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50 Years In, Industry Has Knives Out For Potent Kickback Law

By **Jeff Overley**

Law360 (March 18, 2023, 12:01 AM EDT) -- After 50 years of existence, the nation's signature statute criminalizing health care corruption faces a moment of truth amid industry-led legal challenges and new circuit splits — an inflection point with clear echoes of the landmark law's turbulent evolution into a formidable fraud fighter, attorneys told Law360.

On the federal books since late 1972, the Anti-Kickback Statute is all grown up and constantly called upon by the U.S. Department of Justice and whistleblowers in big-bucks brawls with hospital chains and drugmakers. Originally deployed on its own against individual health care crooks, the AKS nowadays is paired with the False Claims Act against the wealthiest corporations and the most elaborate billing schemes.

"It remains today a cornerstone of the government's efforts to keep federal health care program payment practices free from improper decision-making," Daniel R. Levinson, who led the Office of Inspector General at the U.S. Department of Health and Human Services from 2004 to 2019, told Law360. "The law has aged well."

1972

President Richard Nixon signs the Anti-Kickback Statute, which occupies two pages in a 165-page Social Security bill.

But the law's transformation into a heavyweight weapon has not been smooth. It has instead resembled a back-and-forth bout, with the AKS at times gaining the upper hand in new realms of litigation, only to suffer bruising courtroom counterpunches and head back to its congressional corner for revision and revitalization. The pugilism persists to this day, as the DOJ and the plaintiffs bar rack up wins but simultaneously grapple with rulings and lawsuits that threaten to knock the AKS back on its heels.

"DOJ has recovered billions of dollars pursuant to AKS violations," Tycko & Zavareei LLP partner Renée Brooker, who oversaw nationwide FCA litigation during two decades at the DOJ, told Law360. "The industry's recent efforts to challenge AKS enforcement actions prove just how effective they have been in compelling corporate change towards more compliant practices."

Those recent efforts have played out on multiple fronts, and it's possible to view their legal arguments as the disingenuous handiwork of BigLaw attorneys for disgruntled corporations. But it's also possible to see the arguments as long-overdue pushback on DOJ overreach that — in the pharmaceutical lobby's

recent words — has a "chilling effect on beneficial pharmaceutical company programs" and raises "critical questions about the scope and meaning of the Anti-Kickback Statute."

Whatever one's view on those issues, there's consensus on some fundamental facets of the AKS, which wields intricate and expansive language against financial conflicts of interests in vast and varied forms, including simple wads of cash and complex contractual agreements. Just about everyone agrees that money can warp physicians' judgment, jeopardizing public trust in medical institutions. Few would dispute that financial quid pro quos fuel unnecessary use of health care goods and services, endangering the solvency of Medicare and Medicaid as well as the patients they serve.

And observers in both the defense and plaintiffs bars say that the AKS — which former President Richard M. Nixon signed on Oct. 30, 1972 — is a potent remedy for chronic corruption in America's health care system.

1977

Congress expands the AKS to cover "any remuneration," but also relaxes it to shield certain discounts and payments to employees.

"That statute really is a powerful anti-fraud law," said Greene LLP lawyer Thomas M. Greene, who helped secure a $900 million AKS settlement from Biogen Inc. in September, just before the statute turned 50.

Crowell & Moring LLP partner Troy A. Barsky, a defense lawyer specializing in kickback cases, offered a similar appraisal, telling Law360 that the AKS "clearly has been a tool that the government has used — a very strong enforcement tool — against conduct that they felt was egregious."

Now that the Anti-Kickback Statute is 50 years old, Law360 is publishing a series of articles taking stock of the law's past, present and future. The statute's past still shapes the latest litigation, as decades-old appellate opinions and legislative tweaks continue to carry immense influence. The law's present is lively and bustling, as evidenced by the consistent ranking of health care fraud among the legal industry's hottest practice areas. And the law's future looks dynamic and uncertain, as legal challenges from Big Pharma, as well as new opinions from circuit courts, once again cast doubt on the Anti-Kickback Statute's strength.

'The Turning Point for the Anti-Kickback Statute'

Corporate chicanery is punishable under many statutes, some of which started with a single sector's skulduggery. One of the best-known examples is the False Claims Act, which famously originated amid Civil War profiteering by defense sector swindlers.

1979

After the first AKS prosecution, the Fifth Circuit overturns the convictions of physicians and a laboratory operator.

"The [FCA] was enacted in part because of bad mules. During the Civil War, unscrupulous early day defense contractors sold the Union Army decrepit horses and mules in ill health, faulty rifles and ammunition, and rancid rations and provisions, among other unscrupulous actions," Mitchell DeClerck PLLC senior partner Larry D. Lahman recounted in a seminal Oklahoma Bar Journal article.

Some 160 years later, the FCA still covers the defense industry, but it also applies to almost all government contractors. Fraud settlements in recent years have involved myriad industries, including airlines, apparel, energy, food service, mortgage lending and telecommunications.

Strikingly, however, annual FCA recoveries from all those industries combined are almost always now exceeded by recoveries from a single area: health care. In typical years, roughly 80% of FCA dollars come from sectors overseen by the U.S. Department of Health and Human Services, and in 2021, the share hit 90% for the first time in the FCA's modern history.

It wasn't too long ago that the breakdown looked very different. In the late 1980s, health care delivered about 5% of FCA dollars, and in the early 1990s, it contributed about 30%. But in the late 1990s, health care's share soared to almost 70%.

The sudden spike was no fluke. Around that time, enforcers had realized that Anti-Kickback Statute violations — typically pursued as criminal matters with high burdens of proof — might be better styled as predicate offenses for civil cases under the FCA. That approach had extra appeal because it would permit whistleblowers to bring kickback cases and because the FCA threatens triple damages and eye-popping penalties — punishments that are more fruitful to the government for fraud committed by corporations, which can't be thrown in prison but can usually afford multimillion-dollar settlements.

1980

Congress amends the AKS so that it applies only to conduct committed "knowingly and willfully."

"The turning point for the Anti-Kickback Statute is basically when it started to be enforced through the False Claims Act," Kevin McAnaney, a high-ranking official at the HHS-OIG in the 1990s and 2000s, told Law360. "It's not until about 2000, when they start to use the False Claims Act to enforce it, that it really becomes what it's become now."

What the AKS has become is a crucial contributor to the health fraud enforcement that generates most FCA dollars. It's difficult to quantify the statute's contributions with precision because FCA settlements involving kickbacks often involve other misconduct. But last year, for example, Biogen's $900 million settlement was all about kickbacks, and it represented roughly 40% of the FCA's $2.2 billion haul for all of 2022.

'Groundbreaking Provisions' Quickly Confront 'Vexing Issues'

The outsize recoveries from health care fraud, and from health care kickbacks in particular, reflect the enormous and enduring nature of those problems. Medicare and Medicaid, created in 1965 under then-President Lyndon B. Johnson's "Great Society" program, almost immediately teetered on shaky financial foundations that deteriorated further amid a flood of kickback scams and schemes.

"Fraud and abuse became a focus of concern soon after the enactment of Medicare and Medicaid," and early payment formulas made it "a relatively easy step for a minority of health care providers to take advantage of the reimbursement system through fraudulent activities," a 1987 article in the Emory Law Journal reported.

1985

The Third Circuit recognizes AKS liability when "one purpose of the payment was to induce future referrals." Other courts later embrace this conclusion.

Unlike the FCA — which the U.S. Supreme Court in U.S. v. Neifert-White Co. described as reaching "all types of fraud, without qualification, that might result in financial loss to the government" — the AKS was tasked solely with policing health care. It may have been that Congress, after seeing how swiftly Medicare and Medicaid generated explosive spending and rampant fraud, decided that health care kickbacks would be more than enough work for the young law to handle.

As originally written, the kickback law occupied two pages of a 165-page bill, the Social Security Amendments of 1972. When the Senate Finance Committee advanced the legislation to the full Senate, its report identified scores of societal "problems" and then outlined the bill's solutions.

"Problem. Present penalty provisions applicable to Medicare do not specifically include as fraud such practices as kickbacks and bribes. There is no criminal penalty provision applicable to Medicaid," the committee's report said, urging the creation of "penalties for certain practices which have long been regarded by professional organizations as unethical ... and which contribute appreciably to the cost of the Medicare and Medicaid programs."

Lawmakers had spent several years debating and tinkering with the broader bill, and the lead negotiators finally shook hands on the main elements — including a 20% boost in Social Security benefits — just before the 1972 elections. The U.S. House of Representatives passed it on a 305-1 vote, the Senate approved it 61-0, and Nixon affixed his signature one week before easily winning an ill-fated second term.

The newly enacted kickback policies were "groundbreaking provisions," designed to "bolster public confidence in the integrity of the Medicare and Medicaid programs" and "augment laws already available to prosecutors to combat fraud," Alice G. Gosfield, a practicing attorney and ex-president of the American Health Lawyers Association, wrote in "Medicare and Medicaid Fraud and Abuse," a legal guidebook.

1987

AKS amendments call for safe harbors from liability and empower enforcers to exclude violators from Medicare and Medicaid.

Any honeymoon phase, however, was short-lived. Prosecutors promptly pursued kickback cases, but their early targets mounted furious defenses that gained legal traction and imperiled the statute's reach — an early taste of AKS power struggles that have continued almost nonstop for five decades.

"Several vexing issues under the statute quickly arose," Gosfield wrote. "The first courts to construe the Anti-Kickback Statute did so narrowly, to the benefit of those charged with violations."

'Considerable Alarm' for Industry Over Statute

One of the earliest AKS opinions by an appeals court came from the Second Circuit on Oct. 17, 1978 — six years after the House and the Senate put their stamps of approval on the statute. After observing

that "the legislative history is sparse and inconclusive," the opinion in U.S. v. Zacher overturned a nursing home administrator's conviction, concluding that payments from the families of Medicaid recipients couldn't be viewed as proscribed "bribes."

Just a few months after the Second Circuit's opinion, the Fifth Circuit in U.S. v. Porter overturned the convictions of physicians and a laboratory operator who, after "a heatedly combative four weeks in the courtroom," had been found guilty in the very first prosecution under the AKS.

"As the Second Circuit in Zacher [found], a kickback involves a corrupt payment" or similar misconduct, and under that interpretation, "no crime involving kickbacks has been charged or proven," the Fifth Circuit wrote.

1995

In Hanlester Network v. Shalala, the Ninth Circuit finds that AKS liability requires "specific intent to disobey the law."

By that point, Congress had revisited and revised the AKS through the Medicare-Medicaid Anti-Fraud and Abuse Amendments of 1977. Where the original law covered only "kickbacks," "bribes" and "rebates," the amended law used those three terms as illustrations of "any remuneration" that the AKS would henceforth encompass.

"I believe that the bill we consider today is an extremely important step in efforts to eliminate fraud and abuse," Sen. Frank Church, D-Idaho, said in support of the 1977 revisions. He cautioned, however, that "no one should have the impression that the bill will solve all problems which still cry out for close inspection and early solution."

As the senator predicted, Congress returned for additional alterations over the ensuing decades. Subsequent changes limited the law to offenders who acted "knowingly and willfully," endowed the HHS-OIG with new powers, authorized safe harbors and — crucially yet inconclusively — sought to super glue the connection between kickbacks and False Claims Act liability.

Although lawmakers were often striving to strengthen the statute, they also acted in response to recriminations from corporate America. Gosfield's book, for example, observed that "the 1977 amendments caused considerable alarm within the industry due to their breadth," and that "in the 1980s, as dissatisfaction with the anti-kickback provisions intensified, industry groups redoubled their efforts to curb what they perceived to be a statute run amuck [sic]."

Despite the passage of time, alarm and dissatisfaction haven't dissipated. And in key respects, litigants in the 2020s have remained at loggerheads over some of the same issues that divided them decades earlier.

Decades of Litigation Are United by Recurring Themes

As one example of the continuity, the Second Circuit's opinion 45 years ago in Zacher is still being debated. That debate is not merely an intellectual exercise, but rather a key flashpoint in one of the kickback law's most closely watched clashes. The dispute is about whether the statute requires proof of corrupt intent, and it has played out in lawsuits brought by Pfizer Inc. in New York federal court and the industry-funded Pharmaceutical Coalition for Patient Access in Virginia federal court.

2003

Settlements with hospital chain HCA Inc. reach $1.7 billion, a record amount that includes milestone use of the False Claims Act to enforce the AKS.

Pfizer's suit recently culminated in the U.S. Supreme Court's refusal to examine the corruption question. During briefing at the high court, Pfizer averred that U.S. v. Zacher is "a leading case" in which the Second Circuit analyzed "the AKS as originally enacted" and found that relevant language "proscribed only a corrupt transaction." HHS derided that depiction, insisting that Pfizer offered "no reason to think that Congress or other courts" have read the Zacher opinion and "understood it to narrow the statute's plain meaning."

As another example of recurring themes, the Fifth Circuit's 1979 opinion in U.S. v. Porter vaporized kickback convictions after finding that the defendants were not "given clear warning by [the] statute that their conduct was prohibited." In 2023, the Supreme Court is scrutinizing a nearly identical issue in the FCA context, and its eventual ruling is widely expected to carry landmark significance.

The FCA issue is about scienter, or knowledge of wrongdoing, and it's under the Supreme Court's microscope in a case involving SuperValu Inc. The food-and-pharmacy chain insists that when companies follow "an objectively reasonable interpretation of an ambiguous obligation, and have not been warned away from that view by a clear, authoritative source, [they] do not 'knowingly' violate the law."

Almost immediately after the Supreme Court accepted SuperValu's case, the issue spilled over into AKS litigation. Perhaps most prominently, Regeneron Pharmaceuticals in January urged a Massachusetts federal judge to reject an FCA kickbacks case brought by the DOJ, asserting that "no court of appeals decision or other authoritative guidance warned Regeneron away from its course of conduct."

The use of the FCA to target kickbacks has been yet another steady source of controversy. An early milestone for that use occurred in 1994, when Tenet Healthcare Corp. predecessor National Medical Enterprises agreed to shell out $379 million in criminal fines, civil damages and penalties. The late Michael F. Hertz, a top DOJ official nicknamed "Mr. False Claims Act," helped to orchestrate that resolution, and sources said that he, along with other DOJ lawyers and HHS-OIG enforcers, paved the way for kickback cases utilizing the FCA.

"In my view, DOJ's civil fraud section, under Mike Hertz and subsequent leadership, has played a critical role by developing the theory of FCA civil liability premised on an AKS violation," Laurence J. Freedman, a member at Mintz Levin Cohn Ferris Glovsky and Popeo PC, told Law360.

Another breakthrough occurred two decades ago — when health care started to dominate FCA recoveries — in a pioneering civil and criminal investigation of HCA Inc., also known as Columbia/HCA Healthcare Corp., which was awash in kickback suits brought by ex-employees and other whistleblowers.

2010

The Affordable Care Act creates liability for false billing claims "resulting from" AKS violations and says the AKS doesn't require "specific intent," overruling Hanlester.

The hospital giant, once led by future Sen. Rick Scott, R-Fla., had agreed by 2003 to resolutions worth $1.7 billion, which the DOJ at the time called "by far the largest recovery ever reached by the

government in a health care fraud investigation."

Health care providers "hold a public trust, and when that trust is violated by ... the payment of kickbacks to the physicians on whom patients and the programs rely for uncompromised medical judgment, health care for all Americans suffers," Robert D. McCallum Jr., then a top DOJ official, said at the time.

The DOJ was emboldened, but the defense bar was unbowed — and in fact, even before the HCA case concluded, defense lawyers had already begun mobilizing.

Defense Bar Fears 'Worst of All Possible Worlds'

The mobilization was conspicuous by 1999, when Fried Frank Harris Shriver & Jacobson LLP attorneys penned a 42-page article in the Alabama Law Review denouncing an early ruling in favor of an HCA whistleblower and inveighing against "misuse of the False Claims Act to enforce the Anti-Kickback [Statute]."

The article — co-authored by John T. Boese, a prominent FCA expert who died in 2020 — contended that permitting whistleblowers to use the criminal AKS for civil FCA cases could create "perhaps the worst of all possible worlds for health care providers."

2020

Enforcers advise industry to make permanent a COVID-19 pandemic-era pause of in-person educational events that have long fueled AKS cases. Separately, safe harbors protect care coordination.

"To the extent [AKS] violations might give rise to FCA liability ... the FCA liability would have to be premised upon alleged direct violations," the article asserted.

That sentiment resonated with some judges, and by the time Congress decided to get involved, "most courts required some nexus between an Anti-Kickback Statute violation and the government's decision to pay a claim — e.g., condition of payment — in order for the violation to be used as the basis for a False Claims Act violation," the law firm Stevens & Lee noted in 2010.

The same year, the Affordable Care Act clarified that a billing claim "resulting from a violation of [the AKS] constitutes a false or fraudulent claim." That clarification, however, has turned out to be unclear, because shortly before the AKS turned 50, it produced a new circuit split.

On one side is the Third Circuit, which in Greenfield v. Medco Health Solutions Inc. explored the FCA and the AKS, and then found that "neither [statute] requires a plaintiff to show that a kickback directly influenced a patient's decision to use a particular medical provider." On the other side is the Eighth Circuit, which analyzed the amendment in Cairns v. D.S. Medical and ruled in July 2022 that FCA plaintiffs "must prove that a defendant would not have included particular items or services but for the illegal kickbacks."

The consequences of the "but-for causation" standard could be profound, according to DOJ briefs. Before the Cairns ruling, for example, the government warned the Eighth Circuit of an "onerous burden" on FCA plaintiffs that would "undermine the purposes of the 2010 amendment and the AKS." It voiced similar concerns in a pending Sixth Circuit case, Martin v. Hathaway, writing in a September amicus brief that the standard "would significantly complicate the litigation of FCA cases based on AKS violations."

Perhaps wary of deepening the circuit split, the DOJ also told the Sixth Circuit that it "need not — and thus should not — weigh into that nascent dispute" about the 2010 amendment. The allegations in the case — which was argued on March 8 — "are sufficient to establish even the more demanding causal nexus required by the Eighth Circuit," the DOJ wrote.

2022

Just weeks before AKS turns 50, Biogen agrees to pay $900 million in one of the largest AKS settlements.

The government didn't seek review at the Supreme Court, which has barely ever examined the AKS closely during the past 50 years. One possible reason such examinations have been rare is that it's costly and risky to litigate kickback cases to that point, McDermott Will & Emery LLP partner Tony Maida, a former deputy chief at the HHS-OIG, told Law360.

"A lot of Anti-Kickback Statute cases don't get litigated because of the significant consequences to the defendant," Maida said. "A lot of those cases settle while the cases are litigated."

Levinson, the former HHS inspector general, told Law360 that another factor is that "the government has been conscientious, has been careful," about setting big precedents in AKS litigation.

Sometimes, however, big precedents can be set unexpectedly. And shortly after the AKS hit the half-century mark, the prospect of such a precedent suddenly appeared in a surprising place.

Pharma Sees Surprise Opening in New Supreme Court Case

Near the end of 2022, the U.S. Supreme Court agreed to review the Ninth Circuit's invalidation of statutory provisions involving immigration. Soon after, an amicus brief arrived from a party that seemingly had no dog in the immigration fight: Pfizer, which had recently failed to convince the Supreme Court to review its AKS challenge.

The amicus brief — authored by the same lawyers who represented Pfizer in its AKS challenge — averred that the drugmaker had "a direct interest" in the case. That's because the case involves statutory liability for "any person who encourages or induces" a noncitizen to enter the U.S. illegally — language that echoes Anti-Kickback Statute liability for those who pay "any person to induce" purchases in Medicare and Medicaid.

The Ninth Circuit found that the immigration provisions infringed on "a substantial amount of protected speech" because "commonplace statements and actions could be construed as encouraging or inducing" someone to enter the U.S. unlawfully. During its AKS challenge, Pfizer contended that the government's views of AKS provisions "infringe on Pfizer's First Amendment right to engage in speech" tied to charitable assistance.

But while the government accused the Ninth Circuit of construing "induce" too broadly, it had accused Pfizer of construing "induce" too narrowly. Pfizer's amicus brief suggested that it had caught the government contradicting itself.

"In the context of AKS, the United States has argued that 'to induce' should be construed the same way the Ninth Circuit did here," broadly encompassing influence and persuasion, as opposed to narrowly

encompassing corrupt activities, Pfizer wrote.

"The court should adopt the narrower construction of 'induce' for which the United States advocates in this case," the drugmaker wrote in its amicus brief. "So holding would ensure that the statutory term 'induce' has consistent meaning across the federal criminal code."

At 50-Year Mark, AKS Eyes a Transformed Health Care Landscape

Pfizer's dogged attacks on the AKS, and the saga surrounding the FCA's use in kickback cases, can be seen as microcosms of the Anti-Kickback Statute's 50-year history. That history is a tale of a statute constantly under siege — arguably, at times, for good reason — and periodically in need of tweaks and tuneups.

The never-ending cycle is seemingly a tacit validation of the Anti-Kickback Statute's deep and enduring impact. If companies weren't fearful of AKS actions, they presumably wouldn't spend millions of dollars hiring BigLaw firms to curtail the law's reach. Similarly, if the AKS weren't a serious threat to corporate profits, companies probably wouldn't pour huge sums of cash into congressional advocacy. Details of that advocacy are rarely publicized, but the U.S. Senate's lobbying database contains hundreds of reports with vague disclosures of AKS conversations on Capitol Hill.

Recent examples have come from hospital chain Advocate Aurora Health ("Anti-Kickback Statute Reform"), the California Life Sciences Association ("reforms to Anti-Kickback Statute"), trade group Pharmaceutical Research and Manufacturers of America ("Anti-Kickback Statute policy issues") and the doctor-appointment platform Zocdoc ("issues related to Anti-Kickback Statute"), among many others.

At the same time, despite the statute's long legacy of discord, its history includes important instances of stability and bipartisan consensus.

Some court opinions, for example, have clearly stood the test of time. A noteworthy example came in an early AKS case called U.S. v. Greber, where the Third Circuit in 1985 held that "if one purpose of the payment was to induce future referrals, the [Anti-Kickback] Statute has been violated," even if other purposes of the payment were legitimate. Other circuits have widely adopted that ruling, and the "one-purpose test" is frequently pivotal in AKS cases to this day.

Other examples exist in the policymaking realm, where regulators have carved out AKS immunity to support coordinated care and value-based reimbursement. Safe harbors finalized near the end of Trump administration sought to "protect certain payment practices and business arrangements from sanctions under the Anti-Kickback Statute." Although the Biden administration unwound much of the prior administration's health care work, it has preserved the AKS protections.

Efforts like those, former HHS official Levinson said, have kept the Anti-Kickback Statute "current with the evolution of new payment models" as the health care system undergoes swift and dramatic change. More broadly, he added, the efforts have "helped ensure that the 50-year-old law addresses the health care landscape as it exists today."

--Editing by Jill Coffey and Jay Jackson Jr.