

Second Circuit clarifies Anti-Kickback Statute's scienter requirement

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APRIL 3, 2024

On March 12, the U.S. Court of Appeals for the Second Circuit issued an important decision that sheds light on the test for determining scienter under the federal Anti-Kickback Statute (AKS).

- The Second Circuit held that to act “willfully” under the AKS, a defendant “must act knowing that its conduct is in some way unlawful.”
- Applying this holding, the Second Circuit affirmed the dismissal of AKS-based False Claims Act (FCA) claims because the relator failed to plead facts showing that the defendant believed its conduct was unlawful.

The Second Circuit reasoned that the AKS is not meant to apply to defendants who acted in a good-faith belief that their conduct was lawful, and its holding may make it more difficult for plaintiffs to bring FCA cases based on alleged violations of the AKS.

Background

In *U.S. ex rel. Hart v. McKesson Corp.*, the relator filed a *qui tam* complaint asserting claims under the federal False Claims Act and the false claims acts from 27 different states and the District of Columbia. The relator alleged that McKesson granted oncology practices free access to valuable business management tools only if they agreed to use McKesson as their primary wholesale drug supplier.

The case reached the Second Circuit after the U.S. District Court for the Southern District of New York granted McKesson's motion to dismiss the complaint in its entirety.

Interpretation of scienter

The Second Circuit affirmed the district court's holding that to act “willfully” under the AKS, a defendant “must act knowing that its conduct is in some way unlawful.”

In doing so, the Second Circuit found that “willfully” under the AKS “means what it typically means in federal criminal law” — that is, the defendant must act “with a ‘bad purpose;’” although it need not be specifically aware of or intend to violate the AKS. This interpretation, the Second Circuit stressed, “protects” those “who innocently and inadvertently engage in prohibited conduct.”

The Second Circuit rejected the relator's request for a broader interpretation of AKS scienter, under which a defendant would act

willfully when it provides something of value in connection with a medical purchase while having the general knowledge “that it is illegal to provide things of value in connection with such purchases.” The Second Circuit reasoned that this interpretation would encompass too much innocent conduct since it could be met even where a defendant believed it was acting lawfully.

Application to McKesson

The Second Circuit held that the relator did not plausibly allege that McKesson possessed AKS scienter.

The Second Circuit affirmed the district court's holding that to act “willfully” under the AKS, a defendant “must act knowing that its conduct is in some way unlawful.”

Specifically, it disagreed that the relator's three categories of allegations gave rise to a plausible inference of willfulness:

- (1) Allegations that McKesson destroyed documents after receiving a Civil Investigative Demand from the Department of Justice seeking documents related to the relator's *qui tam* action were insufficient because concealment generally only shows wrongful intent when the concealment is concurrent with the violation.
- (2) Allegations that the relator had “suggested to certain McKesson employees that McKesson's use of the business management tools violated the company's compliance policies or was otherwise inappropriate” did not establish willfulness because those allegations did not suggest that *others* at McKesson agreed with the relator's concerns.
- (3) An email between McKesson executives referring to the business management tools and stating, “You didn't get this from me ... ok?” was insufficient because the attached documents encompassed 170 pages covering a wide variety of topics and mentioning the business management tools only five times in other contexts.

State law claims

The Second Circuit did not affirm the entire district court decision. It vacated the district court's ruling that the relator's state-law false claims act causes of action were based solely on violations of the federal AKS. The Second Circuit pointed to the relator's argument that many state anti-kickback laws have less stringent scienter requirements than that for the federal AKS — or none at all — leaving open the possibility of McKesson's liability on state-law grounds in the future.

Observations

The Second Circuit's test for scienter under the AKS is good news for those trying to navigate decision-making in a complicated healthcare regulatory landscape. By interpreting "willfully" to require that a defendant act knowing that its conduct is in some way unlawful, the Second Circuit reinforced a standard that protects those who inadvertently engage in otherwise prohibited conduct — an important limitation given the broad reach of the AKS.

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At the same time, the Second Circuit's decision to remand the state-law claims to the district court serves as a reminder that the analysis may not end with consideration of the federal AKS.

Hart is one of several recent impactful decisions about AKS-based FCA claims. *Hart* comes on the heels of the Second Circuit's 2022 opinion in *Pfizer, Inc. v. U.S. Dep't of Health & Hum. Servs.*, where the court held,¹ as we have covered previously, that a defendant need not have a "corrupt" intent to violate the AKS.

Federal circuit courts also remain split² over the causation standard to be applied in AKS-based FCA claims. The First Circuit appears³ most likely to address this issue next.

Notes

¹ <https://bit.ly/3IY4VO4>

² <https://bit.ly/3IWMoBr>

³ *Id.*

This article was published on Westlaw Today on April 3, 2024.

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