PG Bulletin
October 14, 2024

Supreme Court Denies Cert on Anti-Kickback Statute "Willfulness" Case

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While much of the health care enforcement world has been focused on the potential for qui tam constitutionality to make its way through the appellate system, the United States Supreme Court recently made a big decision that impacts health care providers right now. On October 7, 2024, the Justices denied review of a Second Circuit decision holding that, to act "willfully" under the Anti-Kickback Statute (AKS), a defendant must have known its conduct was in some way unlawful.

The *Hart* Case

A key element of the AKS is willfulness. "Willfulness" is a word typically reserved by Congress for only certain types of crimes, and it generally means that, in order to violate the statute, one must know that he or she is doing something unlawful as opposed to acting inadvertently or by mistake. In the health care context, there can be no violation of the AKS where someone pays kickbacks but has no idea that it is wrong to do so. Willfulness also appears as the required *mens rea* in several other commonly charged federal statutes, like health care fraud and false statements, but does not appear in other statutes of interest to the health care world, like the False Claims Act (FCA) and the Stark Law. Simply put, Congress decided that some statutes require willfulness, while other statutes could be violated with lesser mindsets.

In *U.S. ex rel. Hart v. McKesson*, 96 F.4th 145 (2d Cir. 2024), the Second Circuit held that those alleging AKS violations as a premise to an FCA case must plausibly allege that defendants knew that their conduct was unlawful to establish willfulness. *Hart* was perceived as a blow to the relator's bar because the AKS is a principal statute relied upon in qui tam actions, with an impact stretching across the health care and life sciences industries. While other courts have allowed relators to allege willfulness in qui tam actions generally, the Southern District of New York dismissed Hart's qui tam case at the pleadings stage on the theory that the relator's complaint failed to allege plausible facts to support his contention that the defendants knew that what they were doing was unlawful.

After the Second Circuit affirmed dismissal, a trio of prominent whistleblower firms united forces to seek Supreme Court review, arguing two key points. First, the relator argued that the Second Circuit's decision deepens a circuit split on how to interpret "willfulness" in light of Fifth and Eighth Circuit decisions that do not require knowledge of unlawfulness. Second, the relator emphasized the centrality of the AKS to health care enforcement—both in terms of resources expended by the government and the quality of health care provided to patients—such that the Supreme Court needed to clarify the required *mens rea*.

On the other hand, the defense disagreed that there was a circuit split, arguing that the bulk of the case law from those supposedly conflicting circuits supported the Second Circuit's holding in *Hart*. The defense framed the relator's position as asking the Supreme Court to reject both sides of the purported split and, instead, adopt a position that, according to the defense, no circuit had ever held—that "willfully" does not require knowledge of illegality.

The Supreme Court ultimately denied the *cert* petition, indicating that the Court likely viewed any circuit split as minimal or non-existent, such that the need to fix any disagreement among the circuits was not critical, at least at this juncture.

What *Hart* Means for the Health Care Industry

Hart was already an important case, and the Supreme Court's denial of the *cert* petition only reinforced its significance. The relator argued that an important circuit split existed regarding the meaning of "willfulness" under the AKS, but that argument plainly failed to gain traction with the Supreme Court.

That means the *Hart* holding is valuable persuasive authority for the propositions that the Justice Department and relators must allege plausible facts to show that defendants accused of violating the AKS knew that what they were doing was unlawful, and that the same is a consistent holding among the circuits.

For those defending federal investigations into alleged AKS violations, the "willfulness" element becomes an even more critical factor. The *Hart* complaint that was dismissed attempted to find willfulness through the defendant's contracts, code of conduct, and filings with the United States Securities and Exchange Commission, and sought to argue that each of those "indicated an awareness of the requirements of the AKS and the general unlawfulness of inducements." But the trial court and Second Circuit disagreed, holding that general knowledge of the AKS does not mean that the defendant knew that specific programs violated the AKS or was otherwise unlawful. Furthermore, the trial court focused on the lack of efforts to conceal the alleged kickbacks, finding that public acknowledgment of the program at the center of the qui tam showed that the defendant lacked the mindset required to maintain an AKS complaint.

For members of the health care and life sciences industries defending allegations of AKS violations, great attention must be paid to "willfulness." Generalized knowledge of the AKS is simply not enough to maintain a complaint. Instead, the Justice Department or relator must plausibly allege that the defendant knew that the specific act constituting the kickback was unlawful. Moreover, if the defendant made public the purported kickback in some way, or did not take steps to conceal it, the *Hart* decision counsels that should weigh in favor of a lack of AKS violation. Finally, *Hart*'s requirement that plaintiffs plausibly allege knowledge of wrongdoing provides an avenue for AKS defendants to seek dismissal at the pleadings stage notwithstanding that mental states may be alleged generally under Rule 9(b).

