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FCA Chases 'Shrewder' Kickbacks As 50-Year Hunt Intensifies

By **Jeff Overley**

Law360 (May 10, 2023, 7:20 PM EDT) -- When sophisticated drug and device companies have confronted deadly diseases and daunting approval standards, they've hired the brightest scientific and legal minds — or bribed prescribers with cash, liquor, steaks, vacations and lap dances. The latter approach undergirds a landmark law that has been fueling litigation, wrecking physician careers, sullying corporate reputations and generating jaw-dropping headlines for 50 years — and that enters its next half-century chasing a new generation of camouflaged kickbacks.

The Anti-Kickback Statute has targeted pervasive payola in America's vast health care system virtually nonstop since its passage in late 1972. Its raisons d'etre are all about protecting the budgets and beneficiaries of Medicare and Medicaid from treatments **tainted by the temptations** of wealth, luxury and spicy chicken wings at Hooters.

> There are boatloads and boatloads of kickback cases being brought.

Laura Laemmle-Weidenfeld

Jones Day

"The AKS' animating principle [is] that financial conflicts make it impossible to trust a provider's judgment," the U.S. Department of Justice wrote last year in **a Sixth Circuit showdown** — one of several closely watched clashes carrying immense implications for the law's vitality.

With so much on the line at the Anti-Kickback Statute's 50-year mark, Law360 is publishing a series of articles assessing the law's past, present and future. The half-century history is distinguished by recurring themes, including cycles of industry-led legal challenges and circuit court setbacks that are **once again jeopardizing** the law's double-prong powers, which threaten prison time as well as staggering civil remedies under the False Claims Act.

Another recurring theme involves the kickbacks themselves. Despite five decades of cautionary tales about disgraced doctors and corporations, kickbacks keep popping up, elusive targets on an enforcement landscape often **likened to legal whack-a-mole**. Improper payments are still so pervasive that the nation's top AKS enforcers have struggled to summarize even a small sample of key kickback cases.

"We continue to be concerned about the corrupting influence of money," Robert K. DeConti, chief counsel to the U.S. health care inspector general, said during a 30-minute speech at an American Health Law Association event in March. "And honestly, when I was preparing for this presentation, I was trying to pick kickback cases to talk about, and there were too many to talk about in the time that we have."

Jones Day partner Laura Laemmle-Weidenfeld, a longtime FCA defense lawyer in the Anti-

Kickback Statute space, echoed that point at the same AHLA event in Baltimore during a panel discussion of hot topics in health care fraud.

"It is important to note: There are so many kickback cases now," Laemmle-Weidenfeld said. "There are boatloads and boatloads of kickback cases being brought."

There are also boatloads of kickback categories encompassing everything from the simplest sweeteners to the most elaborate enticements. In interviews with Law360, plaintiffs attorneys expressed optimism that brazen bribes are ebbing. But the attorneys cautioned against thinking that kickbacks overall are abating, arguing that the lesson many companies have seemingly learned from AKS enforcement is that they should be more discreet when defrauding taxpayers.

"There's your traditional, 'Here's a bag of cash.' We're seeing less of that," Employment Law Group PC principal Janel Quinn, whose firm represents FCA whistleblowers in kickback cases, told Law360. "Things are trending more toward the appearance of legitimacy."

Stephen S. Hasegawa, a Phillips & Cohen LLP partner in San Francisco, shared a similar assessment, describing "a shift in the types of remuneration that are being offered" in quid pro quo schemes by drug and device manufacturers and health care providers.

"Manufacturers and providers ... are not stupid. They know that there's a high risk of enforcement if they give money or vacations or dinners or burlap sacks full of cash," Hasegawa said. "Instead, what we're seeing is a rise in attempts by companies to cloak their kickbacks in something that looks a little bit respectable."

> The defense bar certainly believes that the AKS has been stretched beyond recognition.

Matthew M. Curley

Bass Berry

And so, from the vantage point of the plaintiffs bar, even though enforcers have been dropping the hammer for 50 years, the proverbial whack-a-mole game is getting harder to play. Kickbacks are still out there, plaintiffs lawyers say, and now they're hiding behind Potemkin villages of counterfeit compliance, or masquerading as innocuous business services, or enriching individuals who are exempt from financial sunshine rules.

Defense counsel see the same litigation landscape very differently: Kickback suits are surging because other FCA theories have faltered. Plaintiffs firms are so dependent on wielding the AKS hammer that virtually everything looks like a kickback to them. Payments have the appearance of legitimacy and respectability because they really are legitimate and respectable.

"There is a real battle going on right now," Matthew M. Curley, a Bass Berry & Sims PLC member in Nashville, told Law360 this month. "The defense bar certainly believes that the AKS has been stretched beyond recognition with some of the theories of liability we are seeing."

Who's right and who's wrong about those theories will take years to shake out. For now, defense and plaintiffs lawyers do agree about one thing: A historic health care project involving drug and device makers, doctors, hospitals, laboratories and technology vendors is likely to become a top target for Anti-Kickback Statute suits in the coming years. It also appears likely — judging by interviews with those lawyers, new government guidance, early court cases and disclosures buried in securities filings — that the target will be very big.

How big, exactly? Jason D. Popp, the Atlanta-based chair of Alston & Bird LLP's health litigation and False Claims Act teams, offered this estimate: "The answer is, it can be as big as the health care industry itself."

'That Really Sent a Shockwave Through the Industry'

The persistent presence of kickbacks can be seen by looking to the very first AKS prosecution, a 1970s case called U.S. v. Porter. The Porter case involved "handling fees" that a laboratory paid to doctors for blood samples, since Medicare reimbursed labs at higher rates than doctors.

Fast forwarding to modern times, the DOJ and whistleblowers, have in recent years, secured settlements worth $1.5 million with Singulex Inc., **$6 million** with Quest Diagnostics, **$19 million** with Labcorp, **$26 million** with Boston Heart Diagnostics and **$47 million** with Health Diagnostics Laboratory Inc. — all in cases accusing laboratories of disguising kickbacks to doctors as "handling fees."

In interviews for this story, defense and plaintiffs attorneys shared disparate theories for why kickbacks have been a stubborn scourge. But they agreed that kickbacks — or at least the perception of kickbacks — will probably always exist. That's partly because the AKS has capacious language covering "any remuneration" for goods or services in taxpayer-funded health care programs.

Another factor is the distinctive, industry-specific focus of the Anti-Kickback Statute. Bribery is punishable under many laws that span the economy, but the AKS applies solely to health care, and forcing sales representatives to play by special rules is a challenging thing.

> What we're seeing is a rise in attempts by companies to cloak their kickbacks in something that looks a little bit respectable.

Stephen S. Hasegawa

Phillips & Cohen

"In any other industry, a sales force would be wining and dining customers, and paying for rounds of golf or giving them tickets. But you can't do that with federal health care programs," Greene LLP lawyer Thomas M. Greene, whose Boston firm secured a **$900 million settlement** over kickback allegations against Biogen Inc. just before the AKS turned 50, told Law360. "Their customers are the doctors, and ... the inclination is to woo those customers."

Covington & Burling LLP partner Michael S. Labson, writing in the American Medical Association's Journal of Ethics, described that dynamic in a 2003 paper about the AKS and its state-level counterparts, noting that "the scope of these laws is extremely broad and potentially encompasses marketing practices that are common in other industries."

Kickbacks might also have staying power because of the sheer scale of Medicare and Medicaid. The programs utilize hundreds of thousands of doctors and businesses, serve more than 100 million people and cost around $1.5 trillion annually. With so much money circulating among so many parties, and with legions of lawyers doing data analytics and soliciting whistleblowers, it's inevitable that some payments will seem suspicious.

"When you have those very high expenditures, the government is going to continue to, in their view, detect that fraudulent activity occurs," Crowell & Moring LLP partner Troy A. Barsky, an Anti-Kickback Statute attorney in Washington, D.C., said in an interview. "As long as that law remains in place in some form, I think we'll continue to see these cases."

Observers have also urged prosecutors to reach more regularly for the Anti-Kickback

Statute's strongest medicine — felony charges targeting captains of industry — when sophisticated companies that profit immensely off Medicare and Medicaid are **accused of AKS recidivism**.

The dearth of criminal cases against prominent health care executives is arguably understandable, because it's a tall legal task to connect top brass to illicit payments. And it's true that the DOJ has indicted bigwigs in especially egregious circumstances. **One of the most sensational examples** involved a fentanyl marketing scheme at Insys Therapeutics, where the company's founder was sentenced to prison along with doctors whom Insys regaled with "a private room, alcoholic drinks and lap dances" during a **$4,100 visit to a Manhattan strip club**.

C-suite accountability is imperative because corporate cultures are "driven from the top — whether or not high-level executives" weigh legal risks against financial rewards "when promoting a company culture of sell, sell, sell," Employment Law Group's Quinn told Law360. "If I, personally, were facing a slap on the wrist that impacted a percentage of the hundreds of millions, to billions of dollars, that I had made, versus sitting in a jail cell in an orange jumpsuit, that might change my calculus."

Quinn's firm brought the lead whistleblower suit in kickback litigation against Avanir Pharmaceuticals that, in 2019, led to a settlement worth more than $100 million. Most of that money reflected a civil settlement, but the deal also included criminal penalties and forfeitures under a deferred prosecution agreement. Most notably, the DOJ **indicted four individuals** — including former employees of Avanir and two prescribers — on conspiracy charges involving health care kickbacks.

"That really sent a shockwave, I think, through the industry," Quinn said.

'I Don't Want to Make it Sound Like There's Some Blacklist'

Anti-Kickback Statute cases have been seen in virtually every nook and cranny of the health care system, including durable medical equipment, home health, hospitals, genetic testing, pharmacy compounding, retail pharmacies, sober living homes, telemedicine and urinalysis.

Dialysis companies, which serve America's large diabetic population, have also been deeply immersed in litigation and legislation linked to kickbacks. As one example, divisions of DaVita Inc., one of the largest such companies, settled for **$64 million** in 2017 over "unlawful financial inducements to health program beneficiaries" and for **nearly $400 million** in 2014 over "kickbacks to induce the referral of patients to its dialysis clinics," according to the DOJ.

> It just becomes astronomical very quickly, which is why so many people settle.

Jennifer E. Michael

Bass Berry

But mega-settlements have overwhelmingly occurred in the drug and device industries, which have long been notorious for the extravagant entertainment of physicians whose prescription pads can be a golden ticket to blockbuster sales. Looking broadly at AKS resolutions, it can seem like virtually every major pharmaceutical company has struck a sizable settlement at some point. Even looking narrowly at AKS resolutions, such as recent ones involving purportedly charitable assistance for patients, there are still lots of household names.

Since 2017, for example, the DOJ has obtained **more than $1 billion** from settlements involving patient assistance programs with divisions of Actelion, Aegerion Pharmaceuticals Inc., Amgen Inc., Astellas Pharma Inc., Biogen, Gilead Sciences Inc., Incyte Corp., Jazz Pharmaceuticals, Lundbeck LLC, Mallinckrodt PLC, Novartis AG, Pfizer Inc., Sanofi and United Therapeutics Corp., as well as several charities supported by drugmaker dollars.

Daniel R. Levinson, whose 2004-2019 tenure as U.S. health care inspector general coincided with surging scrutiny of pharmaceutical industry fraud, demurred when Law360 recently asked him whether any individual AKS settlements stand out from the pack.

"There are so many famous companies that are on that list," Levinson said in an interview. "I wouldn't try to now recall just one or two, because I don't want to make it sound like there's some blacklist that exists."

Lobbying group Pharmaceutical Research and Manufacturers of America in 2002 adopted an ethical code to help ensure "interactions with health care professionals not be perceived as

inappropriate," and it repeatedly revised the code in ensuing years as kickback cases continued to unearth stunning schemes and spawn super-sized settlements.

A similar backstory surrounds the medical device sector. Lobbying group AdvaMed oversees a code that debuted in 1993 and promotes "ethical interactions and relationships with health care professionals." AdvaMed's ethics code has also undergone multiple revisions against the backdrop of kickback settlements with manufacturers of defibrillators, drug infusion pumps, pacemakers, surgical instruments, spinal implants and ventilators — a small sample of products in the vast and varied medical device industry.

Each industry has principled reasons for finding creative ways to cultivate thought leaders who can convincingly communicate cutting-edge research. Sometimes, however, creativity has taken the form of sending doctors and their spouses on "**luxury all-expense paid vacations** to exotic international destinations" or paying for **fine dining delicacies** at the upscale Eleven Madison Park in New York City. Less glamorously, creativity has also included roundtable programs during "**75 events at Hooters**" as well as **meals and wine** at a Brazilian grill in South Dakota that advertises "a festival of meat."

Settings like those are "not conducive to an educational presentation," the Office of Inspector General for the U.S. Department of Health and Human Services wrote in a **2020 special fraud alert** that urged drug and device companies to sharply curtail in-person events.

But educational value is the least of the concerns. The HHS-OIG has identified many pitfalls, warning on multiple occasions that kickbacks can "distort medical decision-making" and "result in unfair competition by freezing out competitors who are unwilling to pay kickbacks."

> As long as [the Anti-Kickback Statute] remains in place in some form, I think we'll continue to see these cases.

Troy A. Barsky

Crowell & Moring

Similarly, physicians at Memorial Sloan Kettering Cancer Center in New York published research in 2021 that found "industry spending on drug promotion disproportionately targets drugs that are less effective or offer little therapeutic advancement." There appears to be a link between "industry payments and increased prescribing of low-value drugs — including both less-effective drugs and those that are similarly effective but more expensive that competitors," the research found.

Congressional concerns about such consequences were a driving force behind the passage of the Physician Payments Sunshine Act, or Open Payments, as part of the Affordable Care Act in 2010. Championed by Sen. Chuck Grassley, R-Iowa, architect of the modern False Claims Act, the Open Payments system has illuminated multibillion-dollar financial ties among providers and the drug and device sectors.

Many of those ties are likely beneficial, given that payments frequently fund research. But transparency can reveal whether top recipients of a manufacturer's largesse also happen to be top prescribers of a manufacturer's products, and federal enforcers **cited Open Payments data** when announcing Anti-Kickback Statute charges against Insys employees.

As time goes by, there's more money to investigate. When Open Payments launched nearly a decade ago, annual payments hovered near $8.5 billion, and they have consistently climbed higher, adding up to nearly $11 billion in 2021. Industry groups have insisted the payments reflect crucial collaboration among providers and manufacturers. But there's been suspicion from plaintiffs counsel and other observers, including the entertainer John Oliver, who discussed Open Payments in a 2015 episode where an actor portrayed a doctor

enjoying lobster and driving a Porsche.

In any event, the trend of more money changing hands aligns with another trend that both sides of the FCA bar are seeing: After decades of enforcement, Anti-Kickback Statute cases are only becoming more common, and AKS theories are only becoming more diverse.

'A Kickback Typically is More Explainable to a Court or Jury'

"AKS issues are really hot right now," Bass Berry's Curley told Law360 this month, adding that kickback cases have overtaken suits alleging medically unnecessary care as a leading FCA theory.

Paul D. Werner, a Buttaci Leardi & Werner LLC member in New Jersey, volunteered a nearly identical observation in a recent interview with Law360. "Cases that hinge on the medical necessity of the services" are "not necessarily the most common type of False Claims Act case — a lot of them lately are AKS-based," Werner said.

It would make sense if the uptick in AKS cases reflects a pivot away from medical necessity cases. The latter theory attracted industry ire in recent years, with the American Medical Association **denouncing** "improper second-guessing of ... physicians' clinical judgment." Also, in a **high-profile and chaotic case**, the DOJ saw years of work **go down the drain** in FCA litigation involving clinical judgments at hospice chain AseraCare Inc.

"These cases are attractive from a plaintiff's perspective because the concept of a kickback or bribery typically is more readily explainable to a court or jury than ... theories of medical necessity," Curley said.

> Pharmaceutical companies have become shrewder in their attempts to evade fraud detection.

Eva Gunasekera

Tycko & Zavareei

The Department of Justice's annual FCA statistics don't include details about the AKS or other legal theories. But starting last year, the government's narrative summary of FCA highlights suddenly began devoting an entire section to "unlawful kickbacks." The most recent summary described "the resolution of numerous matters involving kickback violations," and proceeds from those matters — including Biogen's $900 million deal — generated roughly half of all FCA proceeds across all industries in 2022.

The growing volume of kickback cases has been accompanied by a growing variety of kickback theories. After countless kickback cases succeeded spectacularly during the past decade or so, health care companies rejiggered their jiggery-pokery, plaintiffs lawyers say. Some companies started shrouding skulduggery in glosses of good corporate citizenship. Others ratcheted up incognito inducements and dialed back ersatz educational events at tropical resorts and Michelin-starred restaurants.

"Pharmaceutical companies have become shrewder in their attempts to evade fraud detection," Tycko & Zavareei LLP partner Eva Gunasekera, formerly a senior health fraud lawyer at the DOJ, told Law360. "As the government enforces fraudulent kickback schemes, the pharma companies adapt their schemes rather than stop paying kickbacks."

'They're Putting Policies in Place That on Paper Look Great'

One such adaptation relates to the health care industry's much-ballyhooed commitments to conscientious corporate citizenship. One of the best-known commitments came from British pharmaceutical giant GlaxoSmithKline PLC, which in 2013, announced **revolutionary**

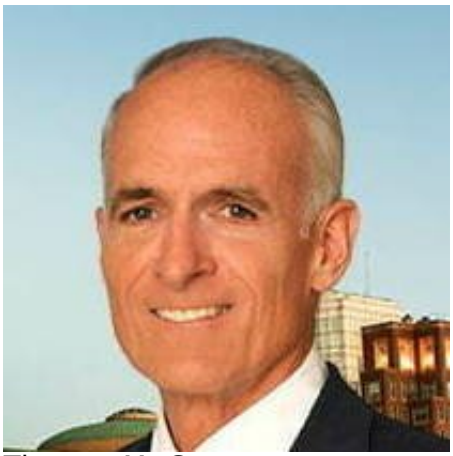
restrictions on payments to physicians after a **$3 billion civil and criminal resolution**, which overwhelmingly stemmed from kickback allegations.

Some commitments are undoubtedly sincere. But when businesses elevate compliance officers to C-suite status, they're sometimes just lifting a compliance curtain to conceal newfangled forms of fraud, plaintiffs counsel say.

"I call it 'compliance theater,'" Greene, the Greene LLP lawyer, said in an interview. "They're putting policies in place, and practices, and codes of business, that on paper look great. ... But they're not being enforced, and they're being ignored."

As one example of compliance theatrics, a pending AKS case against Regeneron Pharmaceuticals and Sanofi in California federal court alleges that "compliance for both drug companies was nothing more than words on paper." The drugmakers — which have denied wrongdoing — feigned compliance by designing provider payment tiers pegged to experience and credentials, but the "tiering system was a sham" and "window dressing to give the appearance of legitimacy," according to a complaint.

> Their customers are the doctors and ... the inclination is to woo those customers.



Thomas M. Greene

Greene LLP

The legitimacy of compliance efforts can have concrete consequences. In recent months and years, DOJ officials have **hammered home** the message that good-faith compliance efforts **might merit leniency**. And relatively new **guidelines** say the DOJ may consider "the nature and effectiveness of ... a compliance program in evaluating whether any violation of law was committed knowingly," as required to prove an FCA case.

In another adaptation, cash kickbacks have fallen out of favor, supplanted by a head-spinning assortment of services for consulting, advertising, marketing, patient education, data analytics and more. Those services can be just as lucrative as stacks of greenbacks, but also tougher to discover and punish under the AKS.

"Instead of providing cash, manufacturers are looking for ways to help doctors improve the bottom line," Hasegawa, the Phillips & Cohen partner, said in an interview. "They're providing [services] for free in exchange for referrals or recommendations or purchases.

That, in our view, is a kickback, even though it doesn't look like the traditional kind of kickback."

'Bad Apples are Appreciating That People are Looking More Closely'

On yet another front, myriad forms of freebies are flourishing yet again in doctor's offices — longtime targets for drug industry largesse — but with a twist that keeps things under the radar. According to Tycko & Zavareei's Gunasekera, "the next big wave of fraud allegations" starts with payments to staff at doctors' offices. Office staff, who generally aren't subject to Sunshine Act reporting, are then given proprietary digital tools to accelerate prior authorizations, a gatekeeping mechanism to ensure that high-cost drugs are appropriate.

"Pharma companies have adapted," Gunasekera said. "Paying nonmedical staff in doctors' offices to circumvent prior authorization protections is the up-and-coming fraud scheme that pharma insiders are reporting to the government."

The alleged circumvention scheme, exemplified by the suit against Regeneron and Sanofi, is an example of drugmakers becoming "a little bit more sophisticated" about kickbacks, Tycko & Zavareei partner Renée Brooker, co-counsel for whistleblowing ex-employees of Regeneron, told Law360.

"Some in the pharma industry — the bad apples, the bad players — are appreciating that people are looking more closely at them, and they try not to be so transparent about their fraud," Brooker said.

Another emerging form of cashless kickback is allegedly coming from specialty providers, pharmacies and suppliers of medical equipment. One example of the allegation appears in a pending FCA suit filed in Illinois federal court by a whistleblower named Michael Gill, who was a compliance director at CVS Health Corp. and Caremark Rx divisions from 1992-2018.

According to the suit, CVS home care unit Coram LLC entered into "illegal quid pro quo contracts ... in violation of the AKS" by "assuming the cost of post-discharge care" for uninsured hospital patients, effectively subsidizing the hospitals' charity care budgets in exchange for referrals of home care patients.

> They weren't sting operations, where the government came up with a kickback idea and tried to get someone to do it. It was the defendants who came up with the idea.

Gregg Shapiro

Gregg Shapiro Law

Phillips & Cohen's Hasegawa, who is familiar with the Gill case, told Law360 that the suit's allegations illustrate how "companies have started to try to figure out if they can somehow provide value to the recipient without actually making a transfer to the recipient."

"It looks on the books like this is great — that this company is providing charity care. But it's not really charity care," Hasegawa said. "It's a way of saying, 'We're going to take an expense that you, the hospital, would otherwise pay, and we're going to pay it ourselves.' And from the hospital's standpoint, that's the same as cash."

It's noteworthy that newer AKS theories can require some squinting to discern dirty dealings. The emergence of such theories might suggest that older AKS theories — such as sham speaker fees for prolific prescribers — are running low on companies and conduct to target.

"You'll probably see whistleblowers hunting harder for hidden payments, if they exist," Bass Berry member Stewart W. Kameen said in an interview. "Because the more low-hanging-fruit speaker programs have been cleaned up, in large part, at least by the large stakeholders."

And individuals hunting for newer types of AKS violations might come home empty-handed. In the California case alleging circumvention of prior authorizations, Regeneron has cited the government's **scuttling in 2018** of a dozen cases that also involved prior authorizations and alleged kickbacks. "DOJ has ... sought to curb meritless qui tam litigation attacking routine prior authorization practices like those at issue here," Regeneron

wrote in a motion to dismiss.

There's a lot on the line as newer theories trend toward arrangements with the outward appearance of propriety. Success could suggest that the FCA plaintiffs bar — once heavily reliant on the DOJ — no longer needs training wheels and can chase down even the most cunning kickbacks. Failure, however, could vindicate the view that plaintiffs counsel should look in the mirror if they want to see shrewdness.

"I'm not aware of any of these companies trying to come up with creative or alternative kickbacks," Alston & Bird's Popp said in an interview. "What I've seen is increased creativity and scrutiny in the relators bar to find a kickback when a kickback is not really there."

It's obviously true that overzealous plaintiffs exist. At the same time, it's also true that new enforcement frontiers have to start somewhere.

"I remember as a prosecutor that defense lawyers would accuse us of developing these novel enforcement tactics," Gregg Shapiro, a former DOJ prosecutor who now represents whistleblowers, said in an interview. "And my response to that was, 'No, we're just following the money, and it's the pharmaceutical companies that develop novel ways of paying remuneration that violate the Anti-Kickback Statute.'"

"They weren't sting operations, where the government came up with a kickback idea and tried to get someone to do it," Shapiro added. "It was the defendants who came up with the idea — something that nobody had thought of before."

'Transition to Digital' Means 'New Opportunities for Fraud'

Until fairly recently, nobody had thought of kickbacks involving electronic health records, because until fairly recently, electronic health records barely existed. But the federal stimulus law in 2009 launched a nationwide project, bankrolled by tens of billions of dollars in government investment, to propel the U.S. health care system into the digital age. The goal was to make electronic health records, or EHRs, as conventional as stethoscopes dangling from doctors' necks.

Almost immediately, the same sorts of kickbacks that AKS enforcers had hammered for decades began popping up in the fast-growing EHR field, according to court records. Starting in 2011, a leading EHR vendor called eClinicalWorks began paying cash kickbacks, and during the next few years, it doled out "American Express gift cards, iPads, meals, travel and entertainment," as well as purported consulting and speaker fees, "to influential users who promoted its software," the DOJ alleged in connection with a **$155 million FCA settlement**.

That settlement in 2017 marked one of the Anti-Kickback Statute's first uses in the context of EHR sales and marketing. And it was a sign of things to come, because the DOJ has subsequently struck more than a half-dozen additional kickback deals involving EHRs. But those settlements are almost certainly just the tip of the iceberg, defense and plaintiffs attorneys told Law360.

> The relators bar is like a moth to a flame. ... They're going after electronic health record companies.

Jason D. Popp

Alston & Bird

"The relators bar is like a moth to a flame. … They're going after electronic health record companies," Alston & Bird's Popp said. "In terms of newest trends, I think EHR is really at the top of the list."

Government enforcers have offered similar observations. Brian M. Boynton, who now helms the DOJ's Civil Division, said at a Federal Bar Association conference in 2021 that EHRs were "likely to be a focal point of ... future enforcement efforts." Boynton, who specifically spotlighted EHRs and kickbacks, added that "the transition to a digital format has ... introduced new opportunities for fraud and abuse," according to a DOJ transcript.

One reason EHRs are a top target is their ubiquity: As of 2021, nearly 80% of office-based physicians were using certified EHRs, and nearly 90% were using some form of EHR, federal data show. Another reason is that Uncle Sam offered considerable cash incentives — roughly $44,000 in Medicare and $64,000 in Medicaid — to individual clinicians in exchange for using EHRs. Hundreds of thousands of clinicians collected incentive payments, and in a few early cases, the DOJ has averred that kickbacks tainted many such payments.

"Athena's payment of illegal remuneration to hundreds of clients and several EHR vendors throughout the United States [caused] Medicare and Medicaid to pay millions of dollars in incentive payments that were not payable," the government alleged when it struck an **$18 million fraud settlement** in 2021 with EHR developer Athenahealth Inc.

But kickbacks can taint not just EHR incentive payments, but also Medicare and Medicaid reimbursement more generally. In a 2020 settlement, for example, the government contended that Practice Fusion Inc. manipulated "a key functionality of EHR software" in exchange for kickbacks from OxyContin seller Purdue Pharma LP. As a result, "the claims for payment that providers submitted between April 2014 and April 2019 to Medicare, Medicaid and Tricare for prescriptions which were tainted by these kickbacks are false claims," the DOJ alleged.

The U.S. attorney's office in Vermont, with help from whistleblowing insiders, has led much

of the FCA enforcement involving kickbacks and EHRs; it has helped reach settlements with eClinicalWorks, Practice Fusion and Purdue, as well as EHR companies Greenway Health LLC and Modernizing Medicine Inc. The settlements with EHR companies ranged from $45 million to $155 million; even the smallest of those deals was substantial for an FCA case in any context, and the largest was a record-setting sum for an FCA settlement in the Green Mountain State.

The office declined to address detailed questions from Law360 about its enforcement, instead supplying a short statement in which U.S. Attorney Nikolas Kerest said, "While, as you note, this office has been at the forefront of kickback cases involving EHRs, we have no comment as to your questions regarding the future of AKS enforcement and litigation."

Despite the office's reticence, there are strong signs it's still scrutinizing the intersection of EHRs and kickbacks. Among EHR developers, for example, Atlanta-based NextGen Healthcare Inc. has disclosed an investigation by the U.S. Attorney's Office for the District of Vermont into the company's "marketing programs and payments provided for the referral of EHR business."

> We're talking [about] the tech companies and the 'move fast, break things' kind of mentality.

Colette G. Matzzie

Phillips & Cohen

The office has sought information on the company's "EHR product and its performance, including defects that relate to patient safety or meaningful use certifications," NextGen

wrote in a January earnings report, adding that it had recently learned of "a sealed qui tam lawsuit concerning the issues NextGen has been discussing" with the office.

EHR companies with a Silicon Valley ethos might be distinctly vulnerable to Anti-Kickback Statute headaches, sources said, pointing to freewheeling business cultures in tension with strict compliance obligations in health care.

"We're talking [about] the tech companies and the 'move fast, break things' kind of mentality — you do see that," Phillips & Cohen partner Colette G. Matzzie, counsel to whistleblowers in several successful suits involving EHRs, told Law360.

Even the most conscientious companies are susceptible to slip-ups, Alston & Bird's Popp said, because billing federal health care programs "requires ramping up and understanding the arcane and convoluted" rules and regulations.

AKS safe harbors have **shielded certain EHR activities**, such as donations of cybersecurity software. But the safe harbors have required compliance with precise provisions. In a $45 million FCA settlement last year with Florida-based Modernizing Medicine, the DOJ said donations improperly reflected referral volume or value, and that they "therefore did not meet the requirements of the AKS safe harbor exception applicable to EHR donations."

All that said, the tech industry's risks alone don't explain why the FCA bar is intensively tracking kickback cases involving EHRs.

'A Lot of People Aren't Going to Be Happy'

The long-term, big-picture issue is the DOJ's kickback crackdown could expand far beyond health technology, potentially reaching any entity — such as drugmakers, device manufacturers and laboratories — with business affected by EHRs. Early signs of that expansion appeared in 2020, when Purdue Pharma and the DOJ struck a multibillion-dollar opioid deal, which described EHRs being deliberately designed to drive up painkiller prescribing.

"Purdue paid kickbacks to Practice Fusion, an electronic health records company, to induce it to recommend and arrange for prescriptions of opioids by creating alerts that would appear within Practice Fusion's software while providers were seeing patients," according to a settlement agreement.

And the DOJ might be searching for similar schemes. In a February earnings report, for example, New Jersey-based Merck & Co. outlined an escalating inquiry in which the U.S. attorney's office in Vermont subpoenaed records about the drugmaker's ties to Practice Fusion and later subpoenaed records "relating to Merck's relationship with any EHR company." The second subpoena was followed by a civil investigative demand that said the DOJ was conducting an FCA investigation "concerning whether Merck and/or [Practice Fusion] submitted claims to federal health care programs that violate the federal Anti-Kickback Statute," the earnings report said.

In yet another sector, Texas-based Inform Diagnostics, a pathology lab business formerly known as Miraca Life Sciences Inc., in 2019 **paid $64 million** in an AKS case involving electronic health records subsidies in exchange for patient referrals. That deal was followed by the settlement with Modernizing Medicine, or ModMed, in a case alleging EHR kickbacks

involving Miraca. According to a DOJ complaint, Miraca paid hundreds of thousands of dollars to ModMed for software with "enhanced features [that] were highly attractive to physicians."

"However, if a physician sent a laboratory order to a lab other than Miraca, the physician could not use the enhanced features," the complaint said. It added that "ModMed was warned that its arrangement with Miraca violated the AKS," because the HHS-OIG had publicly stated that "EHR vendors could violate the [AKS] through arrangements that favored one laboratory over another."

In late March, the HHS' Office of Inspector General delivered a much broader warning when it launched an online FAQ about health fraud issues. In one section, the OIG focused on arrangements between EHR vendors and their customers, and it seemingly claimed sweeping authority to police the platforms.

"To the extent the EHR software is ... used in the furnishing of items or services reimbursable by a federal health care program, various financial arrangements could implicate the federal Anti-Kickback Statute," the OIG wrote.

In an interview with Law360 one day after the FAQ debuted, Bass Berry member Jennifer E. Michael, a former chief of the OIG's Industry Guidance Branch, spotlighted the EHR section and dubbed it "a big deal."

"A lot of people aren't going to be happy when they see OIG's answer," Michael said.

'You Very Quickly Get Into the Billions of Dollars'

But the answer probably isn't surprising, because the nation's EHR apparatus checks virtually every box that the government considers when allocating its health fraud resources. It's a big area that's only getting bigger. A tremendous amount of taxpayer money is at stake. Patient well-being is directly implicated.

"Where the EHR might be directing the decision, the government appropriately is concerned about clinical decisions being skewed by nonclinical factors," Popp, of Alston & Bird, said.

The increasingly pervasive presence of EHRs, and their potential links to manufacturers of many types of medical products, are also crucial. Especially salient are links to drugmakers, which in recent years have paid the steepest settlements in the Anti-Kickback Statute's history, largely because each prescription tainted by fraud can trigger breathtaking penalties and damages under the FCA.

"You very quickly get into the billions of dollars, with a B," Michael said. "It just becomes astronomical very quickly, which is why so many people settle."

Indeed, there has thus far been little in the way of active FCA litigation involving the Anti-Kickback Statute's use in the EHR realm. Sooner or later, companies will likely lock legal horns with the DOJ and whistleblowers, giving courts an opportunity to assess fraud theories in a new context — and decide which side is playing fast and loose with the AKS.

> EHR is a very different beast than the traditional kickback case.

Stewart W. Kameen

Bass Berry

"EHR is a very different beast than the traditional kickback case," Bass Berry's Kameen noted.

And it's possible that EHR cases will become even more different in the near future. That's because the new digital circuitry connecting patients, providers and manufacturers is neither simple nor static. Far from merely being methods of electronic messaging, EHRs often offer so-called clinical decision support. CDS is a booming area of health information technology where products can resemble medical devices and shepherd specialists toward treatment decisions for seriously ill patients.

Kickback litigation in the EHR space is "going to continue to evolve into additional health technologies," eventually exploring "the relationships with all of these health technologies — even with each other — and the relationships with pharma and device companies," Phillips & Cohen's Matzzie told Law360.

Matzzie represented whistleblowers in the ModMed and eClinicalWorks cases, plus a kickback case against EHR vendor CareCloud Health Inc., which two years ago settled for almost $4 million. Asked for her sense of other EHR kickback cases that are under seal or in the works, Matzzie paused for a few seconds, then laughed and replied, "I'm not going to really be in a position to tell you that."

But, she added, "you can expect continued enforcement," and it will probably entail two categories of kickbacks: the traditional category of "strip clubs, cash and other kinds of things of value" and the newer category featuring a "whole different kind" of remuneration for "a preferential position within the EHR."

"You will see both of those kinds," Matzzie said. She then backtracked slightly on that prediction, tacitly nodding to the Anti-Kickback Statute's legacy at the 50-year mark: "Maybe not so many strip clubs."

--Editing by Kelly Duncan and Lakshna Mehta.

This is the final installment in Law360's series about the past, present and future of the Anti-Kickback Statute, which has now been on the federal books for 50 years. Other installments have explored ***the long history of industry challenges to the AKS****,* ***how the AKS fueled the dramatic rise of False Claims Act recoveries****,* ***the increasingly likely prospect of a major AKS showdown at the U.S. Supreme Court****,* ***the enduring legacy of a 1985 decision establishing the "one-purpose test" for AKS liability****, and* ***rising tensions in the FCA bar as the AKS' power has grown****.*
