

Fraud & Abuse

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Buyers Beware: The Drug Supply Chain Security Act and the False Claims Act

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In November 2013, President Obama signed into law the Drug Quality and Security Act (DQSA), which was designed in part to address weaknesses in the United States' drug supply chain that jeopardize patient safety by permitting counterfeit, contaminated, or otherwise unsafe prescription drugs to enter the market.¹ Title II of the DQSA—the Drug Supply Chain Security Act (DSCSA)—requires, among other things, that drug dispensers purchase drugs from “authorized trading partners.”² This article discusses that requirement and the ways in which noncompliance with the DSCSA can expose health care providers to potential liability under False Claims Act (FCA).

The DSCSA

Effective January 1, 2015, the DSCSA required that dispensers purchase prescription drugs from “authorized trading partners.”³ This means that any person authorized to dispense or administer prescription drugs—including, for example, hospitals, medical practices, and both retail and hospital pharmacies—must purchase prescription drugs from properly licensed entities, referred to by the DSCSA as authorized trading partners.⁴

The licensure requirements for DSCSA trading partners vary depending on the type of partner, e.g., drug manufacturers, wholesale distributors, repackagers, etc. For example, wholesale drug distributors must have a valid license under state law or comply with certain provisions of federal law that require (1) licensure by the Department of Health and Human Services in the event that the state has not yet established a licensure requirement, and (2) licensure of the person distributing drugs into the state where drugs are distributed interstate.⁵ In the case of a dispenser, the DSCSA's only licensure requirement is that the entity be properly licensed under applicable state law.⁶ These requirements are in addition to the longstanding requirement that the drug dispensed be approved by the U.S. Food and Drug Administration (FDA).

False Claims Act Liability for DSCSA Violations

Where dispensers fail to comply with the DSCSA and seek reimbursement from federal health care programs for drugs that were purchased from sources other than “authorized trading partners,” they are exposed to potential liability under the FCA. This liability could include both the professional fee for the drug’s administration as well as the reimbursement for the drug itself. Because such liability can be enormous, it is crucial for health care providers and their counsel to understand the DSCSA’s requirements and when a violation of those requirements amounts to a violation of the FCA.

Proactive Compliance Can Help Avoid Liability

As an initial matter, providers should take steps to ensure that they are purchasing their drugs from an authorized trading partner before seeking reimbursement from government payers. Providers can do so by both seeking assurance from the trading partner itself, and by checking federal and state databases for proper approval and licensing. The FDA has advised providers to “[c]heck with [their] trading partner directly to confirm they are authorized,”⁷ and (a) in the case of manufacturers and repackagers, refer to the FDA’s drug establishment registration database for registration;⁸ or (b) in the case of wholesale distributors, third-party logistic providers, and dispensers, check with the appropriate state authority to confirm licensure.⁹

Possible Defenses to FCA Liability

The mere fact that a provider dispenses or administers a drug that was not purchased from an authorized trading partner as required by the DSCSA does not, of course, mean that the provider violates the FCA by submitting claims for such drugs. Specifically, a provider might avail itself of several defenses, most notably lack of materiality and knowledge, both of which are required under the FCA.

Materiality. As the Supreme Court recently highlighted in *Universal Health Services, Inc. v. United States ex rel. Escobar*, misrepresentations regarding compliance—whether express or implied—must be material to the government’s payment decision to be actionable under the FCA.¹⁰ The FCA defines the term “material” as “having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.”¹¹ However, the Supreme Court in *Escobar* held that the materiality standard is a “demanding” one, and a number of lower courts applying *Escobar* announced a more stringent approach to materiality than that which existed pre-*Escobar*.¹² As noted by the District of Columbia Court of Appeals, *Escobar* stands for the proposition that “[t]he statutory test for ‘materiality’ . . . appears to be ‘the effect on the *likely or actual* behavior of the recipient of the alleged misrepresentation’ upon learning about it, not on its mere potential to affect the recipient’s [*i.e.*, the government’s] decision” to pay.¹³ It is insufficient “for a finding of materiality that the Government would have *the option* to decline to pay if it knew of the defendant’s noncompliance.”¹⁴ Although a drug being FDA-approved is likely material to the government’s decision to pay under any standard, arguably the fact that an otherwise approved drug is purchased from a wholesale distributor that is not licensed under state law in violation of the DSCSA is not material for purposes of the FCA.¹⁵

Requisite Knowledge. To be found liable under the FCA, a health care provider must act “knowingly,” meaning that the provider (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information.”¹⁶ Often, providers who find themselves the subject of an FCA investigation for purchasing and administering drugs from unauthorized trading partners have no reason to believe the drugs they have purchased originated from an unauthorized source. Absent actual knowledge of any wrongdoing, the government must establish either deliberate ignorance or reckless disregard. Where a health care provider takes good-faith steps to ensure compliance with the DSCSA, but nevertheless winds up purchasing otherwise-approved drugs from an unauthorized trading partner, it would be difficult for the government to prove that the provider acted knowingly for purposes of the FCA.





Conclusion

The DSCSA is focused on policing the industry and forcing active cooperation with the government in securing the drug supply chain. Even the most vigilant of dispensers can fall short of these demands, making frontend compliance critical in order to avoid potentially tremendous FCA liability.

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- 1 For example, in 2012, the Food and Drug Administration (FDA) discovered that a counterfeit version of Avastin, an injectable medicine used to treat cancer, was being administered in at least 19 medical practices across the country; critically, the counterfeit drug was missing the active ingredient of Avastin, severely compromising patient care. FDA, *Counterfeit Version of Avastin in U.S. Distribution* (July 10, 2012), available at <http://www.fda.gov/Drugs/DrugSafety/ucm291960.htm>.
- 2 In addition to dispensers, the authorized trading partner requirement of the DSCSA applies to drug manufacturers, wholesale distributors, and repackagers. See 21 U.S.C. § 360eee et seq.
- 3 The term “authorized” means—
 - (A) in the case of a manufacturer or repackager, having a valid registration in accordance with section 360 of this title;
 - (B) in the case of a wholesale distributor, having a valid license under State law or section 360eee-2 of this title, in accordance with section 360eee-1(a)(6) of this title, and complying with the licensure reporting requirements under section 353(e) of this title, as amended by the Drug Supply Chain Security Act;
 - (C) in the case of a third-party logistics provider, having

a valid license under State law or section 360eee-3(a)(1) of this title, in accordance with section 360eee-1(a)(7) of this title, and complying with the licensure reporting requirements under section 360eee-3(b) of this title; and (D) in the case of a dispenser, having a valid license under State law.

- Id.* § 360eee(2); see also *id.* § 360eee(23) (defining “trading partner,” in part, as “a manufacturer, repackager, wholesale distributor, or dispenser from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct ownership of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct ownership of a product”); *id.* § 360eee-1(d)(3) (“Beginning not later than January 1, 2015, the trading partners of a dispenser may be only authorized trading partners.”).
- 4 *Id.* § 360eee(23); *id.* § 360eee-1(d)(3); see also FDA, *Are You Ready for the Drug Supply Chain Security Act?* (Mar. 1, 2016), available at <http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm427033.htm>.
 - 5 21 U.S.C. § 360eee(9); 21 U.S.C. § 353(e).
 - 6 21 U.S.C. § 360eee(9).
 - 7 *Are You Ready for the Drug Supply Chain Security Act?*, *supra* note 4.
 - 8 FDA, *Drug Establishments Current Registration Site* (Nov. 29, 2016), available at <http://www.accessdata.fda.gov/scripts/cder/drls/default.cfm>.
 - 9 *Are You Ready for the Drug Supply Chain Security Act?*, *supra* note 4.
 - 10 *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S.Ct. 1989, 2002 (2016).
 - 11 31 U.S.C. § 3729(b)(4).
 - 12 See, e.g., *Johnson v. District of Columbia*, 144 A.3d 1120, 1137 (D.C. 2016).
 - 13 *Id.* at 1138.
 - 14 *Id.* at 2003 (emphasis supplied).
 - 15 For example, although Botox is an FDA-approved drug, if a provider purchases authentic Botox from an unlicensed wholesale distributor, that supplier has violated the DSCSA. See Sarah N. Lynch, *Special Report—‘Botox Police’: FDA Crime Unit Draws Fire Over Important Crackdown*, available at <http://www.reuters.com/article/us-usa-fda-cases-special-report-idUSKCN11E1Y0>. It is arguable, however, whether this fact is material under the FCA.
 - 16 31 U.S.C. § 3729(b)(1).

Emerging Trends and Expanding Theories of Liability in Criminal Health Care Fraud Enforcement

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According to the Department of Health and Human Services Office of Inspector General's (HHS-OIG's) Semiannual Report to Congress, during fiscal year (FY) 2016, Medicare Fraud Strike Force efforts led to charges being filed against 255 individuals or entities, 207 criminal actions, and \$321 million in investigative receivables.¹ The Strike Force's June 2016 nationwide takedown alone ensnared 301 individuals, including 61 doctors, nurses, and other licensed medical professionals, for their alleged participation in health care fraud schemes involving approximately \$900 million in false billings.² Former Attorney General Loretta Lynch and former HHS Secretary Sylvia Burwell lauded the takedown as the largest in history, both in terms of the number of defendants charged and loss amount.³ In total, OIG reported recoveries of nearly \$5.7 billion in both audit and investigative receivables,⁴ surpassing by over \$2 billion the recoveries that were obtained during FY 2015.⁵

Despite these impressive statistics, the latest available data from the U.S. Department of Justice (DOJ) show that the government reported only 626 new health care fraud prosecutions for FY 2016.⁶ Although this number is up 0.6% over the past fiscal year, which saw a total of 622 prosecutions, it reflects a nearly 50% decrease from five years ago, when there were 1,235 federal health care fraud prosecutions.

Before the June 2016 Strike Force takedown, FY 2016 had been on pace to have the fewest number of federal health care fraud prosecutions in 16 years.⁷

There may be fewer prosecutions these days, but the cases are arguably bigger and more complex, particularly those involving alleged violations of the federal Anti-Kickback Statute (AKS), which broadly prohibits giving or receiving anything of value in exchange for referrals of federal health care program business. While kickbacks are nothing new, and have been the subject of federal criminal prosecution for the last four decades, the growing complexity of health care business relationships has led to more opportunities for improper influence and fraud, which in turn has led to progressively novel applications of the AKS to what were once considered routine business arrangements and transactions. Conventional kickback schemes involving straightforward cash payments in exchange for patient referrals, though still alive and well, have given way to cases targeting more elaborate physician-vendor arrangements that could conceivably come within one of the statute's safe harbor provisions. Modern day AKS cases typically involve payments made under management, consulting, and speaking agreements, services contracts, physician compensation and recruitment arrangements, and facility rental arrangements, among others, which enforcement authorities increasingly view as illegal remuneration cloaked in false legitimacy.

Although the government has traditionally aimed its sights on the hospitals, labs, pharmaceutical companies, and medical device manufacturers who pay for referrals, the physicians on the other side of the transaction are now finding themselves under equally close scrutiny as the government steps up efforts to deliver on its promise—made in OIG's June 2015 Fraud Alert, which warned physicians that they could be prosecuted for entering into payment agreements that violate the AKS, and echoed in last September's Yates Memo, which announced an increased focus on individual liability—to go after providers and not merely the companies that pay them.⁸

Several recent prosecutions reflect this enforcement trend. In a highly publicized case out of the District of New Jersey, 43 individuals, including 29 physicians, have been convicted of accepting or soliciting kickbacks from Biodiagnostic Laboratory Services (BLS) in exchange for referring patient blood specimens to BLS. Although virtually all of the individuals entered guilty pleas, one of the physicians who had been charged in connection with his role in the scheme, Bernard Greenspan, took his chances at trial and was convicted by a jury on March 6, 2017 on all ten counts of the indictment.⁹ The evidence at trial showed that Greenspan received bribes, paid not only in cash but in the form of payments under sham rental, services, and consultant agreements, totaling approximately \$200,000 from BLS employees and associ-

ates. In exchange, BLS received from Greenspan referrals that generated approximately \$3 million in lab business.

In other cases involving physician/provider liability under the AKS, the medical director of a Miami clinic was sentenced on April 18, 2016 to nine years in prison and ordered to pay \$30 million in restitution after pleading guilty to receiving kickbacks in exchange for prescribing home health care and other services for Medicare beneficiaries that were either not medically necessary or not provided.¹⁰ In June 2016, a Texas chiropractor was sentenced to 14 years in prison and ordered to pay nearly \$18 million in restitution after pleading guilty to soliciting and receiving millions in kickbacks from pharmacies, hospitals, and ambulatory surgical centers, in return for referring patients to those providers for medical items and services, including prescription drugs and surgeries.¹¹

And while the former president of Warner Chilcott's pharmaceutical division, W. Carl Reichel, was acquitted in June 2016 of conspiring to pay kickbacks to doctors to induce them to prescribe the company's drugs, Dr. Rita Luthra, a gynecologist who had prescribed osteoporosis medications manufactured by Warner Chilcott to her patients, was indicted in a related case in late 2015 for allegedly accepting \$23,500 in meals and speaker fees from the company.¹² Although no other doctors have been charged in the case thus far, the indictment of Dr. Luthra, notwithstanding the relatively small amount of money she allegedly received, sends a clear message that the government intends to pursue the doctors who improperly profit from their relationships with drug manufacturers and other vendors.

The Warner-Chilcott case is, of course, noteworthy for a variety of reasons, not the least of which is because it dealt a significant blow to the government in one of its first post-Yates Memo prosecutions of an individual health care executive. In October 2015, the pharmaceutical company entered into a global settlement with the government resolving allegations that it illegally marketed prescription drugs for the treatment of osteoporosis.¹³ As part of the settlement, a Warner Chilcott subsidiary pled guilty to a felony count of paying kickbacks to physicians through medical education events and speaker programs to induce them to prescribe its drugs.¹⁴ The company further agreed to pay \$125 million in settlement of both criminal charges and a parallel civil False Claims Act suit.¹⁵

But the government did not stop there. The day before the global resolution was announced, a federal grand jury returned a one-count indictment charging Reichel with conspiring to pay kickbacks to physicians.¹⁶ According to the indictment, Reichel instructed Warner-Chilcott's sales force to take physicians to expensive dinners and to pay them fees for giving medical-education speeches to other doctors, which, the government contended, were more social than instructive, for the purpose of inducing physicians, like Dr. Luthra, to prescribe the company's osteoporosis drugs. The government's evidence showed that in total, Warner Chilcott paid nearly \$25 million in speaker fees and picked up the tab for over 200,000 physician dinners.

Reichel was found not guilty following a three week trial featuring testimony from numerous former members of



Warner Chilcott's sales force, who described the company's aggressive sales tactics under Reichel's reign. Importantly, the court instructed the jury that Reichel could not be convicted of conspiring to violate the AKS "merely because he sought to cultivate a business relationship or create a reservoir of goodwill that might ultimately affect one or more purchase or order decisions." Instead, it was the government's burden to prove that at least one purpose of the speaker fees and medical education programs was "to effect a quid pro quo transaction of payments of remuneration for order or purchase of drugs." The court further instructed the jury that because an essential element of an AKS violation is that it be undertaken knowingly and willfully, "good faith on the part of the defendant is a complete defense," that is, "however intentional the conduct may have been, the law is not violated if the defendant acted in good faith and held an honest belief that his actions were proper and not in furtherance of some illegal venture." The jury ultimately found that the government had not met its burden of proving that Reichel acted with a guilty mind.

The jury's verdict in the Reichel case underscores the difficulty of proving criminal intent on the part of individual executives, especially where the misconduct was carried out by those in lower-level positions. It also may reflect the

reluctance of juries to find individuals criminally accountable for corporate wrongdoing, particularly since decision making often is diffuse within an organization. This may be why, in another high-profile prosecution in the District of Massachusetts, a jury on July 20, 2016 acquitted two former medical-device company executives, William Facticeau and Patrick Fabian, on more than a dozen felony counts of fraud related to the marketing and distribution of a medical device for uses not approved by the FDA, but convicted them on ten misdemeanor counts—based on the same conduct—for which no finding of criminal intent was required.¹⁷

While criminal prosecutions of executives like Reichel, Facticeau, and Fabian are not necessarily new and likely would have been undertaken with or without the Yates Memo, the current surge in prosecutions of individual physicians in addition to the hospitals and other vendors of health care services and items who pay them does appear to mark a new trend in health care enforcement that has been emerging over recent years and shows no signs of slowing. Given the scope and magnitude of potential liability under the AKS, and the government's demonstrated commitment to investigating and criminally prosecuting potential violations, physician-vendor relationships have never been more fraught with peril.

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- 1 See U.S. Department of Health & Human Services Office of Inspector General, Semi-Annual Report to Congress (April 1–September 30, 2016), available at <https://oig.hhs.gov/reports-and-publications/archives/semiannual/2016/sar-fall-2016.pdf>.
- 2 See June 22, 2016 DOJ Press Release, available at <https://www.justice.gov/opa/pr/national-health-care-fraud-takedown-results-charges-against-301-individuals-approximately-900>.
- 3 *Id.*
- 4 See *supra* note 1.
- 5 See U.S. Department of Health & Human Services Office of Inspector General Semi-Annual Report to Congress (April 1 – September 30, 2015), available at <https://oig.hhs.gov/reports-and-publications/archives/semiannual/2015/sar-fall15.pdf>.
- 6 See Syracuse University’s Transactional Records Access Clearinghouse (TRAC) Report on Healthcare Fraud Prosecutions for 2016, generated March 23, 2017, available at https://trac.syr.edu/cgi-secure/product/login.pl?p_series=annual&p_stat=fil&p_month=sep&p_year=16&p_procat=03G&_SERVICE=express9&_DEBUG=0&_PROGRAM=interp.annualreport.sas.
- 7 See May 2016 TRAC Report, available at <http://trac.syr.edu/tracreports/crim/424/>.
- 8 This heightened focus on individual accountability is not limited to criminal investigations and prosecutions. As Acting Associate Attorney General Bill Baer noted in his June 9, 2016 remarks at the American Bar Association’s 11th National Institute on Civil False Claims Act and Qui Tam Enforcement, while individual accountability in criminal investigations and prosecutions has received the lion’s share of attention in the year since the Yates Memo was released, “individual accountability applies with equal force and logic to the department’s civil enforcement.” Baer went on to note that, just as those who engage in white-collar fraud will be held criminally accountable, those who act on the company’s behalf to commit and profit from civil wrongs will not be “given a pass.”
- 9 DOJ, Press Release, *Bergen County Doctor Convicted of Taking Bribes in Test-Referral Scheme with New Jersey Clinical Lab* (Mar. 6, 2017), available at <https://www.justice.gov/usao-nj/pr/bergen-county-doctor-convicted-taking-bribes-test-referral-scheme-new-jersey-clinical-lab>.
- 10 DOJ, Press Release, *Miami Physician Sentenced to 108 Months in Prison for His Role in \$30 Million Health Care Fraud Scheme* (Apr. 18, 2016), available at <https://www.justice.gov/opa/pr/miami-physician-sentenced-108-months-prison-his-role-30-million-health-care-fraud-scheme>.
- 11 See DOJ, Press Release, *Austin Area Chiropractor Sentenced to 14 Years in Federal Prison for Receiving Millions in Kickbacks and Money Laundering* (June 10, 2016), available at <https://www.justice.gov/usao-wdtx/pr/austin-area-chiropractor-sentenced-14-years-federal-prison-receiving-millions-kickbacks>.
- 12 DOJ, Press Release, *Springfield Doctor Indicted in Anti-Kickback Case* (Oct. 22, 2015), available at <https://www.justice.gov/usao-ma/pr/springfield-doctor-indicted-anti-kickback-case#sthash.3N7qiLQo.dpuf>.
- 13 DOJ, Press Release, *Warner Chilcott Agrees to Plead Guilty to Felony Health Care Fraud Scheme and Pay \$125 Million to Resolve Criminal Liability and False Claims Act Allegations* (Oct. 29, 2015), available at <https://www.justice.gov/usao-ma/pr/springfield-doctor-indicted-anti-kickback-case>.
- 14 *Id.*
- 15 *Id.*
- 16 In a nod to the Yates Memo, the U.S. Attorney for the District of Massachusetts noted that Reichel’s indictment “demonstrate[d] that the government will seek not only to hold companies accountable, but will identify and charge corporate officials responsible for the fraud.” *Id.*
- 17 DOJ, Press Release, *Former Acclarent, Inc. Executives Convicted of Crimes Related to the Sale of Medical Devices* (July 20, 2016), available at <https://www.justice.gov/usao-ma/pr/former-acclarent-inc-executives-convicted-crimes-related-sale-medical-devices>.

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An Insider's Guide to Anti-Kickback Statute Prosecutions

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Over the course of 14 years as the Criminal Health Care Fraud Coordinator for the U.S. Attorney's Office for the District of Nevada, I had the opportunity to review, investigate, and prosecute a wide range of cases under the federal Anti-Kickback Statute (AKS). Since returning to private practice several months ago, I have perceived significant misconceptions on the part of health care providers, and even the health care defense bar, regarding the manner in which these cases are investigated and prosecuted. In some instances, these misconceptions border on paranoia—a deep fear that Special Agents with the Federal Bureau of Investigation (FBI) or the Department of Health and Human Services, Office of Inspector General (HHS-OIG) are lying in wait, ready to pounce on providers seek criminal sanctions for technical violations of the AKS or substantial, but not full, compliance with the statutory and regulatory safe harbors. The purpose of this article is to correct these misconceptions, and demystify the process in which allegations are reviewed, matters are investigated, and cases are indicted.

The Anti-Kickback Statute

As most fraud and abuse attorneys understand, the AKS is an extremely broad statute. It criminalizes the payment, offer, receipt, solicitation of remuneration in an effort to induce the referral of federal health care program business.¹ There are four key concepts that contribute to the breadth of the statute.

First, remuneration constitutes “anything of value.” It can take many forms, including cash payments, free rent, discounts, favorable investment terms and opportunities, and disproportionate compensation for medical directorships or consultancies.

Second, the AKS imposes liability on “whoever” engages in the prohibited conduct.² Unlike certain state analogues to the AKS, which only prohibit payments from a certain class of defendants,³ the AKS prohibits the payment, offer, receipt, solicitation of remuneration from anyone, creating a potentially limitless class of defendants.

Third, a plurality of federal circuits apply the “one purpose” test, which holds that the AKS is violated if “one purpose of the payment was to induce future referrals . . .”⁴ Even assuming there are other justifiable business reasons for an arrangement, if one purpose of the arrangement is to induce or compensate for federal program referrals, the statute is violated.

Finally, to violate the AKS, the defendant must act “knowingly and willfully.” Prior to the enactment of the Affordable Care Act (ACA) in 2010, the federal circuit courts were divided on the proper construction of the phrase “knowingly and willfully.” The majority position was that “knowingly” meant to do something voluntarily, not deliberately or by mistake or accident, and “willfully,” for purposes of the AKS, meant to do something purposely, with the intent to violate the law, or doing something purposefully that the law forbids.⁵ The Ninth Circuit, by contrast, construed the phrase “knowingly and willfully” to require the government to prove that a defendant: (1) knew the AKS prohibited offering or paying remuneration to induce referrals; and (2) engaged in prohibited conduct with the specific intent to disobey the law.⁶ The Ninth Circuit was the only court to conclude that the phrase “knowingly and willfully” in the AKS required proof of a violation of a known legal duty. The ACA eliminated this split by defining the term “willfully” to clarify that a person no longer needs actual knowledge of the AKS or a specific intent to commit a violation of the statute.⁷ The effect of the ACA was to lower the intent standard to make it easier for the government to prosecute AKS cases.

The Criminal Referral Process

It is axiomatic that the broader a statute is, the greater the discretion offered to the people responsible for enforcing that statute. So how do investigators and prosecutors exercise their discretion in deciding whether to charge AKS cases?

Let's start with the premise that every criminal indictment presented to a grand jury by an Assistant United States Attorney (AUSA) starts as a referral from a law enforcement agency, typically the FBI or HHS-OIG, but occasionally local law enforcement agencies as well. The agent receives a complaint—from a disgruntled business partner, an angry spouse, a discontented employee, or a dissatisfied customer—that allegedly illegal conduct has or is taking place. The agent receiving the complaint is responsible for vetting it initially. That vetting process may be as straightforward as conducting an interview with the complainant and attempting to verify the most basic aspects of the information provided. This is the point at which the agent (usually with input from his/her supervisor) will make a decision on whether to open an investigation formally.

Now, I've worked with, and while in private practice preceding my stint as a federal prosecutor, against some outstanding agents who are smart, hardworking, and dedicated to ferreting out crime. But the reality of the situation is that, outside some of the larger cities with reputations for robust health care fraud prosecutions, such as Boston, Philadelphia, Miami, and Los Angeles, most of the FBI agents working AKA cases are part of a larger white collar unit. Their caseload will include as many, or more, securities fraud, investment fraud, or non-health care mail/wire fraud cases, as they will AKS investigations. While hardworking

and intelligent, these agents rarely have technical expertise or mastery of the AKS and the safe harbors. The HHS-OIG agents, while equally diligent, might be more focused and better versed on billing fraud cases than AKS cases.

This impacts the types of cases that get open for investigation in a significant way. Everyone understands that it is illegal to pay for referrals. As a result, the vast majority of AKS investigations focus on blatant arrangements in which money is exchanged for referrals. A review of recent Department of Justice prosecutions tends to support this:

- As recently as December 1, 2016, the U.S. Attorney's Office for the Northern District of Texas announced an indictment against 24 people as part of a "massive bribery and kickback conspiracy." Two bariatric surgeons and three spinal surgeons received approximately \$18,000,000 in payments from the hospital and shell companies controlled by hospital insiders.⁸
- In October 2016, the U.S. Attorney's Office for the Southern District of Indiana indicted executives of a nursing home chain received kickbacks in excess of \$5.5 million from vendors seeking to do business with the nursing homes managed by the defendants.⁹
- In September 2016, the U.S. Attorney's Office for the District of Maryland indicted two physicians and the owner of a medical testing laboratory, among others, as part of a scheme in which the physicians agreed to refer

urine specimens to the lab in exchange for approximately \$1.3 million in kickbacks.¹⁰

- In June 2016, the U.S. Attorney's Office for the Southern District of New York indicted a pair of pharmaceutical company employees in connection with their participation in a scheme to pay doctors thousands of dollars, under the guise of sham educational programs, to induce the doctors to prescribe a powerful painkiller they detailed.¹¹
- In June 2016, the Middle District of Tennessee indicted a physician who accepted cash bribes from the supplier of durable medical equipment.¹²
- In October 2015, the District of Massachusetts indicted a physician for accepting cash and benefits from a pharmaceutical company in return for prescribing its drugs.¹³

These cases are perfectly consistent with the cases I prosecuted. While the schemes all take different forms, and the criminal proceeds are obtained by the defendants in financial transactions of varying complexity (from direct payments of cash to multiple transfers of money through shell corporations), they are, at their essence, blatant cash for referral arrangements. These are not complicated business transactions implicating substantial compliance with arcane portions of the safe harbors, for example. The agents investigating these cases—no matter how diligent they are—lack the inclination and the most precious commodity of all, time, to focus on anything other than the most egregious cases.





The Decision to Indict

Once a prosecutor receives a case referral from an agent, additional considerations impact her decision to indict. In making a charging decision, the initial and primary concern for federal prosecutors is whether they have sufficient evidence to prove each element of a crime beyond a reasonable doubt. For white collar prosecutors, such as health care prosecutors, the focus almost always is on whether they can prove the intent element—in the case of the AKS, whether the defendant acted “knowingly and willfully.” Indeed, this is the sine qua non of a health care fraud prosecution; unlike other types of crimes, like violent crime and drug offenses, there is usually little dispute over what actually happened, such as whether a payment was made. Instead, prosecutors are required to marshal facts from which a jury could infer a defendant’s criminal intent circumstantially.

Prosecutors tend to be pragmatists. They understand that, as a general rule, the more complex the business transaction: (a) the harder it will be to explain the case to a jury; and (b) the more difficult it will be to demonstrate criminal intent. No prosecutor wants to be in a position where she is arguing that a rental charge was *slightly* less than fair market value,¹⁴ or that only 20% (as opposed to 40%) of an entity’s gross revenue was generated by investors.¹⁵ She would much rather argue that space was given for free, or that ownership interests in an entity were provided at no cost, or self-financed, as a reward for referrals. “Something for nothing” is both a phrase that every juror understands and one that leaves a criminal defendant with little room for explanation.

Lessons Learned

The point of this article is not to suggest that the health care industry has *carte blanche* to disregard the AKS’s prohibitions, or that we, as attorneys, should be anything less than incredibly meticulous when advising clients or helping to structure arrangements. Leaving aside any civil or administrative exposure (both of which are genuine deterrents to risky conduct, albeit with somewhat less severe consequences), we need to be reminded that an incredibly small subset of AKS cases are referred for criminal prosecution, and those that are will be, by and large, the most egregious examples of remuneration for referrals.

1 42 U.S.C. § 1320a-7b(b).

2 *Id.* at § 1320a-7b(b)(1).

3 For example, the Nevada Anti-Kickback Statute prohibits “health facilities” from offering a provider of medical care “any financial inducement . . . to induce the referral of a patient or group of patients to the health facility.” NEV. REV. STAT. § 439B.420. To the extent the entity making the financial inducement does not fall within the definition of “health facility,” NEV. REV. STAT. § 439A.015, the Nevada Anti-Kickback Statute does not apply. As a practice note, when dealing with state statutes, health care lawyers should be sensitive to the fact that their statute may not apply to the type of provider they are representing, even if the conduct arguably falls within the scope of the statute.

4 *United States v. Greber*, 760 F.2d 68, 69 (3d Cir. 1985), *cert. denied*, 474 U.S. 988 (1985); see *United States v. Davis*, 132 F.3d 1092 (5th Cir. 1998); *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989); and *United States v. McClatchey*, 217 F.3d 823 (10th Cir. 2000) (*reaff’d.*, *United States v. LaHue*, 261 F.3d 993 (10th Cir. 2001)).

5 *United States v. Baystate Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 33 (1st Cir. 1989).

6 *Hanlester Network v. Shalala*, 51 F.3d 1390, 1400 (9th Cir. 1995).

7 See 42 U.S.C. 1320a-7b(h); *United States v. Mathur*, 2012 WL 4742833 (D. Nev. 2012).

8 DOJ, Press Release, *Executives, Surgeons, Physicians, and Others Affiliated with Forest Park Medical Center (FPMC) in Dallas Indicted in Massive Conspiracy* (Dec. 1, 2016), available at <https://www.justice.gov/usao-ndtx/pr/executives-surgeons-physicians-and-others-affiliated-forest-park-medical-center-fpmc>.

9 DOJ, Press Release, *Former American Senior Communities executives indicted* (Oct. 12, 2016), available at <https://www.justice.gov/usao-sdin/pr/former-american-senior-communities-executives-indicted>.

10 DOJ, Press Release, *Five Defendants Face Federal Charges in Pain Management Clinic Kickback Scheme* (Sept. 22, 2016), available at <https://www.justice.gov/usao-md/pr/five-defendants-face-federal-charges-pain-management-clinic-kickback-scheme>.

11 DOJ, Press Release, *Former Pharmaceutical Company Employees Arrested For Participating In Fentanyl Kickback Scheme* (June 9, 2016), available at <https://www.justice.gov/usao-sdny/pr/former-pharmaceutical-company-employees-arrested-participating-fentanyl-kickback-scheme>.

12 DOJ, Press Release, *Hendersonville Physician Indicted on Federal Kickback Charges* (June 8, 2016), available at <https://www.justice.gov/usao-mdtn/pr/hendersonville-physician-indicted-federal-kickback-charges#sthash.aXHlnYYi.dpuf>.

13 DOJ, Press Release, *Springfield Doctor Indicted in Anti-Kickback Case* (Oct. 22, 2015), available at <https://www.justice.gov/usao-ma/pr/springfield-doctor-indicted-anti-kickback-case>.

14 42 C.F.R. § 1001.952(b)(5).

15 *Id.* at § 1001.952(a)(2)(vi).

A wide-angle photograph of the Golden Gate Bridge in San Francisco, California. The bridge's iconic red-orange towers and suspension cables are prominent, stretching across the frame from the left towards the right. The bridge spans a deep blue body of water, with a small white boat visible in the lower right. In the background, the city of San Francisco is visible on the hills under a clear blue sky with some light clouds. The overall scene is bright and scenic.

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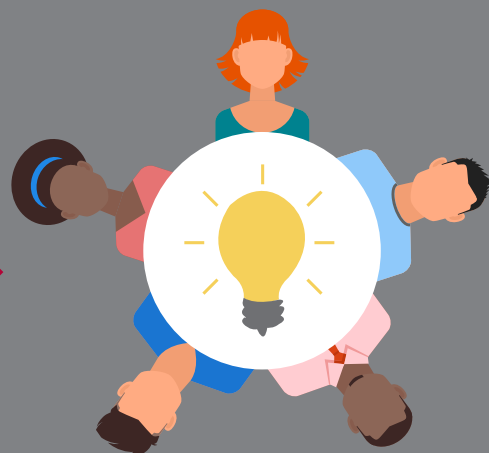
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