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Anti-Kickback Statute: A Powerful Tool in DOJ's Corporate Arsenal Grows Stronger

By Robert J. Anello and Richard F. Albert
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In recent years, the Department of Justice has wielded the Anti-Kickback Statute (AKS) to exact steep penalties from corporate actors and individuals alike for the improper exchange of something of value to generate healthcare business funded by a federal program.

When coupled with the False Claims Act (FCA), the AKS turns into a potent civil enforcement tool that carries many of the same draconian penalties as criminal enforcement, achieved via a less demanding path.

A recent decision by the Second Circuit joins other circuits in expanding liability for defendants by interpreting the AKS to require that only one purpose, rather than the sole or primary purpose, of a payment is to induce the purchase of a federally reimbursable healthcare product. *United States ex rel. Camburn v. Novartis Pharms. Corp.*, 124 F.4th 129, 136 (2d Cir. 2024).

Trained on a favorite DOJ target – pharmaceutical company-funded programs that compensate doctors to speak at drug seminars and other physician wining and dining -- the "at-least-one purpose" rule can permit juries to find AKS violations where such events serve legitimate objectives.

In addition to adopting the "one purpose" rule, in *Camburn* the Second Circuit clarified that a plaintiff "need not state a *quid pro quo* exchange," obviating any requirement to show that the improper payment was the but-for cause of the purchase of a healthcare product. *Id.* at *137. *Camburn* underscores the minefield of risk that physician speaker programs pose to health care companies, and the need for the utmost attention to the design and execution of such programs.

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Although the Second Circuit limited its holding to civil actions, because the same operative language of the AKS applies in both civil and criminal contexts, and the court relied on criminal decisions in other circuits in reaching its holding, *Camburn* also promises expansive liability for criminal defendants as well.

The Anti-Kickback Statute

The AKS, 42 U.S.C. §1320a-7b, prohibits individuals from "knowingly and willfully offer[ing] or pay[ing] any remuneration . . . to induce" an individual to purchase a federally reimbursable healthcare product. Enacted in 1972, the AKS is a criminal statute that is intended to protect the integrity of government healthcare programs by penalizing

those who solicit, offer, or pay kickbacks or bribes that could influence medical decision-making.

Violations of the AKS can bring up to ten years imprisonment and $100,000 in fines. An AKS violation also can trigger liability under the Civil Monetary Penalties Law, *id.* §1320a-7a, which authorizes the Office of Inspector General for the Department of Health & Human Services (OIG) to seek penalties of up to $50,000 per kickback, and three times the amount of the remuneration. Violators may face debarment, that is, complete exclusion from federal health care programs and reimbursement. *See id.* §1320a-7a(a)(10).

Business owners, physicians, pharmacists, and drug manufacturers have faced criminal convictions and hefty civil settlements for illegal kickback schemes. *See, e.g.*, U.S. Attorney's Office, District of New Jersey, "Former Pharmacy President Sentenced to Three Years in Prison for $32 Million Health Care Kickback Scheme," (Jan. 18, 2024), https://www.justice.gov/usao-nj/pr/former-pharmacy-president-sentenced-three-years-prison-32-million-health-care-kickback.

The sweep of the AKS is broad – so much so that a significant portion of the statute lists a series of bona fide business relationships and transaction types that are excluded from the reach of the statute's prohibition. Further, the Department of Health and Human Services has promulgated a series of "safe harbor" regulations establishing detailed criteria that various categories of ostensibly legitimate business relationships and payment practices must meet in order to be excluded from criminal or civil liability under the AKS. *See* 42 C.F.R. §1001.952.

One area of conduct that has come under particular scrutiny under the AKS is pharmaceutical or medical device manufacturer-funded programs that compensate physicians to speak about a drug, device, or disease. Industry sources assert that having leading physicians speak at such programs plays a critical role in helping inform and educate other health care professionals regarding the benefits and risks of their treatments.

According to a 2020 OIG-issued "Special Fraud Alert" regarding speaker programs, over the prior three years, drug and device companies reported paying nearly $2 billion to health care professionals for speaker-related services.

The 2020 OIG Special Alert lists a series of characteristics that may make a speaker program worthy of particular scrutiny under the AKS, such as conditioning speaker selection on sales targets, repeatedly holding programs when no new substantive information to report exists, holding speaking events at entertainment venues or high-end restaurants while serving alcohol, and including as audience members repeat participants, family members, or others without legitimate business reason to attend.

Courts' broad interpretation of the AKS, however, suggests that even companies and physicians that participate in paid peer-to-peer education programs designed to avoid these pitfalls can take little comfort that they will not be accused of running afoul of the statute.

Every federal appellate court to consider the issue has found that the language and intent of the AKS requires only that one purpose of the payment be improper to violate the statute. This means that even if a bona fide reason for compensation existed, a defendant could still violate the AKS if one purpose was to also induce prescriptions.

Courts have grappled with the bounds of this expansive theory of liability, with some cabining the test to require a showing of willful intent to violate the law, or "bad purpose," and others distinguishing between "a collateral hope or expectation" of referrals versus referrals being a "motivating factor" behind the relationship. *See United States v. McClatchey*, 217 F.3d 823, 835 n.7 (10th Cir. 2000); *United States v. Holland*, 396 F. Supp. 3d 1210, 1239 (N.D. Ga. 2019). Not all courts have imposed such limitations, however, meaning that in many jurisdictions the AKS's broad reach poses a real risk of criminalizing commonplace business behavior.

AKS-Based Claims under the False Claims Act

In 2010, Congress amended the AKS to create an express link to the False Claims Act. The FCA proscribes individuals from "knowingly . . . caus[ing] to be presented[] a false or fraudulent claim for payment or approval" or "knowingly . .

. caus[ing] to be made or used[] a false record or statement material to a false or fraudulent claim." 31 U.S.C. §3729(a)(1)(A)-(B).

The amendment provides that a claim "resulting from a violation of [the AKS] constitutes a false or fraudulent claim" for the purposes of the FCA. 42 U.S.C. §1320a-7b(g), *as amended by* the Patient Protection and Affordable Care Act, Pub. L. No. 1110148, 124 Stat. 119 (2010). The government is thus expressly authorized to use the FCA to undertake civil enforcement and recover alleged losses from AKS violations.

The FCA also permits private citizen whistleblowers, known as "relators," to file claims against an individual or entity for defrauding the federal government. Relators initially act on behalf of the government and file a *qui tam* suit, which is sealed while the government investigates the relator's claims to decide whether to intervene in the suit.

Even if the government decides not to intervene, the relator can continue to pursue the action but the government remains the real party in interest. The relator receives a percentage of the ill-gotten gains resulting from the fraud, plus civil fines of up to $20,000 per false claim. FCA lawsuits, including those predicated upon AKS violations, have been lucrative for the government and relators, with settlements and judgments exceeding $2.9 billion in Fiscal Year 2024 and totaling over $78 billion since Congress strengthened the FCA in 1986.

Camburn

On Dec. 27, 2024, the Second Circuit Court of Appeals held in a matter of first impression that in relator-initiated actions "a defendant violates the AKS when at least one (rather than the primary or sole) purpose of the remuneration she provides is to induce purchase of a federally reimbursable healthcare product." *Camburn*, 124 F.4th at 136.

In *Camburn*, the relator, sales employee Steven M. Camburn, alleged that Novartis Pharmaceuticals Corporation illicitly remunerated physicians to prescribe its multiple sclerosis drug, Gilenya, causing physicians and pharmacies to submit false claims for healthcare reimbursement. The government declined to intervene, and Novartis moved to dismiss the action.

Southern District Judge Kimba M. Wood dismissed the complaint with prejudice in September 2022, finding that despite allegations that Novartis put on "sham" speaker and patient programs, supplied promotional materials to physicians, outfitted medical offices, coached physicians to overbill, and wined and dined physicians, Camburn did not adequately plead the existence of a kickback scheme because the allegations did not establish fraudulent inducement. *United States ex rel. Steven M. Camburn v. Novartis Pharms. Corp.*, 2022 WL 4217749, at *10-11 (S.D.N.Y. Sept. 13, 2022).

On appeal, the parties disputed whether the district judge applied the "at-least-one purpose" test or the primary purpose test to the relator's claims. A Second Circuit panel concluded in a 3-0 decision that the district court had erred in finding that no part of the complaint stated a cognizable violation of the AKS and clarified the proper standard.

The panel reasoned that in relator-initiated civil actions, plaintiffs must allege only that at least one purpose of the remuneration was to induce prescriptions. Further, no cause-and-effect relationship (a quid pro quo exchange) between the remuneration and physicians' prescribing conduct is required. The panel relied on decisions adopting the same standard of liability in seven other circuit courts – the First, Third, Fourth, Fifth, Seventh, Ninth, and Tenth – as well as the approval of the standard in an unpublished decision in the circuit and by lower courts in the circuit. *See Camburn*, 124 F.4th at 136 n.2.

Applying the "at-least-one purpose" rule, the panel found that Camburn's allegations involving "(1) speaker events with few or no legitimate attendees;" "(2) excessive compensation of speakers for canceled events;" and "(3) the selection of speakers to reward and influence high prescribers" taken together "give rise to a strong inference that one purpose of Novartis's conduct was to illicitly compensate physicians" to prescribe Gilenya. *Camburn*, 124 F.4th at 139.

The court remanded the case to the district court to evaluate whether Camburn had stated the other elements of an FCA claim now that the AKS predicate had been established.

Camburn's Criminal Effect

Although the Second Circuit expressly limited its interpretation of the AKS in *Camburn* to relator-initiated actions, no principled reason confines the court's decision to civil FCA cases pursued by relators, rather than the government, or suggests it would not reach criminal cases. In fact, five of the seven circuit court decisions *Camburn* cites as support for its interpretation arise from challenges to jury instructions in criminal cases, rather than civil *qui tam* actions like *Camburn*.

AKS-based FCA claims still require a court to find that the elements of an AKS violation have been established. No part of the AKS is exclusively reserved for criminal versus civil cases, and the operative statutory language is the same in both contexts. Following *Camburn*, every reason exists to believe that courts in the Second Circuit will apply the "at-least-one purpose" rule in AKS criminal cases as well.

Prior to *Camburn*, an unpublished Second Circuit decision interpreted the AKS similarly in the criminal context. In *United States v. Krikheli*, 461 Fed. Appx. 7, 11 (2d Cir. 2012), the Second Circuit upheld, without precedential effect, a jury instruction stating that the prosecution had to prove that *one* purpose of the remuneration was to induce patient referrals.

Unlike in *Camburn*, however, the court in *Krikheli* found that an accurate interpretation of the AKS requires the government to prove that the remuneration was offered or paid to induce referrals in a *quid pro quo* transaction. The *Krikheli* court explained that such proof would prevent a situation where defendants were convicted "simply for paying middlemen" to recommend services to physicians who could make independent referral decisions. *Id.*

Camburn clarified that, at least in civil FCA actions, the government will not be required to demonstrate some heightened standard of proof of a *quid pro quo* transaction, an element of the AKS that recently has been weakened in another jurisdiction as well. *See Pharm. Coal. for Patient Access v. United States, et al*, No. 24-1230, Dkt. 30 (4th Cir. Jan. 23, 2025) (finding *quid pro quo* existed where forbidden payment was not directly correlated to defendant's conduct).

Conclusion

Although *Camburn*'s rule can be expected to apply irrespective of whether the DOJ undertakes criminal or civil enforcement, civil enforcement provides the government the same or bigger bang for its buck when pursuing corporate actors, which of course cannot face incarceration. Civil FCA suits enable the government to impose substantial financial penalties and, through the threat of the debarment "death penalty," obtain a company's agreement to a variety of other expansive remedial actions.

Civil enforcement also has the added benefits of a lower standard of proof and greater flexibility in resolution. With little distinction in enforcement outcomes and an easier procedural path, in the corporate context the government is likely to continue to focus on civil FCA actions.

Camburn's confirmation of a lower liability standard will continue to make civil enforcement against corporations attractive to the government, even as it underscores the expansive risk of criminal liability under the AKS to any who participate in educational and entertainment activities that, in other fields, are commonplace and seen as serving a worthy purpose.

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