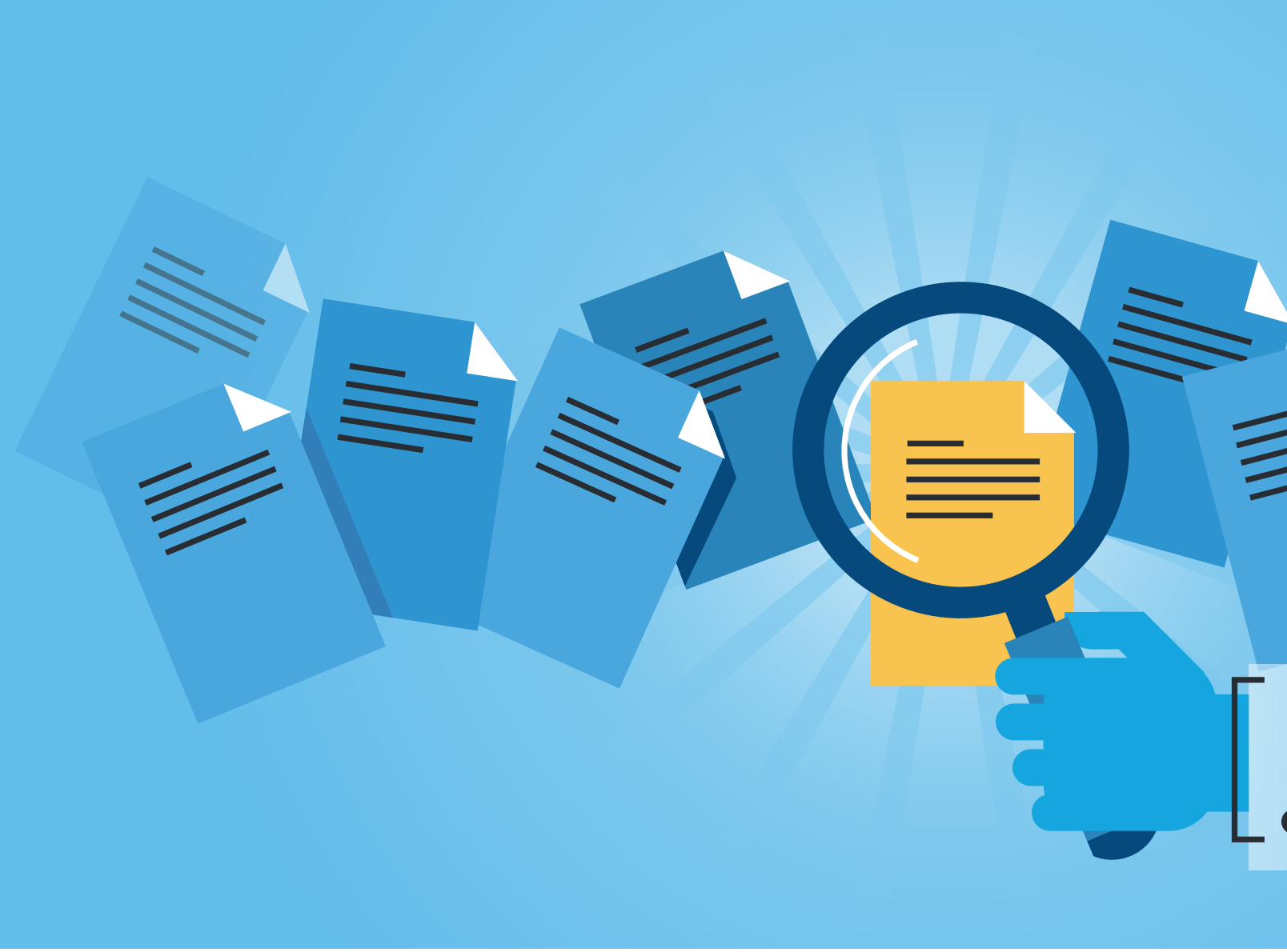
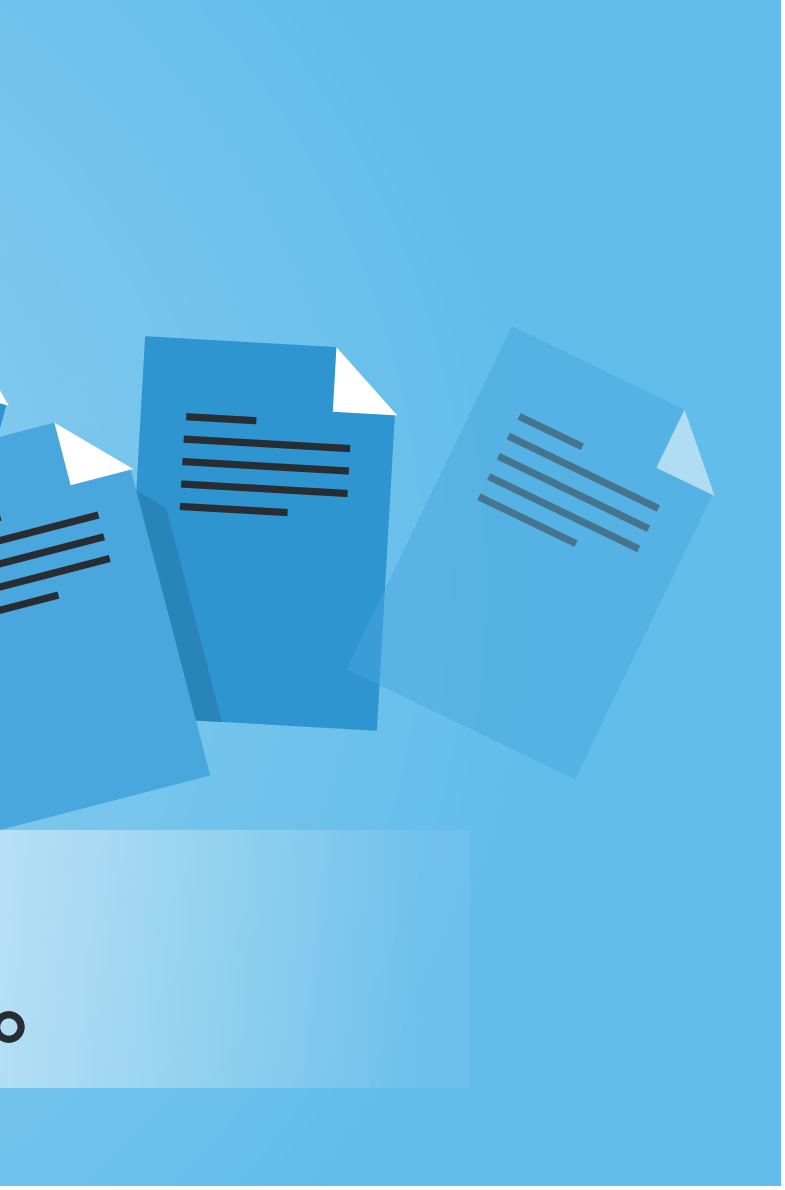


A Practitioner's Primer on the History and Use of the Federal Anti-Kickback Statute

By Marc S. Raspanti and Douglas E. Roberts, Pietragallo Gordon Alfano Bosick & Raspanti LLP

When Congress discovered that Great Depression-era employers were scheming to circumvent wage provisions in federal contracts, it enacted the first anti-kickback law, the Copeland Act, in 1931. The statute, which is still good law, prohibits federal building contractors and subcontractors from inducing their workers to "kick back" or return any part of the compensation to which they are entitled under their employment agreements.

Over the last 45 years, however, federal kickback enforcement has changed dramatically. Beginning in the 1970s, it became focused on the health care industry—and the billions of dollars flowing from massive government programs like Medicare and Medicaid. This article traces the development of the federal Anti-Kickback Statute (AKS), one of the government's most potent weapons to fight fraud, waste, and abuse in the health care industry. It then reviews some of the major anti-kickback cases that have unfolded over the past few years to highlight the particular relationships and schemes on which the government and private attorney generals known as qui tam relators are focusing their enforcement efforts.



Enactment and Expansion of the Federal Anti-Kickback Statute

Created in 1965, the Medicare and Medicaid programs afforded access to health care insurance for millions of Americans. The programs' deep pockets and flawed mechanisms for reimbursement quickly gave rise to fraud, waste, and abuse. More patients meant more claims which meant more revenue for health care providers. In an effort to ensure that only necessary items and services were being provided to Medicare and Medicaid beneficiaries, Congress passed the AKS in 1972, as an amendment to the Social Security Act. As originally written, the statue made it a misdemeanor to:

> "furnish[] items or services to an individual for which payment is or may be made [through Medicare or Medicaid]" where the provider "solicits, offers, or receives any (1) kickback or bribe in connection with furnishing of such items or services or making receipt of such payment, or (2) rebate of any fee or charge for referring any such individual to another person for furnishing of such items or services."

Despite the breadth of the AKS, its punitive power was limited, dulling its effect as a viable enforcement tool. Congress fixed that in 1977, when it amended the statute to make AKS violations felonies punishable by up to five years' imprisonment. At the same time, it broadened the statutory language to prohibit "any remuneration" provided to induce referrals.

Now capable of yielding felony sentences and seemingly broadened to punish a wider range of conduct, the AKS was a potent weapon to combat fraud. Questions remained, however, as to the precise definition of "any remuneration" and, thus, a "kickback." The government gave the courts ample opportunity to address those questions over the next few years, as it ratcheted up its AKS prosecutions.

The *Greber* "One Purpose" Test

Dr. Alvin Greber was a Pennsylvania-based osteopath who specialized in cardiology. He also was the president of Cardio-Med, a company that provided other physicians with Holter monitors, portable devices that record the rhythm of the heart by electrodes attached to patients' chests, and diagnostic services related to the monitors. Cardio-Med would bill Medicare for the services provided to the program's beneficiaries and then forward a portion of the payments to the referring physicians.

In 1983, the government charged Greber in the U.S. District Court for the Eastern District of Pennsylvania with Medicare fraud. The fraud allegations were based on the theory that Greber paid physicians bogus fees to "interpret" the monitor readings to induce referrals to Cardio-Med in violation of the AKS. He was convicted by jury in 1984 and sentenced to six months' imprisonment.

Greber appealed his conviction to the Third Circuit, arguing, in part, that there was insufficient evidence to sustain the Medicare fraud convictions because he had not provided "kickbacks," but rather had paid the physicians for providing legitimate medical services.[1] Noting that Congress in 1977 expanded the AKS to cover "any remuneration," the court interpreted the AKS to apply "if one purpose of the payment was to induce future referrals."[2] Because the evidence was sufficient for the jury to conclude that "one purpose" of Greber's remuneration to physicians was to induce referrals, and thus that he had violated the AKS (thereby committing Medicare fraud), the court affirmed the conviction.

In articulating the "one purpose" test, the Third Circuit followed a line of cases that interpreted "kickback" to have an expansive meaning. In *United States v. Hancock*,[3] the Seventh Circuit defined "kickback" broadly to include payments from laboratories to chiropractors, even if those payments were made in part to cover the cost of packaging patients' tissue samples and sending them to the labs. The Sixth Circuit adopted a similarly broad definition in *United States v. Tapert*.[4]

A number of other courts rejected *Hanlester's* expansive reading of "knowing and willfully," holding that the AKS did not require the government to prove a willful violation of a known legal duty, but rather only that the defendant's conduct was voluntary.

However, because *Greber* provided the clearest expression of what constitutes a kickback under the AKS, it became the seminal case to define the scope of the statute, and it remains so today.

Intersection of the AKS and the False Claims Act

The "any remuneration" amendment to the AKS and the development of the "one purpose" test benefited not only federal prosecutors, but also private relators suing on behalf of the United States under the federal False Claims Act (FCA). The FCA holds liable any entity or individual that "knowingly presents, or causes to be presented [to the federal government], a false or fraudulent claim for payment or approval," or conspires with another to engage in such conduct.[5] While the AKS does not contain a private right of action, courts have long recognized that "false or fraudulent claim[s]" include all of those claims tainted by kickbacks. Claims are "false" if they are not eligible to be paid, and all claims tainted by kickbacks and improper referrals satisfy that condition.[6]

An interesting interpretive issue that arose in the civil arena was the *mens rea* necessary to commit AKS violations. In 1980, Congress amended the AKS to require that one "knowingly and willfully" solicit, receive, or offer remuneration for a conviction to lie. Casting aside the old adage that ignorance of the law is no excuse, the Ninth Circuit, in *Hanlester Network v. Shalala*, held that, under the amended AKS, an individual must "know that [it] prohibits offering or paying remuneration" to violate the statute.[7]

A number of other courts rejected *Hanlester's* expansive reading of "knowing and willfully," holding that the AKS did not require the government to prove a willful violation of a known legal duty, but rather only that the defendant's conduct was voluntary.[8] In *United States v. Starks*,[9] the Eleventh Circuit distinguished the AKS from the sort of highly technical law that "poses a danger of ensnaring persons engaged in apparently innocent conduct."[10] While it may be appropriate to require that the latter type of statute or regulation be violated with the knowledge that it prohibits the conduct at issue, such was not the case with the AKS, which addresses typical, pedestrian instances of fraud. The cases that followed *Starks* tended to apply the distinction it made, and *Hanlester* died on the vine.

In 2010, Congress amended the AKS, through the Patient Protection and Affordable Care Act (ACA), to make clear that "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the False Claims Act]."[11] The amendment stands as a clear rebuke of *Hanlester*. As expressed by Senator Ted Kaufman, the rule laid down by the Ninth Circuit may be appropriate for "criminal violations of hyper-technical regulations, but it is inappropriate for these crimes, which punish simple fraud . . . . [This bill] clarifies that 'willful conduct' in this context does not require proof that the defendant had actual knowledge of the law in question or specific intent to violate that law."[12]

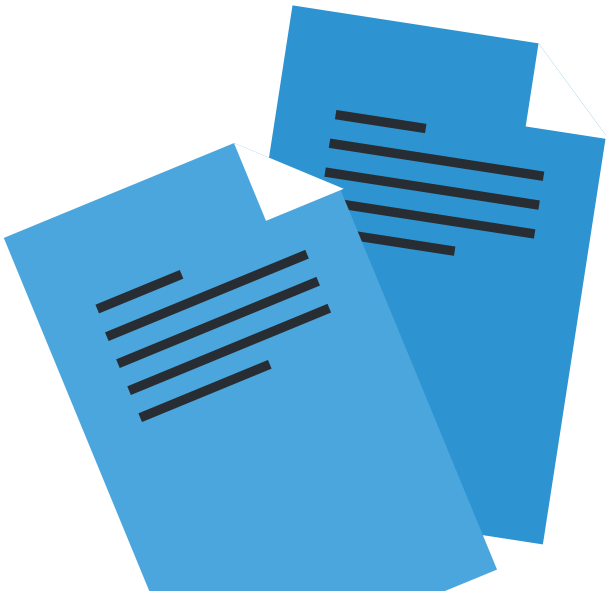
Contemporary Applications of the Federal Anti-Kickback Statute

The years since the 2010 amendment have witnessed an escalation in AKS criminal prosecutions and FCA lawsuits girded on a theory of unlawful kickbacks. High-profile cases implicating the laboratory, pharmaceutical, and hospital industries have set records for individuals prosecuted, length of prison sentences, and financial recoveries. This section highlights some of the most significant cases and interesting kickback theories pursued across various health care industries.

Laboratory Fraud

Recent years have seen a resurgence of government prosecutions and enforcement actions concerning laboratory fraud. At the root of many of those cases are financial benefits provided by labs to health care providers who refer patients to the labs, often for expensive, and sometimes medically unnecessary, testing covered by federal and state health care programs.[13]

In the $100 million Biodiagnostics lab scam, 26 physicians pleaded guilty to accepting kickbacks from the laboratory in the form of sham consulting fees, above-market payments for blood-processing services, and phony leases, pursuant to which Biodiagnostics placed its phlebotomists in physicians' offices and paid for far more space than the blood draw operations occupied.[14] Paul Fishman, the U.S. Attorney for the District of New Jersey, called it "the largest number of medical professionals ever prosecuted in the same case."[15] Many of those medical professionals were sentenced to prison time that can be



measured in years, and not just months. The New Jersey physician who received the most remuneration—an admitted $1.8 million—was slapped with a sentence of more than five years' imprisonment.[16]

In April 2015, Health Diagnostic Laboratories (HDL) and Singulex entered into ability-to-pay settlements with the United States and various state governments (for $47 million and $1.5 million respectively) to resolve allegations that, from 2009 to 2012, they violated federal and state FCAs and anti-kickback laws.[17] Three separate qui tam actions consolidated in the U.S. District Court for the District of South Carolina alleged HDL, Singulex, and Berkeley HeartLab induced physicians to drive patients to their labs for medically unnecessary and expensive blood testing by offering the physicians unearned and illegal "processing and handling fees" ostensibly related to the drawing and packaging of the patients' blood.[18]

Prior to the case, Richmond, VA-based HDL had grown rapidly. From early 2010 through 2011, its business increased at the rate of 5% a month, according to then-Chief Executive Officer Latonya Mallory.[19] After the settlement, HDL filed for Chapter 11 bankruptcy and the bulk of its assets were purchased at auction by True Health Diagnostics in October 2015.[20] The FCA action persists against Mallory; HDL and Singulex's marketing agent, BlueWave HealthCare Consultants; and BlueWave's principles, Floyd Calhoun Dent and Robert Bradford Johnson, III.[21]

In June 2016, OPKO Health, a.k.a. OurLab, and its president, James Oppenheimer, agreed to pay $9.35 million to resolve allegations that, from 2007 to 2015, they contributed to customer-physicians' costs associated with their electronic health record (EHR) systems in exchange for patient referrals.[22]

Among the key issues in the OPKO matter was the applicability of a safe harbor provision. From 2006 to 2013, the AKS contained a safe harbor that permitted a vendor to pay part of the purchase price of an EHR system on a health care provider's behalf. But the vendor could not consider the volume of patient referrals in determining whether and how much to contribute to a given provider. According to the relator, OPKO and Oppenheimer based its contributions on patient referrals, thus forfeiting the protection of the safe harbor. Per the terms of the settlement, OPKO and Oppenheimer are excluded from participating in federal health care programs for five years.

Pharmaceutical Industry

Kickback concerns arise when pharmaceutical companies provide anything of value to prescribers or pharmacies in an effort to increase their market share. With pharmacies, the "anything" at issue is typically a rebate. With prescribing health care providers, it can take various forms—from a lavish meal to a trip to a lucrative role with the company as an advisor, a speaker, or an author. In recent years, the government and relators have scrutinized drug companies' relationships with both pharmacies and physicians alike.

In 2013, the U.S. District Court for the Eastern District of Pennsylvania unsealed a non-intervened FCA case in which the relators alleged that Allergan, Inc. violated the AKS by

The years since the 2010 amendment have witnessed an escalation in AKS criminal prosecutions and FCA lawsuits girded on a theory of unlawful kickbacks.

providing ophthalmologists with inducements, in exchange for prescribing Allergan eye care drugs.[23] The complaint alleged a litany of the usual types of remuneration, such as speaker and consultant fees for high-prescribing doctors.[24] But, quite uniquely, it also asserted that Allergan provided well-heeled business consultants to help its physician clients maximize their revenues. The case came in the wake of Allergan's September 2010 entry of a guilty plea and payment of a $600 million settlement to resolve allegations that it had engaged in the off-label marketing of Botox.[25]

2013 also saw two FCA settlements involving large pharmaceutical companies that allegedly paid rebates to induce pharmacies to steer Medicare and Medicaid patients towards their drugs and away from their competitors. Amgen, Inc. paid $24.9 million to release kickback claims related to the promotion of its bone marrow stimulant, Aranesp.[26] Likewise, as part of a gargantuan $2.2 billion settlement with the federal government, Johnson & Johnson agreed to pay $149 million to dispose of allegations that it had offered rebates to induce Omnicare nursing home pharmacies to switch its patients from competitor drugs to the anti-psychotic, Risperdal.[27]

Three years later, Omnicare signed its own FCA settlement agreement, which required it to fork over more than $28 million to resolve claims that it had accepted kickbacks from Abbott Laboratories in exchange for prescribing Depakote to elderly patients.[28] Omnicare's settlement was the cherry on the top of the government's civil and criminal prosecution of Abbott for (1) marketing Depakote off-label; (2) paying illegal remuneration to health care providers and pharmacies to induce them to prescribe or promote the drug; and (3) improperly influencing the content of company-sponsored Continuing Medical Education programs.[29] That prosecution ended with Abbott agreeing to pay a $1.5 billion settlement.

In November 2015, Novartis Pharmaceutical Corporation agreed to pay $390 million to settle an FCA suit alleging that it provided specialty pharmacies with rebates as inducements to increase the pharmacies' prescriptions of Novartis drugs.[30] Four months after the parties reached the settlement, the government moved to compel the discovery of additional records from Novartis regarding 80,000 events, which were supposed to educate physicians about Novartis products, but, according to the government, served as free wine-and-dines for health care professionals at high-end restaurants and sports bars.[31] The motion is still pending before the court.[32]

Hospitals

Hospitals most commonly violate the AKS when they provide remuneration—either through cash payments or the disburse-

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ment of other benefits—to physicians or other entities for patient referrals. As government health care programs often pay for the services provided to those patients, the U.S. Department of Justice (DOJ) has become aggressive in its pursuit of both the payers and the recipients of the kickbacks.

In *United States v. Atlanta Medical Center, Inc.*,[33] two Georgia hospitals that are part of the Tenet Healthcare system—Atlanta Medical Center and North Fulton Medical Center—pleaded guilty to criminal violations of the AKS. According to the government, over the course of a decade, hospital executives paid more than $12 million to induce Hispanic Medical Management, Inc. to send pregnant immigrants (many of whom were undocumented) to the Tenet hospitals. Hispanic Medical Management did business in Georgia and South Carolina under the name Clinica de la Mama. Under the terms of the plea agreement, the hospitals will forfeit $145 million, the amount that they netted from Medicare and Georgia Medicaid "for services provided to patients referred as part of the scheme," according to DOJ.[34]

On the civil side, Tenet agreed to pay $368 million—$244 million to the United States and the remainder to the state of Georgia—to settle FCA allegations based on the same kickback scheme.[35] All told, the federal government and Georgia are set to recover more than half a billion dollars from the Tenet entities.

Finally, a patient-referral kickback scheme led to the conviction and imprisonment of ten individuals, including five physicians, in Illinois.[36] The center of the scheme was Chicago's now-shuttered Sacred Heart Hospital. According to the government, from 2000 to 2013, the hospital's Chief Executive Officer, Edward Novak, and his colleagues paid physicians to refer their elderly patients for hospital services that would be compensated by Medicare and Medicaid.[37] The kickbacks were disguised as sham lease payments, teaching contracts, and staffing perks, such as free labor from physicians' assistants and nurse practitioners. On July 29, 2015, Novak was sentenced to 54 months' imprisonment and ordered to forfeit $10.4 million. Other executives received shorter sentences of incarceration, which range between a year and a day and 21 months.[38]

Somewhat unusual—though becoming more common—among kickback cases is the fact that the government targeted the kickback recipients, i.e., physicians, in the Sacred Heart case. Among the five doctors convicted of criminal charges and sentenced are podiatrist, Shanin Moshiri, and the professed "King of Nursing Homes," Venkateswara Kuchipudi. Moshiri was sentenced to three months' imprisonment and three months' work release in January 2016 after being found guilty at a bench trial for receiving $200,000 in kickbacks.[39] Kuchipudi, who was convicted by jury, was sentenced to 24 months' imprisonment and ordered to pay $786,000 in fines and forfeiture in March 2016.[40]

Comments from Moshiri and Kuchipudi's counsel harken back to the Ninth Circuit's no-longer-viable decision in *Hanlester*. After the jury found Kuchipudi guilty, his attorney expressed "disappoint[ment] in the verdict because Kuchipudi did not willfully violate the anti-kickback statute."[41] Then, after sentencing, Moshiri's lawyer mused, "Had he appreciated what he was involved in, he wouldn't have gotten involved. He just took the money. He didn't think, 'I wonder if this is a kickback.' I truly believe it never crossed his mind until further down the road."[42]

A defendant's awareness of a criminal statute may be relevant to the sentence he receives under 18 U.S.C. § 3553(a), and perhaps Moshiri's ignorance of whether the payments he obtained were unlawful kickbacks truncated his term of imprisonment. But, as Congress made clear in 2010, actual knowledge of the AKS, and thus willful violation of the statute, is not an element necessary to sustain conviction. Only the conduct—the offer, the payment, or the receipt—of the kickback need be intentional.

A Continuing Enforcement Trend?

Since the AKS was enacted in 1972, amendments and seminal court cases have sharpened the statute into one of the government's most potent weapons in fighting health care fraud. And, given the reigning interpretation that each and every claim that is (1) submitted for payment to a government health care program and (2) tainted by a kickback is false or fraudulent, ample incentive exists to pursue the payers and recipients of kickbacks. These signs point to the continued proliferation of AKS cases through both criminal prosecutions and FCA lawsuits.

Moreover, in light of the so-called Yates Memo, individuals likely are more vulnerable to both criminal and civil prosecution for AKS violations than ever before. Former Deputy Attorney General Sally Quinlan Yates authored the September 2015 memorandum, in which the DOJ announced its intention to ensure that culpable individuals are held responsible for corporate wrongdoing.[43] As it takes at least two willing participants—the giver and the recipient—to effectuate a kickback, the Yates Memo suggests that company executives and physicians face a greater risk of enforcement under the AKS than ever before.

Of course, DOJ is almost certain to pursue a different set of priorities under a new and vastly different administration. Time will tell whether and how the changes to come in the Department's agenda and personnel will affect the investigation and prosecution of kickback cases. C

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