *somehow* unlawful, even though it eschewed any requirement that a  
 157 defendant know about the AKS specifically.<sup>7</sup> \*157

7 Our determination is also consistent with the scienter requirement for health care fraud. In developing the 2010 amendment, Congress addressed the AKS and the health care fraud statute concurrently. *See* 155 Cong. Rec. at S10,853 (statement of Sen. Edward Kaufman) ("Both the anti-kickback statute and the health care fraud statute include the term 'willfully.' The heightened mental state [required by the Ninth Circuit] . . . is inappropriate for these crimes."). Thus, logically, both statutes now require that a defendant act "knowingly and willfully" to be criminally liable. *Compare* 42 U.S.C. § 1320a-7b(b)(2)(B) with 18 U.S.C. § 1347(a). At least one of our sister circuits has explained that a defendant acts "knowingly and willfully" under the health care fraud statute "when he acts with 'knowledge that his conduct was unlawful.'" *United States v. Clay*, 832 F.3d 1259, 1301 (11th Cir. 2016), quoting *United States v. Dominguez*, 661 F.3d 1051, 1068 (11th Cir. 2011). Similarly, in *United States v. Jafari*, 663 F. App'x 18 (2d Cir. 2016), we determined that the *mens rea* requirement of the health care fraud statute was satisfied where the government established that the defendant knew she was committing fraud. *Id.* at 20. In other words, we found that the scienter requirement was satisfied when evidence established that the defendant knew she was committing an unlawful act. The inquiry in *Jafari* stopped before determining whether the defendant knew that she was violating the health care fraud statute specifically.

Finally, a comparison between the criminal provision at issue in this case and its civil counterpart lends further support to our interpretation. The AKS is abutted by a provision that imposes civil liability against, *inter alia*, those who "knowingly" make false representations in certain health care contexts. *See, e.g.*, 42 U.S.C. § 1320a-7a(a)(3). The material difference between the term "knowingly" in § 1320a-7a and the

phrase "knowingly and willfully" in the AKS suggests that Congress intended to require knowledge of illegality for liability under the latter. *See Bishop*, 412 U.S. at 360, 93 S.Ct. 2008; *see also Rehaif v. United States*, 588 U.S. —, 139 S. Ct. 2191, 2205, 204 L.Ed.2d 594 (2019) (Alito, J., dissenting).

Accordingly, we hold that the term "willfully" in the AKS means what it typically means in federal criminal law. To act willfully under the AKS, a defendant must act with a "bad purpose," *Bryan*, 524 U.S. at 191, 118 S.Ct. 1939. In other words, the defendant must act "with knowledge that his conduct was unlawful." *Kukushkin*, 61 F.4th at 332 (internal quotation mark omitted), quoting *Bryan*, 524 U.S. at 191-92, 118 S.Ct. 1939.

None of this is to say, however, that a defendant must know of the AKS specifically or intend to violate that statute. Such a requirement would conflict with the plain language of the 2010 amendment. A person may be criminally liable under the AKS without knowing of that statute or having a specific intent to violate it, provided that the person acts with knowledge that her conduct is, in some way, unlawful. Our interpretation of the AKS's willfulness requirement thus protects those (and only those) who innocently and inadvertently engage in prohibited conduct.

Hart asks us to adopt either of two alternative interpretations of the term willfully, but neither interpretation is satisfactory. First, seizing on the portion of our opinion in *Pfizer* explaining that a "bad purpose" means a voluntary and intentional violation of a known legal duty, *Pfizer*, 42 F.4th at 77, Hart asks us to adopt a two-factor interpretation of willfulness. He argues that the willfulness requirement may be satisfied through evidence that the defendant "(1) intentionally provid[ed] something of value in connection with a medical purchase reimbursed by the government, (2) while knowing that it is illegal to provide things of value in connection with such purchases." Appellant's Br. at 31.



We disagree. At the outset, Hart's proposal is based on a misreading of our opinion in *Pfizer*. Although that opinion explained that a "bad purpose" is "accurately understood as 'a voluntary, intentional violation of a known legal duty,'" *Pfizer*, 42 F.4th at 77, quoting *Bishop*, 412 U.S. at 360, 93 S.Ct. 2008, it also made clear that "a  
 158 person can 'willfully' violate a \*158 statute as long as he knows that *his conduct* is illegal, even if he is not aware of the exact statutory provision that his conduct violates," *id.* at 77 n.8 (emphasis added). The full context of the opinion thus indicates that the relevant knowledge that a defendant must possess is knowledge that "his conduct" is illegal; according to *Pfizer*, a defendant's knowledge of his general legal obligations is not enough if he does not also know that his actions violate those obligations.

Second, Hart's two-factor definition would criminalize too much innocent conduct. Suppose that a pharmaceutical company creates a free 24/7 customer support hotline to allow providers to ask questions about the company's products. Even if the company is generally aware of the AKS's prohibition on kickbacks, the company still could create the hotline out of a good-faith desire to help doctors treat their patients more effectively, without knowing that the hotline violated the AKS or any other law. In such circumstances, one could hardly say that the company acted with the "vicious will" that "our criminal law seeks to punish," *Ruan*, 597 U.S. at 457, 142 S.Ct. 2370 (internal quotation marks omitted), quoting *Morissette*, 342 U.S. at 251, 72 S.Ct. 240. But under Hart's proposed definition, the company could suffer criminal penalties anyway if the hotline was deemed prohibited remuneration.

Third, although Hart cites a handful of out-of-circuit opinions to support his two-factor test, those opinions do not help him. In the first, *United States v. Sosa*, 777 F.3d 1279 (11th Cir. 2015), the defendant engaged in conduct that was plainly illegal - writing checks to a "recruiter" who, in exchange, paid patients in cash to encourage them

to visit a certain medical clinic for treatment. *Id.* at 1287-88, 1293-94. Indeed, the defendant in *Sosa* admitted to law enforcement that "he knew that [the recruiter] was in charge of bringing patients to the clinic," that the checks the defendant wrote the recruiter were "payment for bringing those patients to the clinic," "that the patients were being paid," and "that it was illegal to pay the patients." *Id.* at 1288. *Sosa* therefore had no occasion to consider whether a defendant whose actions are closer to the perimeter of the AKS's proscriptions must understand that his specific conduct was unlawful. Although, as Hart points out, *Sosa* stated in passing that a "defendant need not have known that a specific referral arrangement violated the law" to be liable under the AKS, that statement paraphrased another Eleventh Circuit opinion. *Id.* at 1293, citing *United States v. Vernon*, 723 F.3d 1234, 1256 (11th Cir. 2013). That opinion stated more precisely that a defendant does not need to know "that a specific 'referral arrangement violated the *Anti-Kickback statute* in order to be convicted' " because the Eleventh Circuit correctly rejected the argument that a defendant needs to be *specifically aware of the AKS* to be criminally liable. *Vernon*, 723 F.3d at 1256 (emphasis added), quoting *United States v. Starks*, 157 F.3d 833, 837 (11th Cir. 1998). Thus, the law in the Eleventh Circuit is consistent with our holding here - to act willfully, a defendant need not be aware of the AKS or have a specific intent to violate that statute, but she must act knowing that her conduct is in some way unlawful. Indeed, *Sosa* itself explained that willfulness under the AKS requires that the defendant "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*.'" *Sosa*, 777 F.3d at 1293 (emphases added), quoting *Vernon*, 723 F.3d at 1256.

Hart's other primary authorities are likewise inapplicable. As with *Sosa*, those cases all  
 159 involved kickback schemes that \*159 were plainly

illegal. *See United States v. Goodwin*, 974 F.3d 872, 873 (8th Cir. 2020) (defendant shared profits of medical testing company in exchange for referring patients to the company); *United States v. Moshiri*, 858 F.3d 1077, 1082 (7th Cir. 2017) (defendant was aware that his teaching contract with a hospital was a sham designed to disguise kickbacks for patient referrals); *United States v. Nowlin*, 640 F. App'x 337, 340, 344 (5th Cir. 2016) (defendant received commissions from medical equipment company in exchange for referring clients to the company). And, as with *Sosa*, those cases all come from circuits that have elsewhere held or implied that willfulness under the AKS requires knowledge that the defendant's specific conduct is wrongful. *See, e.g., Yielding*, 657 F.3d at 708; *Nagelvoort*, 856 F.3d at 1126; *Nora*, 988 F.3d at 830. Thus, we decline to adopt Hart's two-factor approach to defining willfulness.

Hart's second proposed definition derives from an outlier opinion from the Fifth Circuit, *United States v. St. Junius*, 739 F.3d 193 (5th Cir. 2013). We reject that definition, too. In *St. Junius*, the court stated that to show a criminal violation of the AKS, the government "must prove that the defendant willfully committed an act that violated" that statute. *Id.* at 210. It rejected the argument that the government must prove that the defendant acted knowing that her conduct was unlawful. *Id.* at 210 n.19. In other words, the Fifth Circuit ruled that as long as a defendant intentionally performed an act, and that act in fact violated the AKS, the defendant violated the law even if she had no idea that her conduct was unlawful in any way. In so ruling, the court relied exclusively on the portion of the AKS that provides that to violate the AKS, "a person need not have actual knowledge of [the AKS] or specific intent to commit a violation of [the AKS]," 42 U.S.C. § 1320a-7b(b). *St. Junius*, 739 F.3d at 210 n.19.

*St. Junius*'s reasoning is unpersuasive. As we have established above, there is a distinction between knowledge of unlawfulness in general and

knowledge of a particular statute. The provision of the AKS relied on by *St. Junius* addresses the latter, not the former.<sup>8</sup> *St. Junius*'s use of that provision to conclude that defendants need not have *any* knowledge of unlawfulness to act willfully under the AKS is therefore not well supported. Perhaps for that reason, the Fifth Circuit has failed to follow the reasoning of *St. Junius* in several subsequent published opinions. *See, e.g., United States v. Shah*, 84 F.4th 190, 239-40 (5th Cir. 2023) ("Willfulness, under the AKS, means acting with specific intent to do something the law forbids."); *Nora*, 988 F.3d at 830 (similar); *United States v. Ricard*, 922 F.3d 639, 648 (5th Cir. 2019) (similar). We therefore decline to apply *St. Junius* here.

<sup>8</sup> Hart briefly argues that the AKS is the only federal statute that prohibits offering remuneration in connection with medical purchases that are reimbursed by the federal government. So, he continues, when Congress clarified that a defendant need not have knowledge of the AKS to be criminally liable, it also removed any requirement that a defendant have *general* knowledge of illegality. That argument fails out of the gate. Contrary to Hart's suggestion, conduct underlying an AKS conviction can easily implicate other crimes including, among others, wire fraud, health care fraud, and bribery. Thus, the statutory language providing that a defendant need not know about the AKS to act willfully does not mean that a defendant need not have any knowledge of unlawfulness.

Accordingly, neither of Hart's proposed definitions has merit. Instead, to act "willfully" under the AKS's criminal provisions, a defendant must act knowing that his conduct is unlawful, even if he is

160 not aware of the AKS specifically. \*160

### *B. Sufficiency of Hart's Allegations*

Having established the proper definition of willfulness, we now turn to whether Hart has alleged sufficient facts pertinent to that definition to survive a motion to dismiss. Hart points to three categories of allegations that he contends give rise to a plausible inference of willfulness as we have defined it - allegations that McKesson destroyed certain documents after receiving notice that its conduct may be unlawful, that Hart himself suggested to certain McKesson employees that McKesson's use of the Business Management Tools violated the company's compliance policies or was otherwise inappropriate, and that one McKesson executive sent an email to another executive that attached a document that included a reference to the Business Management Tools and stated, "You didn't get this from me . . . . ok?". We hold that none of those allegations alone or together gives rise to a plausible inference that McKesson acted willfully.<sup>9</sup>

<sup>9</sup> Hart spends much of this section of his brief arguing that he plausibly alleged willfulness by alleging that McKesson was aware of the AKS's prohibitions and still offered the Business Management Tools for free, even though McKesson knew that those tools were valuable. That argument fails, as it is nothing more than an attempt to resuscitate his proposed two-factor definition of willfulness, which we have already rejected. Hart also suggests that the district court erred by imposing a "heightened pleading standard," Appellant's Br. 42, by listing certain kinds of allegations that could plausibly suggest willfulness under the AKS. But by including an illustrative list of potentially relevant allegations, the district court did not hold Hart to a more stringent pleading standard. Rather, the district court considered Hart's allegations on their own terms and concluded, as we do, that they failed to create a plausible inference of willfulness under the typical federal pleading standards.

First, Hart points to McKesson's alleged destruction of certain documents. Hart alleges, for example, that after the Department of Justice sent McKesson a Civil Investigative Demand seeking documents related to Hart's *qui tam* action, McKesson asked Hart to return the laptop he used when he worked there. He further alleges that, although the laptop contained "a trove of relevant documents," App'x 321, ¶ 168, McKesson scrubbed the laptop of its contents after Hart returned it. According to Hart, that allegation plausibly suggests that McKesson attempted to conceal its alleged prior misconduct, which in turn suggests that McKesson acted willfully.

Under the circumstances, we disagree. At most, the allegation suggests that at some point during this litigation, McKesson determined that its use of the Business Management Tools may have been improper. But courts that have found concealment probative of wrongful intent have typically done so when the concealment happened *concurrently* with the violation. *See, e.g., Vernon*, 723 F.3d at 1269 (defendant concealed kickback payments through "a sham job title" given to the kickback recipient while the payments were ongoing); *Ricard*, 922 F.3d at 648-49 (defendant concealed her monthly income while receiving unlawful kickbacks); *see also United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 752, 143 S.Ct. 1391, 216 L.Ed.2d 1 (2023) (whether, under the FCA, a defendant acted "knowingly" in submitting a false claim turns on "what the defendant thought when submitting the false claim - not what the defendant may have thought *after* submitting it"). Hart does not allege that McKesson took any efforts to conceal its alleged wrongdoing before the litigation began.<sup>10</sup>

<sup>10</sup> We note, moreover, that Hart does not allege that it was not standard practice for McKesson to reclaim, scrub, and recycle company-owned laptops previously used by former employees. Nor does Hart suggest that laptops of his colleagues were

scrubbed, even though he alleges that McKesson was engaged in a "nationwide" scheme. App'x 298, ¶ 120.

Hart also alleges that McKesson removed a  
161 customer testimonial video \*161 about the Margin Analyzer from its website and claims to have lost or destroyed the video and the footage used to make that video. But there is nothing to suggest that McKesson attempted to conceal the testimonial video other than the fact that McKesson currently does not possess that video or the footage used to make it. Hart does not allege that McKesson had an obligation to preserve those materials or that McKesson would have normally retained the materials under other circumstances. Accordingly, the document destruction allegations are insufficient.

Second, Hart relies on a handful of allegations that, while he was still employed at McKesson, he discussed his concerns about the propriety of McKesson's use of the Business Management Tools. He relies, for example, on a message that he sent to his supervisor while both of them attended a training session on McKesson's compliance policies that included a presentation on the AKS. During the session, Hart told his supervisor that he felt that McKesson's current sales practices violated the policies discussed at the session. Even interpreting that allegation in the light most favorable to Hart, it suggests only that *Hart* believed that McKesson's use of the Business Management Tools violated the AKS.<sup>11</sup> Hart does not allege that his supervisor agreed with him or even expressed any concern that Hart may have been right. Hart's own belief that McKesson's use of the Business Management Tools was unlawful does not help show that *McKesson* believed the same.

<sup>11</sup> Even that is a generous interpretation of Hart's allegations, which are peculiarly indirect. Hart, who can presumably recall his own concerns with the Business Management Tools, does not allege outright that he told his supervisor that he

thought McKesson's use of the Business Management Tools violated the law. Instead, he says that he told his supervisor that he thought McKesson's "sales practices" violated "the compliance policies that were presented in the training session." App'x 320, ¶ 164. He suggests that because McKesson's sales practices included the use of the Business Management Tools to secure purchase agreements and the training session included a presentation on the AKS, we should infer that the supervisor would have concluded that Hart meant that making the Business Management Tools available to certain Open Market Division customers was illegal. We assume for purposes of this discussion, without deciding, that such an inference in Hart's favor is reasonable.

Hart similarly alleges that he had "frequent conversations" with the creator of the Margin Analyzer, during which the two employees "discussed concerns that McKesson was inappropriately exploiting the value-added business tool . . . by giving the tool for free to open market customers." App'x 320, ¶ 166. Again, Hart does not allege that the tool's creator *shared* Hart's concerns. Even assuming that he did, however, Hart does not allege that the belief was shared by others on McKesson's sales team or that the views of the tool's creator can be imputed to McKesson as a whole.

Finally, Hart points to his allegation that one of McKesson's senior sales executives sent another McKesson executive an email that stated, "You didn't get this from me . . . ok?" and attached three documents. The attached documents total 170 pages and cover a host of topics, including valuations of over 150 services provided by McKesson.<sup>12</sup> The documents mention the Business Management Tools only five times, buried in discussions and analyses of numerous other topics that have nothing to do with Hart's case. To  
162 whatever \*162 extent that the email suggests that the sender acted surreptitiously in providing the

documents to the recipient, there is nothing to connect that sentiment to the references to the Business Management Tools, or even to suggest that the reason for secrecy involved revelations of corporate misconduct. Thus, Hart has not plausibly alleged that the sender of the email intended to convey any information about the Business Management Tools - still less, that the email's sender or recipient believed that McKesson's use of the Business Management Tools was unlawful or that McKesson as a whole shared such a view.

<sup>12</sup> The SAC does not attach the three documents, but the district court concluded that it could consider the documents in deciding the motion to dismiss because they were incorporated by reference in the complaint and the complaint relied heavily on their terms and effect. *See Hart*, 2023 WL 2663528, at \*9; *see also, e.g., Clark v. Hanley*, 89 F.4th 78, 93 (2d Cir. 2023) (courts reviewing a motion to dismiss pursuant to Rule 12(b)(6) may review, *inter alia*, documents that are incorporated in the complaint by reference or are integral to the complaint). Hart does not argue on appeal that the district court erred in considering those documents.

The district court noted that the SAC lacked allegations similar to those that other courts have found support an inference of willfulness. For example, Hart did not allege that McKesson took steps to conceal its behavior, had notice that its sales practices might be unlawful, stopped offering the Business Management Tools for no charge out of a concern that doing so might be unlawful, or believed that the Business Management Tools were shams. Although no such allegations are necessary to plead willfulness, Hart's inability to raise any similar allegations underscores that it is implausible to infer that McKesson believed that offering the Business Management Tools was unlawful.

Accordingly, none 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 AKS or any other law. As a result, the district court did not err in dismissing Hart's federal FCA claim for failure to state a claim.<sup>13</sup>

<sup>13</sup> Hart's federal FCA claim is based solely on McKesson's alleged violation of the federal AKS; he does not argue that he has a claim under the federal FCA that is premised on a violation of one or more state anti-kickback laws. Instead, the only state-law theories that he has articulated arise under various state false claims acts. Accordingly, to the extent that a *federal* FCA claim could exist based on a violation of a *state* anti-kickback statute, Hart has abandoned such a claim.

### III. The State-Law Claims

Finally, we turn to Hart's remaining claims under the laws of 27 states and the District of Columbia (the "State-Law Claims").<sup>14</sup> The district court dismissed those claims on the ground that Hart brought his claims under the state FCA analogues only "by way of a violation of the *federal* AKS." *Hart*, 2023 WL 2663528, at \*8 (emphasis in original). That conclusion was erroneous. \*163

<sup>14</sup> McKesson contends that we should not address Hart's argument that the State-Law Claims survived the motion to dismiss because he forfeited that argument by not raising it below. But McKesson's memorandum supporting its motion to dismiss below discussed only the federal AKS. Thus, in his responsive memorandum, Hart addressed McKesson's arguments about the federal claim, while also pointing out that McKesson "ha[d] not moved to dismiss any of [his] state law claims." App'x 876. McKesson contends that Hart's response on the State-Law



Claims is too cursory to preserve his argument that those claims should survive. But we conclude that Hart's failure to develop an opposition to an argument that *McKesson* did not make does not amount to a forfeiture by Hart.

To be sure, the focus of the SAC is Hart's contention that McKesson's conduct violated the federal AKS. But he alleges that "[t]he States also have enacted statutes prohibiting kickbacks in connection with State Medicaid services," App'x 265, ¶ 37, and that "McKesson's conduct violates the federal AKS *and similar State laws*," *id.* at 270, ¶ 53 (emphasis added). Indeed, Hart even listed the various state anti-kickback statutes that he contends McKesson violated.<sup>15</sup> Thus, the district court erred in dismissing Hart's State-Law Claims on the basis that they were premised solely on violations of the federal AKS.

<sup>15</sup> In general, the "[f]ederal pleading rules . . . do not countenance dismissal of a complaint for imperfect statement of the legal theory supporting the claim asserted." *Johnson v. City of Shelby*, 574 U.S. 10, 11, 135 S.Ct. 346, 190 L.Ed.2d 309 (2014). McKesson argues, however, that Hart's state *qui tam* claims are subject to Rule 9(b), Fed. R. Civ. P., and therefore he must plead with particularity "the circumstances constituting fraud." According to McKesson, that requires specifying what law McKesson allegedly violated and how it violated that law. Hart argues that the rule that McKesson argues for applies only in cases implicating the Private Securities Litigation Reform Act. We need not resolve the dispute, however, because even assuming that McKesson is correct, Hart's allegations are adequate. Hart expressly listed the state laws that he contends McKesson violated and explained at length how McKesson allegedly violated those laws - by using the Business Management Tools to induce customers to make purchase commitments with McKesson.

Importantly, Hart argues that many of the state anti-kickback laws have no scienter requirement or a lesser requirement than willfulness. Thus, even though his complaint is insufficient to state a federal FCA claim based on the federal AKS, it may be sufficient to state a state-law claim under one or more of the state anti-kickback laws cited in his complaint.<sup>16</sup> Accordingly, we vacate the district court's dismissal of the State-Law Claims and remand the case for further proceedings.<sup>17</sup>

<sup>16</sup> McKesson briefly argues that Hart fails to state a claim under two of the state anti-kickback statutes cited in the SAC. We decline to address that argument, as McKesson did not move to dismiss Hart's claims on that basis below, nor was it the reason for the district court's decision. We thus express no opinion on whether Hart's SAC adequately alleges a claim under any of the relevant FCA or AKS analogues.

<sup>17</sup> We in no way intimate that the district court should retain jurisdiction over the State-Law Claims; that matter is left to the district court's sound discretion. The point is merely that the dismissal of the state FCA claims *on the merits*, based on an incorrect understanding of the nature of those claims, was error.

## CONCLUSION

For the reasons stated above, we hold that to act willfully under the AKS, a defendant must act knowing that its conduct is unlawful under either the AKS or other law. Because Hart's allegations do not plausibly suggest that McKesson acted with such knowledge of illegality, his federal FCA claim based on the federal AKS must be dismissed. But since he also brought state-law claims under other false claims and anti-kickback statutes that may not have the same *mens rea* requirements, the district court should not have dismissed those claims on the ground that they were premised only on the federal AKS. Accordingly, we AFFIRM the district court's dismissal of Hart's federal FCA claim, VACATE

the dismissal of the State-Law Claims, and  
REMAND for further proceedings consistent with  
this opinion.

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