HEALTH LAW CONNECTIONS

OFFICIAL MAGAZINE OF AMERICAN HEALTH LAW ASSOCIATION

August 2020 Volume 1 | Issue 5

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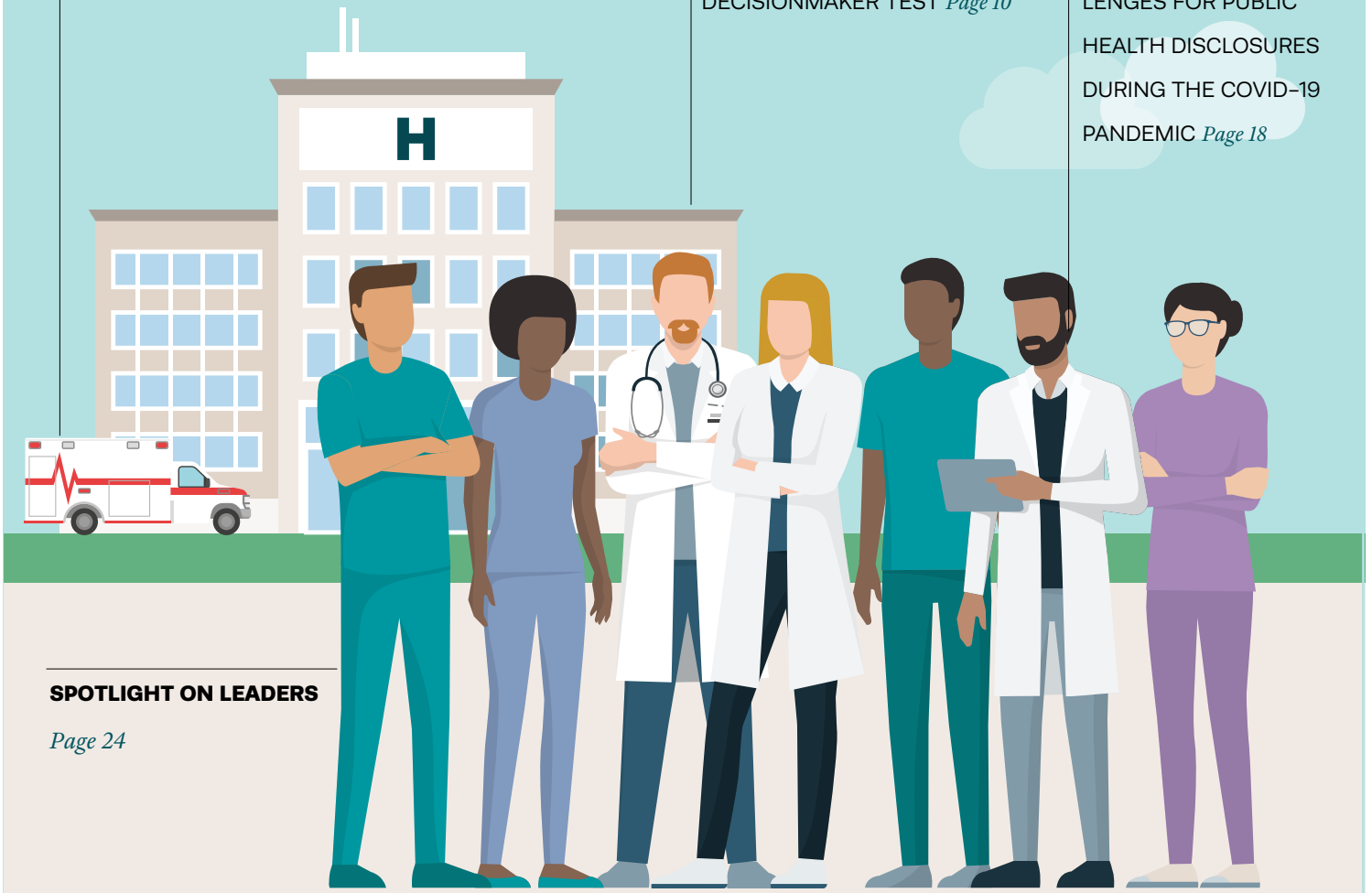

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Feature

Reining in the Anti-Kickback Statute? Commission-Based Payments and the Relevant Decisionmaker Test

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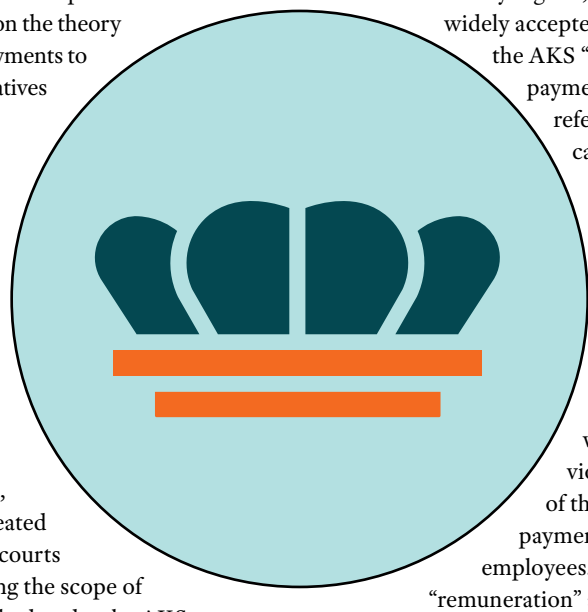
Over the last number of years, the federal Anti-Kickback Statute (AKS)[1] has solidified its place as one of the federal government's most useful tools in health care fraud and abuse prosecutions, both criminal and civil. This is especially true when it comes to investigations involving entities that rely on sales representatives to market their products and services, such as pharmacies, laboratories, and home health agencies. In recent years, the federal government has prosecuted dozens of entities and individuals on the theory that commission-based payments to these marketing representatives are unlawful kickbacks in violation of the AKS.



From this enforcement landscape have arisen a number of federal court opinions discussing the scope of the AKS and what type of arrangements the statute was designed to prohibit. This article discusses the "relevant decisionmaker" test, which the Fifth Circuit created in 2004 and various other courts have considered in deciding the scope of conduct that can be punished under the AKS.

The AKS: A Brief Primer

The AKS makes it a crime to "knowingly and willfully" solicit, receive, offer, or pay, any remuneration in return for the furnishing or arranging for the furnishing of, or the purchasing, leasing, or ordering of, any item, service, good, or facility for which payment may be made in whole or in part under a federal health care program.[2] Criminal violations of the AKS can result in prison sentences of up to ten years and fines of up to $100,000.[3] In addition to criminal penalties, violations of the AKS can result in civil damages and penalties under the federal False Claims Act (FCA)[4] and administrative liability such as civil monetary penalties and exclusion.[5]

According to the U.S. Department of Health and Human Services Office of Inspector General (OIG), one of the purposes of the AKS "is to protect patients from inappropriate medical referrals or recommendations by health care professionals who may be unduly influenced by financial incentives."[6] The government has consistently argued, and federal courts have widely accepted, that a payment violates the AKS "if even one purpose of the payment is to induce or reward referrals of Federal health care program business."[7]

The AKS contains various safe harbors, which serve as exceptions to the prohibitions contained in the statute.[8] If an arrangement fits squarely within a safe harbor, it will not be considered a violation of the AKS. One of those safe harbors covers payments made to bona fide employees. Specifically, the term "remuneration" as used in the AKS does not include "any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer."[9] Another AKS safe harbor covers "personal services and management contracts." Under that safe harbor, prohibited "remuneration" does not include a payment made by a principal to an agent as compensation for the services of the agent, so long as certain standards are met including, among other requirements, that the agreement be set out in a writing and signed by the parties, is for not less than one year, and the aggregate compensation paid to the agent is consistent with fair market value and "is not determined in a manner that takes into account the volume or value of any referrals or business otherwise

generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs."[10]

AKS Prosecutions Involving Commission–Based Payments

Because payments made in exchange for federal health care program referrals implicate the AKS, and because various types of health care entities, such as home health agencies, hospices, pharmacies, and laboratories, often pay individuals on a commission basis for marketing/sales activities, it is not surprising that these types of arrangements are often the subject of enforcement actions. Entities can attempt to avoid liability under the AKS by ensuring that the arrangement falls within the employment safe harbor, which requires that the marketer be a bona fide *employee* of the entity under common law rules applicable to employer-employee relationships.[11]

Absent bona fide employment,[12] however, it is challenging for these entities to ensure that payments to independent contractors fall within a safe harbor. That's because, as discussed above, the safe harbor for personal services and management contracts does not apply where the compensation is determined in a manner that in any way takes into account the volume or value of referrals or business payable by a federal health care program. Put another way, if the entity pays the independent contractor in a way that takes into account the volume or value or federal health care program business (i.e., by paying the contractor a percentage of reimbursement received from the federal health care program or even a flat fee per referral), the government will likely argue that the arrangement does not qualify for safe harbor status and, if the requisite intent exists, both the payer and the payee will likely be viewed as having violated the AKS.

To illustrate this point, in an advisory opinion from 1998, OIG stated:

> Sales agents are in the business of recommending or arranging for the purchase of the items or services they offer for sale on behalf of their principals . . . any compensation arrangement between a Seller and an independent sales agent for the purpose of selling health care items or services that are directly or indirectly reimbursable by a Federal health care program potentially implicates the [AKS], irrespective of the methodology used to compensate the agent.[13]

Eight years later, OIG reiterated its concern with these types of arrangements: "Percentage compensation arrangements are inherently problematic under the [AKS], because they relate to the volume or value of business generated between parties."[14]

Because payments made in exchange for federal health care program referrals implicate the AKS, and because various types of health care entities, such as home health agencies, hospices, pharmacies, and laboratories, often pay individuals on a commission basis for marketing/sales activities, it is not surprising that these types of arrangements are often the subject of enforcement actions.

For these reasons, as one can see by reviewing the cases cited below, the government has initiated a number of investigations and prosecutions under the AKS where an entity pays an independent sales representative on a referral-based commission.

The Relevant Decisionmaker Test

These AKS prosecutions based upon commission-based payments to marketers have led to the development of case law on the issue of the proper scope of the AKS. Specifically, can a commission-based payment to a non-physician marketer violate the AKS? If so, under what circumstances? As with most questions in the area of health care fraud and abuse, the correct answer to both questions is, of course, "it depends."

Fifth and Seventh Circuits: *Miles* and *Polin*

The seminal case is *United States v. Miles*, which the Fifth Circuit decided in 2004.[15] The defendants in *Miles* were convicted on various counts, including violations of the AKS.[16] The entity at issue in *Miles*—APRO—was a home health company that paid the defendants' marketing firm—Premier—to distribute information regarding the entity's home health services to doctors.[17] Specifically, the marketing firm would deliver "literature and business cards to local medical offices" and, from time to time, "plates of cookies to doctors' offices."[18] According to the Fifth Circuit's opinion:

> When a physician determined that home health care services were needed for a patient, the physician's office might contact [the defendant], who would then furnish APRO with the patient's name and Medicare number for billing purposes. APRO paid Premier $300 for each Medicare patient who became an APRO client as a result of Premier's efforts.[19]

The government claimed that APRO's payments to Premier constituted unlawful kickbacks in violation of the AKS, and the defendants were convicted.[20] It

was not disputed that "APRO's payments to Premier were based on the number of Medicare patients that APRO secured from Premier's activities."[21] The Fifth Circuit stated that the "only issue in dispute is whether Premier's activities constituted referrals within the meaning of the statute."[22]

The defendants in *Miles* argued that they could not have violated the AKS because Premier "never actually referred anyone to APRO, but simply engaged in advertising activities on behalf of APRO."[23] They argued that the AKS was "designed to ensure that a doctor's independent judgment regarding patient care is not compromised by promises of payment from Medicare service providers" and that "Premier did not unduly influence the doctors' decisions."[24]

On appeal, the Fifth Circuit agreed with the defendants, holding that there was no evidence "that Premier had any authority to act on behalf of a physician in *selecting* the particular home health care provider."[25] The Fifth Circuit cited testimony that was presented at trial that "Premier had no role in selecting the particular home health care provider but that the decision was made by the doctor's office staff from among ten agencies, including APRO."[26] The Fifth Circuit held that Premier simply supplied promotional materials to doctors and it was only *after* the doctor decided to send a patient to APRO that the doctor's office contacted Premier, which then supplied the necessary billing information to APRO and collected payment.[27] According to the Fifth Circuit, "[t]he payments from APRO to Premier were not made to the relevant decisionmaker as an inducement or kickback for sending patients to APRO."[28]

While the holding in *Miles* certainly seemed to limit the types of arrangements that could properly be considered violations of the AKS, the Fifth Circuit did acknowledge that there were certain situations "where payments to non-doctors would fall within the scope of the statute."[29] As an example, the Fifth Circuit cited the Seventh Circuit's earlier decision in *United States v. Polin*.[30] *Polin* involved payments by a pacemaker monitoring service to a pacemaker sales representative based on the number of patients that the sales representative signed up with the service.[31] In *Polin*,

> [t]he salesman's responsibilities included selling pacemakers, attending implant procedures, and making sure that patients were monitored following implantation. In fulfilling this latter responsibility, the salesman testified that when a physician decided to use an outside service, the salesman would contact a service provider and set up the monitoring for the patient. That is, the salesman would make the decision as to *which* service provider to contact for the patient.[32]

According to the Fifth Circuit, because the salesman in *Polin* was the "relevant decisionmaker and his judgment was shown to have been improperly influenced by the payments he received from the monitoring service," the Seventh Circuit properly upheld the convictions in that case.[33] But *Polin* was "simply different" from *Miles*, the Fifth Circuit held.[34] The Fifth Circuit concluded that APRO's payments to Premier were not illegal kickbacks under the AKS and reversed the defendants' convictions on those counts.[35]

Limiting the *Miles* Holding

The Fifth Circuit has since cautioned lower courts that its ruling in *Miles* should not be construed broadly. Instead, the Fifth Circuit has made clear that *Miles* "stands for a narrow legal proposition: Where advertising facilitates an independent decision to purchase a healthcare good or service, and where there is no evidence that the advertiser 'unduly influence[s]' or 'act[s] on behalf' of the purchaser,' the fact that the healthcare provider compensates the advertiser, on its own, is insufficient to support a conviction under the [AKS]."[36]

In *United States v. Shoemaker*, the Fifth Circuit appears to have significantly limited the *Miles* holding in affirming an AKS conviction.[37] Defendant Shoemaker was the Chief Operating Officer of a community hospital, and defendant Garner owned and operated a nurse staffing business. The hospital entered into a contract with Garner's nurse staffing business and the evidence presented at trial demonstrated that Garner paid the Chairman of the hospital's board of trustees (Chandler) $5 for every nursing hour his company spent at the hospital in return for Chandler ensuring that the

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hospital would continue to use Garner's company for contract nurses.[38] The evidence showed that the parties to this arrangement created false invoices to make it appear that the payments were made for accounting services.[39]

The district court granted judgments of acquittal on the AKS counts of the indictment on the grounds that there was no evidence that the payee was a "relevant decisionmaker" pursuant to the holding in *Miles*.[40] The Fifth Circuit reversed the district court, concluding that the holding in *Miles* was inapplicable. Specifically, the court held that, unlike in *Miles*, *Shoemaker* did not deal with advertising services.[41] Instead, the evidence demonstrated that the payments were designed to induce Chandler to "recommend" Garner's nursing company.[42] According to the Fifth Circuit:

> That is, in paying Chandler, Garner was not asking for a brochure bearing his company's name to be distributed to [hospital] staff; rather, enough evidence showed that he wanted Chandler to exploit his personal access to [hospital] executives, including Shoemaker, and to ensure that [the hospital] favored Garner's company when it chose nursing services. This conduct is an archetypal example of the undue influence prohibited by the statute.[43]

The court in *Shoemaker* held that the real focus of *Miles* was not on labels, but on intent; i.e., "whether the evidence could establish intent to induce 'referrals.'"[44] The court held that this focus on intent "accords with Congress's concerns in enacting the statute—to broaden liability to reach operatives who leverage fluid, informal power and influence."[45] The court in *Shoemaker* concluded that there was sufficient evidence to support a conviction for conspiring to violate the AKS and that the district court erred in granting the defendants' motion for judgment of acquittal.[46]

Eleventh Circuit: *Vernon* and *Starks*

In 2013, the Eleventh Circuit also examined the holding in *Miles* in deciding whether certain AKS convictions were proper. In *United States v. Vernon*, the defendants were convicted of health care fraud and AKS violations.[47] The defendants were executives of Medfusion, a specialty pharmacy that filled prescriptions for hemophilia medications.[48] The government in *Vernon* alleged that, in order to gain more Medicaid business, the pharmacy "made sizable payments to individuals and businesses if they would refer their hemophiliac clients to Medfusion for prescription filling."[49]

Specifically, Medfusion would pay 45% to 50% of its profits to Lori Brill, who worked as a "patient advocate" for hemophiliac patients, attending medical appointments with her clients, helping them with routine life tasks, and assisting them in filling prescriptions.[50] Brill referred her hemophilia clients to Medfusion for the filling of their medications.[51] "To retain control over where her clients filled their [hemophilia] medication prescriptions, Lori Brill continued to provide various services to her clients, serving as their patient advocate."[52]

In contrast to the lack of decisionmaking authority by the defendants in *Miles*, the evidence elicited at trial in *Vernon* demonstrated Brill's overwhelming control over her patients' decisions. For example, several of Brill's former clients testified that Brill would take them to doctors' appointments, speak with doctors on their behalf, receive prescriptions from doctors and ensure they were filled, and call her clients to ensure that they had an adequate supply of the medication on hand.[53] One former client testified that when a doctor wrote a prescription, Brill would take the prescription from the patient and bring it to the pharmacy herself, where she would have them filled.[54]

While the Eleventh Circuit in Vernon rejected the defendants' attempt to shoehorn the facts of their case into the holding of Miles, it is important to note that the Eleventh Circuit did not reject Miles' "relevant decisionmaker" test.

On appeal, the defendants in *Vernon* argued that the conduct at issue did not violate the AKS because the payments at issue were made to Brill, a non-physician who could not "refer" patients to the pharmacy within the meaning of the AKS.[55] The Eleventh Circuit rejected this argument, holding that "the plain language of the statute is not limited to payments to physicians who prescribe medication."[56] The Eleventh Circuit cited the Seventh Circuit's decision in *Polin* and held that, like the defendant in *Polin*, Brill "was effectively responsible for deciding which specialty pharmacy to use for the filling of her [] patients' prescriptions."[57] Specifically, the Eleventh Circuit said that there was "overwhelming evidence" that Brill "had the capacity to, and did, refer their hemophiliac clients to Medfusion" for the filling of prescriptions.[58] In fact, the Eleventh Circuit noted that some of Brill's clients "did not even know which pharmacy filled their prescriptions because they gave control of that decision to Lori Brill."[59] The fact that Brill could not herself prescribe the medication was irrelevant, according to the Eleventh Circuit.[60]

Although the holding in Miles has not been expressly overruled by the Fifth Circuit, and has not been expressly rejected by any other circuit, it has certainly been limited.

In support of its decision, the Eleventh Circuit in *Vernon* also cited its earlier decision in *United States v. Starks*.[61] The court noted that, in *Starks*, it had affirmed AKS convictions based on payments made by a non-physician director of a drug addiction treatment center to two "community health aides" working for a nonprofit agency that advised pregnant woman about drug abuse treatment.[62] The community health aides, neither of whom were physicians, and neither of whom could prescribe treatment, were paid $250 for each patient that they referred to the treatment center.[63]

The Eleventh Circuit in *Vernon* rejected the defendants' reliance on *Miles*, holding that the facts in *Miles* were "materially different" from the facts in *Vernon*.[64] Unlike the defendants in *Miles*, the Eleventh Circuit held, Medfusion's payments *were*, in fact, made to the "relevant decisionmaker," Lori Brill, who had her own personal relationships with her clients "and decided where to fill her clients' prescriptions."[65]

While the Eleventh Circuit in *Vernon* rejected the defendants' attempt to shoehorn the facts of their case into the holding of *Miles*, it is important to note that the Eleventh Circuit did *not* reject *Miles*' "relevant decisionmaker" test. Instead, the Eleventh Circuit simply held that, even under that test, the conduct at issue fell within the purview of the AKS. The court in *Vernon* left open the possibility that it might adopt the relevant decisionmaker test to strike down a conviction in a case where the payments at issue were made to someone who did not exercise control over where referrals were sent.

District Court Decisions Distinguishing *Miles*

A number of federal district courts outside of the Fifth Circuit have cited, and distinguished, the *Miles* holding in opinions discussing the scope of conduct that falls within the purview of the AKS.

In *United States v. Krikheli*, for example, the defendant was charged with violating the AKS by personally, or through intermediaries, arranging for patients to be referred to a radiological testing facility in exchange for payments to the referring doctors and the defendant.[66] According to the government, the defendant arranged for doctors to send patients to the facility in exchange for monetary kickbacks.[67] At first, the defendant made these arrangements himself but at some point, he began to do so through two intermediaries, continuing to receive a commission for each referral arranged by the intermediaries.[68]

Krikheli moved to dismiss the charges against him, in part based on the relevant decisionmaker holding from *Miles*.[69] He argued that "only the doctors were decision-makers under the circumstances of their cases, and that 'any parts of the indictment alleging unlawful payments to non-doctors . . . must be dismissed."[70]

The district court in *Krikheli* rejected this argument. The court held that even if it were to apply the relevant decisionmaker test, it would not help the defendant because there was nothing to suggest that the defendant was "providing advertising or public relations services of the sort provided . . . in *Miles*."[71] Instead, the evidence showed that payments were made to doctors to induce them to refer patients to the facility and the fact that the defendant may have used intermediaries was not relevant since the AKS prohibits both direct and indirect payments.[72]

The district court in *United States v. George* also rejected a *Miles*-based argument.[73] The defendant in *George* owned a referral agency that entered into a written agreement with a home health company which, in part, called for the defendant's agency to "[v]isit doctors, hospital case managers, discharge planners or social workers and convince them to refer patients to the [home health company.]"[74] The defendant's agency received payment for these referrals.[75]

At a bench trial, the defendant argued that the arrangement in question was not covered by the AKS, citing *Miles, Polin,* and *Vernon*.[76] The district court in *George* distinguished the defendant's actions from the actions of the defendants in *Miles*. Specifically, the court held that George referred specific patients to the

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home health company, "effectively telling the patients to go there for home health services."[77] The district court in *George* also rejected the defendant's argument that the arrangement fell within the personal services and management contracts safe harbor.[78] Because the defendant was paid on a "per-patient basis," the compensation took into account the "volume of referrals" and, therefore, did not qualify for safe harbor status.[79]

Similarly, in *United States v. Iqbal*, the defendant, who managed a large number of medical practices, was charged with violating the AKS by attempting to enter into a "50/50 profit sharing" arrangement with a home health agency in exchange for referrals.[80] The government alleged that the primary purpose of the arrangement was "to induce the referral of patients insured by Medicare or Medicaid."[81] After a bench trial, the district court concluded that the government had met its burden of proving that Iqbal solicited remuneration "in the form of 50% of the profits generated by patients for whom he arranged referrals" and that "[t]he payments solicited were for the purpose of inducing" the referrals.[82]

Iqbal cited *Miles* and argued that he could not have violated the AKS because there were no payments to a "relevant decisionmaker."[83] The district court rejected this argument. First, the district court noted that *Miles* was subsequently "limited to its facts" by *Shoemaker*.[84] The district court also noted that Iqbal represented to the home health agency that he "could cause the doctors to make the referrals, and would do so if [the agency] agreed to pay him a share of the profits."[85] According to the court in *Iqbal*, "[t]his is a clear payment based on the value of the referrals, which is a violation of the law."[86]

The district court in *Iqbal* also noted that the Eighth Circuit had not followed *Miles*, but cited an Eighth Circuit opinion from 1996—*United States v. Jain*—affirming an AKS conviction "where the defendant had attempted to shield his receipts of kickbacks for referrals by using a contract purporting to pay him for non-existent marketing services."[87] The court concluded that the situation in *Jain* was very similar to the situation in *Iqbal* and that because Iqbal stated that he could influence referrals, the government had met its burden.[88]

The Current Viability of the Relevant Decisionmaker Test

Although the holding in *Miles* has not been expressly overruled by the Fifth Circuit, and has not been expressly rejected by any other circuit, it has certainly been limited.

In light of *Shoemaker* and other subsequent decisions, it is clear that the Fifth Circuit would be reluctant to apply the holding of *Miles* unless the facts are nearly identical to the facts at issue in that case. The same is true for other circuits, including the Seventh and Eleventh. Specifically, *Miles* appears to be viable only where payments were made to marketers who had no ability to influence where referrals were sent. By contrast, if the payee has the ability to exert such influence, such as through personal relationships with the referral source (as in *Shoemaker*) or through control over the patient (as in *Vernon*), courts will likely be reluctant to apply the holding in *Miles*.

Conclusion

The federal government continues to bring enforcement actions, both criminal and civil, against entities and individuals that enter into commission-based payment arrangements. Although courts around the country seem to have substantially limited the holding of *Miles* and have consistently distinguished factual patterns from the facts at issue in *Miles*, it is important for any defense lawyer representing a client in such an action to analyze the arrangement at issue, compare it with the arrangement at issue in *Miles*, and consider, where appropriate, moving to dismiss AKS charges where payments are made to individuals who cannot be considered "relevant decisionmakers."

Endnotes

1. 42 U.S.C. § 1320a–7b(b).
2. *Id.*
3. *Id.* Until February 2018, the maximum sentence for a violation of the AKS was five years in prison and $25,000. The Bipartisan Budget Act of 2018, signed into law on February 9, 2018, increased these criminal penalties to their current levels.
4. 31 U.S.C. § 3729 *et seq*. The AKS expressly states that, in addition to the penalties provided for by the AKS itself, a claim to a federal health care program that includes items or services "resulting from" a violation of the AKS constitutes a "false or fraudulent claim" for purposes of the FCA.
5. 42 U.S.C. § 1320a–7a.
6. OIG Special Fraud Alert: Laboratory Payments to Referring Physicians, June 26, 2014, https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/OIG_SFA_Laboratory_Payments_06252014.pdf.
7. *Id. See also United States v. Borrasi*, 639 F.3d 774, 776 (7th Cir. 2011) (adopting "one purpose rule"); *accord United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989); *United States v. McLatchey*, 217 F.3d 823, 835 (10th Cir. 2000).
8. 42 C.F.R. § 1001.952.
9. *Id.* § 1001.952 (i).
10. *Id.* § 1001.952 (d).
11. *Id.* § 1001.952 (i) and 26 U.S.C. § 3121(d)(2).
12. Importantly, while not the subject of this article, clinical laboratories will also have to contend with the Eliminating Kickbacks in Recovery Act, 18 U.S.C. § 220 (EKRA). EKRA prohibits essentially the same conduct as the AKS, but is broader in two very important respects. First, EKRA applies to payments that vary based on the volume or value of referrals, whether those payments are made to an employee or an independent contractor. *Id.* § 220(b)(2). Second, EKRA applies to both federal health care programs and commercial health plans. *Id.* § 220(a)(1). EKRA is narrower than the AKS in one respect—it applies only to referrals to clinical laboratories, clinical treatment facilities, and recovery homes. *Id.*
13. OIG Advisory Opinion No. 98-10, https://oig.hhs.gov/fraud/docs/advisoryopinions/1998/ao98_10.htm.
14. OIG Advisory Opinion No. 06-02, https://oig.hhs.gov/fraud/docs/advisoryopinions/2006/ao0602.pdf.
15. 360 F.3d 472 (5th Cir. 2004).
16. *Id.* at 474.
17. *Id.* at 479.
18. *Id.*
19. *Id.*
20. *Id.*
21. *Id.* at 480.
22. *Id.*
23. *Id.*
24. *Id.*
25. *Id.* (emphasis in original).
26. *Id.*
27. *Id.*
28. *Id.*
29. *Id.*
30. 194 F.3d 863 (7th Cir. 1999).
31. *Miles*, 360 F.3d at 480 (citing *Polin*, 194 F.4d at 864–65).
32. *Id.* (emphasis in original).
33. *Id.* at 481.
34. *Id.*
35. *Id.*
36. *United States v. Crane*, 781 Fed. App'x 331, 334–35 (5th Cir. 2019).
37. 746 F.3d 614 (5th Cir. 2014).
38. *Id.* at 617.
39. *Id..*
40. *Id.* at 626.
41. *Id.* at 628–29.
42. *Id.* at 629.
43. *Id.*
44. *Id.*
45. *Id.* at 629–30.
46. *Id.* at 630–31.
47. 723 F.3d 1234, 1240–41 (11th Cir. 2013).
48. *Id.* at 1241.
49. *Id.*
50. *Id.* at 1245.
51. *Id.*
52. *Id.*
53. *Id.* at 1245–46.
54. *Id..* at 1246.
55. *Id.* at 1254.
56. *Id.*
57. *Id.*
58. *Id.*
59. *Id.*
60. *Id.*
61. 157 F.3d 833 (11th Cir. 1998).
62. *Vernon*, 723 F.3d at 1255 (citing *Starks*, 157 F.3d at 835–37).
63. *Id.*
64. *Id.* at 1255.
65. *Id.*
66. 2009 WL 4110306, No. 08-CR-528, at *1 (E.D.N.Y. Nov. 24, 2009).
67. *Id.*
68. *Id.*
69. *Id.* at *4.
70. *Id.*
71. *Id*. at *6.
72. *Id.*
73. 171 F. Supp. 3d 810 (N.D. Ill. 2016).
74. *Id.* at 812.
75. *Id.*
76. *Id.* at 814.
77. *Id.*
78. *Id.* at 815.
79. *Id.* (citing 42 C.F.R. § 1001.952(d)(5)).
80. 2016 WL 520982, at * 1 (E.D. Mo. Feb. 10, 2016).
81. *Id.*
82. *Id.*
83. *Id.* at *3.
84. *Id.*
85. *Id.*
86. *Id.*
87. *Id..* (citing *United States v. Jain*, 93 F.3d 436 (8th Cir. 1996)).
88. *Id.*