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New 11th Circuit Decision Kicks Off Developments Under Anti-Kickback Statute

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On November 24, 2020, the 11th Circuit issued a notable decision in *United States v. Shah*, 981 F.3d 920 (11th Cir. 2020), which clarifies whether, in order to obtain a conviction under the federal Anti-Kickback Statute (“AKS”), the government must prove a defendant’s motivation for accepting kickback payments. The Court held that the statute does not require proof of the defendant’s motivation, after this point was conceded by both parties at oral argument.

Dr. Alap Shah (“Shah”), a podiatrist from Columbus, Georgia, was convicted in the District Court of the Southern District of Florida under the Anti-Kickback Statute (“AKS”) for receiving a flat monthly payment of \$5,000 in exchange for writing prescriptions for certain compounded drugs. Generally, Shah would fax prescriptions to a company called PGRx Group, which, in turn, directed a pharmacy to fill the prescriptions. The pharmacy then paid PGRx Group a kickback for each prescription referred to it, and PGRx Group passed part of that kickback on to Shah.

A grand jury charged Shah with one count of conspiring to receive kickbacks for writing prescriptions and three counts of receiving kickbacks for writing prescriptions over a three-month period. Shah pleaded not guilty and the case went to trial.

At the government’s request, the district court instructed the jury that Shah would have violated the AKS if *one* reason he accepted the payment was because it was in return for writing prescriptions. In his written briefs on appeal, Shah argued that the district court should have instructed the jury that the government was required to prove that his *main or only* reason for accepting the payment was because it was made in return for writing prescriptions.

However, at oral argument, both parties agreed that the district court had given an erroneous jury instruction because the AKS required *no proof of the defendant’s motivation* for accepting the illegal payment, so long as he accepted the kickback knowingly and willfully. But the parties disagreed about whether the error harmed Shah.

In holding the error did *not* harm Shah, the 11th Circuit analyzed the AKS and concluded that even the erroneous jury instruction required more proof from the government than required by the AKS.

Specifically, the court pointed out that the AKS is silent regarding the defendant’s motivation for accepting the payment. The relevant portion of the statute instead provides as follows: “(1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate)... in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering 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...”^[1]

Thus, the court noted that the text of the statute itself does not require proof of a defendant’s “purposes in soliciting or receiving” a payment. The statute’s key phrase—“remuneration . . . in return for [writing prescriptions]”—says nothing

about the defendant's motivation for accepting the payment. And, Congress has separately specified the necessary mental state; namely, the defendant must accept the payment "knowingly and willfully." The 11th Circuit held that the parties were correct to concede at oral argument that the crime required *no proof* of the defendant's motivation for accepting payment.

The 11th Circuit compared the AKS to cases interpreting a federal bribery statute, 18 U.S.C. § 201(b)(2), with similar language and noted that courts interpreting the bribery statute extended liability to defendants that accepted bribes regardless of their motivation, "because the phrase 'in return for' [in the statute] brings into play the purpose of the bribe, not the defendant's motivation for accepting it."²

Thus, the 11th Circuit held that the district court erred by instructing the jury that the government had to prove that Shah accepted the payments at least in part because they were made in return for the prescriptions he wrote. But, the 11th Circuit held the government met its burden of proving beyond a reasonable doubt that the error did not harm Shah because the erroneous instruction actually required the government to prove more than the statute required, so, if anything, the error worked to Shah's advantage.

This decision comes at a time of uncertainty with regard to AKS enforcement. On January 20, 2021, the new Biden administration issued a memorandum, freezing the implementation of a new rule promulgated by the Trump administration in November 2020, which aimed to amend several safe-harbor provisions under the AKS (for additional analysis, please see our prior alert [here](#)). This new rule was set to go into effect on January 29, 2021, but the Biden memorandum delayed its implementation until March 22, 2021. Following this review, the Biden administration may choose to revise or completely reverse the new rule. The recent confirmation of Biden's Health and Human Services Secretary, Xavier Becerra, adds further unpredictability to this area of the law and what we can expect from the government going forward.

Saul Ewing Arnstein & Lehr LLP is monitoring developments in AKS enforcement closely, particularly under the new Biden administration, and is available to assist with any questions related to this statute.

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1. 42 U.S.C. § 1320a-7b(b).
 2. *United States v. Shah*, 981 F.3d at 925 (citing *United States v. Myers*, 692 F.2d 823, 840-42 (2d Cir. 1982) (alteration adopted); accord *United States v. Peleti*, 576 F.3d 377, 382-83 (7th Cir. 2009)).

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