McKesson May Change How AKS-Based FCA Claims Are Pled

By **Li Yu, Ellen London and Erica Hitchings** (April 25, 2024)

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False Claims Act cases based on kickbacks to healthcare providers have long been a priority for the U.S. Department of Justice and the whistleblowers' bar.[1]

In its U.S. ex rel. Hart v. McKesson Corp. decision issued on March 12, the U.S. Court of Appeals for the Second Circuit discussed at length an issue likely to become a focus of further litigation in these cases — namely, what types of scienter allegations as to underlying violations of the Anti-Kickback Statute are sufficient to satisfy Rule 9(b)'s pleading requirements.

Applying Rule 9(b) to AKS-based FCA cases is challenging because the two statutes define scienter differently: Whereas the FCA defines "knowing" to include actual knowledge, deliberate indifference and reckless disregard,[2] the AKS applies to misconduct done "knowingly and willfully."[3]

In McKesson, the Second Circuit held that to "act willfully under the AKS, a defendant must act with a bad purpose."[4] Thus, according to the court's decision, the defendant needs to have "knowledge that his conduct was unlawful," even though it is not necessary for the relator to prove "that a defendant must know of the AKS specifically or intend to violate [the AKS]."[5]

Applying this standard, McKesson affirmed dismissal of the relator's amended complaint for failing to adequately plead scienter.[6]

To help FCA practitioners understand what this aspect of McKesson means for their cases, we start with a brief overview of the evolution of the case law on AKS-based FCA cases.

We then summarize McKesson's holdings and analyze the decision's implications for pleading scienter in AKS-based FCA cases.

Finally, we offer some suggestions to relators' and defense counsel for adapting their practices post-McKesson.

In a nutshell, McKesson suggests that to successfully plead scienter, the relator in an AKS-based FCA case should focus on evidence that the defendant had notice of the potential illegality of its conduct. McKesson also highlights the importance for relators to connect the evidence of concerns about the legality of the conduct at issue to the defendant's key employees.

For FCA defendants, McKesson shows that Rule 9(b) can be a potent tool in AKS-based cases and that carefully parsing the relator's scienter allegations may lead to a successful motion to dismiss.

Evolution of AKS-Based FCA Case Law

The AKS is a criminal statute that makes it a felony to knowingly and willfully offer or accept remuneration in return for inducing or rewarding patient referrals or the generation of business covered by federal programs like Medicare and Medicaid.[7]

Starting in the 1990s, violations of the AKS by hospitals and drug manufacturers became a common predicate for civil liability under the FCA in cases brought by the DOJ and qui tam relators.

These cases have generated significant litigation over issues such as:

- Whether claims associated with kickbacks are "false" for FCA purposes;[8]

- Whether there is FCA liability when the AKS violations involved parties that did not submit claims to Medicare or Medicaid;[9]

- Whether AKS violations are "material" for FCA purposes;[10]

- Whether AKS violations required the existence of "quid pro quo" arrangements;[11] and

- The scope of damages under the FCA for AKS violations.[12]

In 2010, Congress addressed most — but not all — of those issues when it amended the AKS. In that amendment, Congress explicitly imposed FCA liability on claims that result from AKS violations.[13]

Prior to McKesson, the AKS' scienter element, i.e., whether the misconduct alleged was knowing and willful, was the subject of litigation in district courts, albeit often not the main focus. In these cases, courts typically heeded the directive of Rule 9(b) — that "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally" — and found the scienter allegations sufficient as long as they offered some indicia that the defendants had notice of the impropriety of their alleged misconduct.

For example, in its 2019 decision in U.S. v. Teva Pharmaceuticals, an AKS-based FCA case involving speaker programs sponsored by drug manufacturers, the U.S. District Court for the Southern District of New York recognized that the inference of knowing and willful misconduct can arise "from evidence showing that the company violated its own compliance policies and industry standards," including by "failing to monitor [events] and imposing no discipline when sales representatives were reported for [noncompliance]."[14]

Similarly, in a 2012 decision in U.S. v. Kan Di Ki LLC, the U.S. District Court for the Central District of California found the relators' AKS scienter allegations sufficient when the relators cited "reports published by [the U.S. Department of Health and Human Services, Office of Inspector General, regarding the illegality of [similar] swapping schemes under the AKS."[15]

Further, in U.S. v. Genesis Global Healthcare, a 2021 AKS-based FCA case alleging "a kickback scheme to generate patient referrals" in return for investment, the U.S. District Court for the Southern District of Georgia was satisfied with the relator's scienter allegations citing to documents that "warned that investments in healthcare providers were suspect" and concerns by a potential investor "about the scheme's legality under the AKS."[16]

By contrast, district courts have dismissed AKS-based FCA cases on scienter grounds when the complaints lack allegations showing the defendants' awareness that their conduct was problematic. For example, in U.S. ex rel. Piacentile v. Novartis AG, the 2011 opinion of the U.S. District Court for the Eastern District of New York found that allegations a drug company offered inducements "to physicians quite openly" cut against an inference of scienter.[17]

The Central District of California, in Gharibian v. Valley Campus Pharmacy, reached the same conclusion in 2021, based on allegations that several pharmacies "advertised [the alleged kickback] openly on their website and in a [public] presentation."[18]

How McKesson Applies Rule 9(b) to Scienter Allegations Under the AKS

The central issue on appeal in McKesson was whether the relator "plausibly [alleged] that McKesson acted with the mens rea applicable under the federal AKS."[19] Noting that the term "willfully" has "long 'bedeviled' courts," the McKesson court concluded that, to act willfully under the AKS, a defendant must act with bad purpose, i.e., with "knowledge that his conduct was unlawful."[20]

The court explained that a defendant need not know of the AKS specifically — or intend to violate the AKS — they only have to know that the conduct was unlawful in some way.[21] The McKesson court emphasized that, in its view, this definition was fully in line with the Second Circuit's 2022 decision in Pfizer Inc. v. U.S. Department of Health & Human Services, which rejected that a corrupt intent is a prerequisite for a finding of liability under the AKS.

Even under Pfizer, the McKesson court noted, "a defendant's knowledge of his general legal obligations is not enough if he does not also know that his actions violate those obligations."[22]

That, however, was just the start. McKesson next tackled whether the relator in the case before it had alleged sufficient facts to create a "plausible inference of willfulness as [the court] has defined it."[23] The answer, the court said, is no.

The McKesson relator advanced three categories of evidence that, in his view, supported an inference that McKesson had acted willfully in its implementation of the alleged kickback program, which provided valuable business development tools to physicians free of charge in exchange for their purchase of drugs from McKesson. The court rejected each.

First, the relator argued that McKesson's destruction of evidence after receiving a government subpoena was, itself, evidence that McKesson knew that its conduct was

unlawful. Not so, insisted the Second Circuit, pointing out that to support an inference of willfulness, concealment typically occurs concurrently with the alleged violation.[24]

Next, the court found the relator's allegations in which he raised concerns that the program did not align with the company's compliance standards were probative only of the relator's beliefs, not McKesson's.[25]

Third, the court rejected the relator's reliance on an internal company email that was surreptitiously forwarded between employees, noting that there was nothing "to suggest that the reason for secrecy involved revelations of corporate misconduct."[26]

Having rejected all three categories, the court ultimately held that none of the relator's allegations, whether "alone or in combination with each other, plausibly" suggest that McKesson believed that its conduct was unlawful.[27]

The Second Circuit differentiated Hart's willfulness allegations from other cases, in which the relator had alleged specific and contemporaneous attempts by a defendant to conceal its behavior, specific notice to the company that the practices were unlawful, or an understanding that agreements between the doctors and the defendant were shams.

Notably, however, the court explicitly stated that "no such allegations are necessary to plead willfulness," but nevertheless used them as a barometer against which to measure the relator's allegations.[28]

Lessons for FCA Practitioners From McKesson's Scienter Analysis

To start, all practitioners in the space should continue following this line of cases to see whether other courts adopt the Second Circuit's analysis in McKesson.

For relators' counsel, McKesson is, foremost, a reminder that while Rule 9(b) allows so-called conditions of mind to be alleged generally, there still is a need to plead specific scienter evidence in AKS-based FCA cases, particularly evidence suggesting that the defendant had some amount of notice that its alleged kickback conduct may be illegal.

However, as McKesson recognizes, such evidence does not have to be a direct admission by the defendant that they knew they were violating the AKS or otherwise engaging in illegal conduct. Instead, McKesson shows that relators' counsel should emphasize any facts describing how the defendant was voicing worries about paying for sham events or services, taking steps to conceal its behavior, or stopping a practice out of a concern about its legality.[29]

Further, as McKesson acknowledges, these are not the only ways to satisfy the knowing and willful standard, and relators' counsel should not shy away from other types of scienter allegations. As discussed above, courts have found the Rule 9(b) scienter standard satisfied in other ways, including HHS-OIG guidance or other documents — or persons — warning companies away from similar behavior.[30]

McKesson also underscores the importance for relators' counsel to connect their scienter allegations to a defendant's key employees. According to the Second Circuit, for example, the McKesson relator may have fared better if he could show that his concern about legality "was shared by others on McKesson's sales team," particularly his supervisor.[31]

Relators should, however, hold their ground on the issue of which — or how many — employees need to have been told of or share in these concerns. The clear weight of authority makes clear that knowledge can be imputed to the corporation any time that a corporate employee acquires "knowledge within the scope of their employment and are in a position to do something about that knowledge."[32]

On the other hand, defense counsel will want to carefully review allegations in cases for potential motions to dismiss, with a particular focus on whether there is a lack of indicia of intent such as in McKesson.

Counsel may be able to use the lessons of McKesson to push back on arguably vague assertions of scienter even beyond the examples noted in McKesson, for example, to argue that even if there is HHS-OIG guidance, the right people at the company needed to have been aware of this guidance.

This analysis may be used as a barometer by counsel — and future courts — to continue to refine and potentially narrow the scienter standard.

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[1] See, e.g., https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-268-billion-fiscal-year-2023 (DOJ highlighting kickback-based FCA settlements in 2023).

[2] See 31 U.S.C. 3729(b)(1).

[3] See 42 U.S.C. § 1320a-7b(b).

[4] U.S. ex rel. Hart v. McKesson Corp., 96 F.4th 145, 157 (2d Cir. 2024).

[5] Id.

[6] See id. at 167.

[7] See https://oig.hhs.gov/compliance/physician-education/fraud-abuse-laws/ (HHS-OIG summarizing the AKS's history and scope).

[8] See U.S. ex rel. Hutcheson v. Blackstone Med., Inc., 647 F.3d 377 (1st Cir. 2011).

[9] See id.

[10] See U.S. ex rel. Arnstein v. Teva Pharms., 2019 WL 1245656, at *33 (S.D.N.Y. Feb. 27, 2019) ("Arnstein").

[11] See id. at *10.

[12] Compare U.S. ex rel. Greenfield v. Medco Health Solutions, Inc., 880 F.3d 89 (3d Cir. 2018) with U.S. ex rel. Martin v. Hathaway, 63 F.4th 1043 (6th Cir. 2023).

[13] See 42 U.S.C. § 1320a-7b(g); see also Guilfoile v. Shields, 913 F.3d 178, 190 (1st Cir. 2019) ("[A]n AKS violation that results in a federal health care payment is a per se false claim under the FCA.").

[14] Arnstein, 2019 WL 1245656, at * 9 (citing U.S. ex rel. Bilotta v. Novartis Pharms. Corp., 50 F. Supp. 3d 497, 519 (S.D.N.Y. 2014)).

[15] See U.S. ex rel. Pasqua v. Kan Di Ki LLC, 2012 WL 12895529, at * 5 (C.D. Cal. June 18, 2012).

[16] U.S. v. Genesis Global Healthcare, 2021 WL 4268279, at *12 (S.D. Ga. Sept. 20, 2021).

[17] U.S. ex rel. Piacentile v. Novartis AG, 2011 WL 13234720, at *9 (E.D.N.Y. Feb. 8, 2011).

[18] U.S. ex rel. Gharibian v. Valley Campus Pharmacy, 2021 WL 5406148, at *3 (C.D Cal. Oct. 12, 2021).

[19] McKesson, 96 F.4th at 153.

[20] Id. at 153-54.

[21] Id. at 155-56. Among other factors, the McKesson court relied on decisions from several Circuit courts which had explicitly rejected the Ninth Circuit's interpretation, in Hanlester Network v. Shalala, 51 F.3d 1390, 1400 (9th Cir. 1995), that a defendant act with specific knowledge that their conduct was in violation of the AKS. See id. at 156 (citing U.S. v. Starks, 157 F.3d 833, 838 (11th Cir. 1998) (concluding that "ignorance of the law is no excuse" and that "knowledge that conduct is unlawful is all that is required.").

[22] Id. at 158.

[23] Id. at 160-162

[24] Id. at 160.

[25] Id. at 161.

[26] Id. at 162.

[27] Id.

[28] Id.

[29] Id.

[30] See U.S. ex rel. Pasqua v. Kan Di Ki LLC, 2012 WL 12895529, at *5; U.S. v. Genesis Global Healthcare, 2021 WL 4266279, at *12.

[31] McKesson, 96 F.4th at 161.

[32] U.S. v. Anchor Mortgage Corp., 711 F.3d. 745, 747 (7th Cir. 2013); accord U.S. v. O'Connell, 890 F.2d. 563, 57-68 (1st Cir. 1989); Grand Union Co. v. U.S., 696 F.2d 888, 889 (11th Cir. 1983); U.S. v. Hangar One, Inc., 563 F.2d 1155, 1158 (5th Cir. 1977); U.S. v. Inc. Village of Island Park, 888 F. Supp. 419, 438 (E.D.N.Y. 1995); U.S. v. Pierre Bouchet, 1987 WL 11565 at *6 (S.D.N.Y. May 21, 1987).