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9th Circ. Decisions Help Clarify Scope Of Legal Lab Marketing

By **Joshua Robbins** (July 17, 2025, 6:14 PM EDT)

The Eliminating Kickbacks in Recovery Act, enacted in 2018, was a bombshell for the addiction treatment and diagnostic laboratory industries.

For the first time, paying commissions for sales and marketing services was treated as a potential federal felony even if the patient had private commercial insurance, rather than Medicare or Medicaid. Overnight, companies were forced to reassess their marketing and sales practices to avoid criminal exposure.

To make things worse, EKRA was for some time a virtual blank slate for the government. Although EKRA was modeled on the older Anti-Kickback Statute, the government has not issued any advisory opinions to guide compliance, and until last week, there had been only a few reported decisions interpreting EKRA, all from district courts.



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That changed with the U.S. Court of Appeals for the Ninth Circuit's July 11 decisions in *U.S. v. Schena* and *S&G Labs v. Graves*. In both cases, the court adopted the "undue influence" test developed by the U.S. Courts of Appeals for the Fifth and Seventh Circuits in AKS cases.

As the Ninth Circuit held, paying a percentage-based sales commission does not automatically violate EKRA. Rather, there would only be a violation if the marketer receiving the commission exercised effective control over where the patient was treated, stepping into the shoes of the treating physician or other healthcare provider.

But the court left a cautionary note as well: A marketer can exercise undue influence over doctors' ordering decisions, and thus violate EKRA, by giving them misleading information. And the court warned that the line between legal marketing payments and illegal referrals can still be murky in a number of cases.

EKRA's Ambiguity: What Is "Inducement of a Referral"?

In relevant part, EKRA makes it illegal to "pay or offer any remuneration ... to induce a referral of an individual to a recovery home, clinical treatment facility or laboratory." A single violation carries a potential sentence of 10 years in prison.

But what does it mean to induce a referral of a patient? Paying a doctor to direct a blood sample to a particular lab or an addiction patient to a particular provider would presumably qualify. But what about paying an advertising firm, on a per-admission basis, to place promotional videos on social media?

Anti-Kickback Statute Cases and the Undue Influence Test

The same issues had arisen over several decades of AKS cases, which involve payments to induce referrals of patients covered by Medicare or other federal insurance programs.

In *U.S. v. Polin*, decided by the Seventh Circuit in 1999, for example, a pacemaker monitoring company, Center for Vascular Studies, paid a sales representative based on the volume of patients he

persuaded doctors to order monitoring services for.

The court found that these payments were for illegal referrals based in part on the fact that over a 14-year period, no doctor had ever declined to follow the rep's recommendations. In effect, the rep had become the de facto clinical decision-maker.

Similarly, in *U.S. v. Shoemaker*, decided by the Fifth Circuit in 2014, the owner of a nurse staffing business paid the chairman of a hospital's board \$5 for each nursing hour his company billed at the hospital, and the chairman passed on a portion of the funds to the hospital's CEO. Because the chairman and CEO had undue influence over the decision to hire the nursing staff, the court found that the payments were made to induce referrals.

By contrast, in *U.S. v. Miles*, decided by the Fifth Circuit in 2004, a Medicare-certified home healthcare provider hired a marketing firm — and paid on a per-patient basis — to create and distribute promotional materials to physician offices and to organize informational lunches about the provider's services.

The court held that because there was no evidence that the marketers had any strong influence over the doctors' decisions, their services were simply ordinary marketing rather than referrals.

More recently, in *U.S. v. Marchetti*, decided by the Fifth Circuit last year, the court drew a line between forms of legal and illegal marketing within the same case.

In that case, a laboratory first paid a marketer on a revenue-generated basis to run ad campaigns and manage marketing strategies. Later, his role changed to involve actively determining which of two different laboratories would receive which patients' samples.

The court held that the first phase involved legal marketing, but the second phase crossed the line into illegal referral payments, because the marketer exerted direct control over the service orders, rather than merely providing information to the clinical decision-makers.

The Ninth Circuit Applies the Undue Influence Test to EKRA

In *S&G Labs v. Graves*, a lab paid a marketer on commission for managing various accounts with hospitals and doctors, who referred samples to the lab for testing and billing.

The marketer's responsibilities included cultivating relationships with these providers, arranging test orders and overseeing others who performed similar functions.

Eventually, the marketer had a dispute with the lab regarding his compensation. The lab claimed that because the marketer's contract provided for a commission directly tied to the sales revenue from the accounts, it violated EKRA, and thus was unenforceable.

In *U.S. v. Schena*, a lab owner hired marketers to convince doctors to send patients' blood samples to the lab, allegedly by making misleading claims about the lab's capabilities.

The two cases were argued on the same day before the same Ninth Circuit panel, consisting of U.S. Circuit Judges Sydney Thomas, Daniel Bress and Ana de Alba. And on July 11, the panel issued decisions in both cases; a published opinion in *Schena* and an unpublished memorandum in *S&G Labs*.

The court's analysis drew directly from the principles set out in the earlier AKS cases. After reviewing *Miles*, *Shoemaker* and *Marchetti*, the court held that the term "induce" in EKRA should be interpreted as it was in the older statute.

Based on that history, the court noted that "we do not think the mere fact of a percentage-based marketing arrangement, without more, would constitute a per se violation of EKRA"; indeed, it pointed out that the government had agreed with that position.

As the court observed, "[a]ll marketing efforts are intended to influence the recipient. ... [W]e are hard pressed to read EKRA to criminalize (with major federal penalties) a standard payment structure

for marketing personnel, even when the marketing personnel are persuasive in driving business."

Instead, the court adopted the AKS cases' undue influence test, asking whether the marketer had crossed the line from merely providing information to usurping the decision-making role of doctors and other clinicians.

In S&G Labs, the court held that there was no evidence of such influence, and the mere fact of percentage-based compensation did not entail an EKRA violation.

By contrast, in Schena, the court said, the marketer had misled doctors about the speed and efficacy of the lab's tests, along with other information, and there was testimony that the marketer effectively controlled which lab a sample would be sent to. That was enough, the court said, for a jury to find that the lab had paid to induce referrals.

At the same time, the court said that it would be for future cases to establish more precisely which circumstances would and would not amount to unlawful referral arrangements.

Thus, the court suggested, companies subject to EKRA "may consider whether it is preferable to structure their compensation arrangements in accordance with the statute's safe harbor."

Takeaways for Labs and Addiction Treatment Providers

The Schena and S&G Labs decisions provide extremely useful guidance for companies subject to EKRA who want to market both effectively and legally. The undue influence test, and the case studies in how courts have applied it, helps to show how providers can mitigate enforcement risk.

Structuring Marketing Relationships to Preserve Independence

Maintain clear separation between marketing and clinical decisions.

Also, ensure marketers have no authority to direct where patients receive treatment.

It's also important to document that healthcare providers retain complete discretion over referrals, and avoid giving marketers access to clinical systems or decision-making processes.

Use true advertising models, following Miles. Focus on information dissemination rather than patient steering: distribute materials, host educational events and run digital campaigns.

Keep marketing activities transparent and arms-length from providers, and avoid exclusive or special relationships with specific providers.

Manage compensation structures carefully, and consider flat-fee or hourly compensation for marketing services.

If using success-based fees, try to ensure they're tied to legitimate advertising metrics like impressions and clicks, rather than patient admissions. If possible, avoid per-patient or per-test compensation that directly correlates with healthcare services provided.

Avoiding Red Flags

Maintain control over the referral practice, and don't let marketers make decisions about where patients go.

Avoid situations where marketers' recommendations are automatically followed, and don't use marketers as intermediaries who direct patient flow.

Keep an eye on undue influence indicators. Track and document referral patterns — notably high acceptance rates suggest potentially problematic influence.

Avoid paying through intermediaries to influence decision-makers, and don't create financial incentives for specific individuals to steer patients.

Beware deceptive practices. Be transparent about financial relationships, don't disguise marketing payments as consulting or accounting fees, and avoid arrangements that participants feel need to be hidden.

Best Practices

Documentation should be thorough.

Create clear written agreements defining marketing services, document the legitimate business purpose of all payments and maintain records showing providers' independent decision-making.

Training and compliance protocols are important as well.

Train marketing staff on the line between information and influence, establish clear policies about marketer-provider interactions, and conduct regular audits to ensure marketing activities stay within bounds.

When in doubt, consider that a marketing arrangement that feels like it needs to be concealed, as in *Polin*, it is likely problematic.

Consider whether the marketer is truly adding value through advertising/information or just serving as a conduit for payments. Question whether the healthcare provider maintains genuine discretion, or has the marketer become the real decision-maker?

Upshot

We now have the first federal circuit opinion interpreting EKRA and providing guidance on its key terms. This could dramatically affect marketing practices for addiction treatment facilities and laboratories nationwide.

The Ninth Circuit has also further clarified these terms for AKS purposes, potentially influencing healthcare marketing across all sectors. Once again, the undue influence test has prevailed: Marketing remains legal as long as healthcare providers retain genuine discretion over referrals.

For the healthcare industry, this further illumination is a welcome development. The line between aggressive marketing and federal prison has just become a good deal easier to draw.

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