RIGHT-SIZING INFLATION IN ANTI-KICKBACK LAW RHETORIC: AVOIDING UNNECESSARY MARKET DISTORTION IN COMMISSIONS ON MEDICAL DEVICE SALES

THOMAS N. BULLEIT*

> *We, of course, recognize that many of these advertising and marketing activities do not warrant prosecution in part because (1) they are passive in nature, i.e., the activities do not involve direct contact with program beneficiaries, or (2) the individual or entity involved in these promotions is not involved in the delivery of health care.*[1]

"Commissions are the payments prohibited by the Anti–Kickback statute and may be referred to at times as 'kickbacks.' There is no distinction . . . between a commission and a kickback."[2]

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* Mr. Bulleit recently retired from an almost 40-year legal career that included three terms as Chair of the D.C. Bar Health Law Section, and the last decade as head of the D.C. Health Care Practice of Ropes & Gray, LLP. In addition to extensive trade press writings, he has published in *The St. Mary's Journal of Legal Malpractice and Ethics, The Journal of Health & Life Sciences Law*, *The Food & Drug Law Journal*, and *Developmental Psychology*. He is a *cum laude* graduate of Yale College and received his J.D. from the University of Michigan Law School, where he was Article and Symposium Editor of the *Journal of Law Reform* and received the Louis Honigman Award for Greatest Contribution to the *Journal*, before clerking on the Sixth Circuit for the Hon. Bailey Brown. Mr. Bulleit would like to thank Emma Coreno, a longsuffering associate at Ropes & Gray, for her assistance (and perseverance) in the preparation of this article.

1. Medicare and State Health Care Programs: Fraud and Abuse & OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952, 35974 (July 29, 1991) (to be codified at 42 C.F.R. pt. 1001).

2. United States v. St. Junius, 739 F.3d 193, 199 n.6 (5th Cir. 2013). In this and all of the other judicial decisions revealed by our research that express a similar view of the statute, the statements are *obiter dicta*, not part of the holding. *See also United States ex rel. Nicholson v. Medcom Carolinas, Inc.*, 42 F.4th 185, 194 (4th Cir. 2022) (absent an exception or safe harbor "commissions earned by an independent contractor based on volume or value are illegal 'remuneration' under the statute . . . . [I]t would violate the Anti-Kickback Statute . . . to pay a medical-device salesperson by commission per sale or based on the value of sales and get paid back in federal healthcare money."); United States *ex. rel.* Lutz v. Mallory, 988 F.3d 730, 735 (4th Cir. 2021) ("[T]he volume-based commissions paid by [defendant] to [consultant] and its sales contractors violated the Anti-Kickback Statute because these commissions constituted 'remuneration' intended to induce sales representatives to sell as many tests as possible."); United States v. George, 171 F. Supp. 3d 810, 817 (N.D. Ill. 2016) (citing with approval statement in "*Ultimate Guide to Home Health Marketing*": "It is common knowledge that providers *cannot pay anyone* for referring a patient for services, but this statute goes well beyond simply paying someone for a referral [and] prohibits any arrangement between a provider and another party where one purpose of the arrangement is to induce referrals."), *aff'd*, 900 F.3d 405 (7th Cir. 2018); United States v. Brown, 871 F.3d 352, 354 (5th Cir. 2017) ("Federal law forbids commission payments for referrals, as they greatly increase the incentive for fraud (that is, for recruiting patients who do not need equipment)."); United States v. Turner, 561 F. App'x 312 (5th Cir. 2014) (finding that the defendant "recei[ved] kickbacks in the form of Medicare referral commissions"); United States v. Robinson, 505 F. App'x 388 (5th Cir. 2013) ("The Anti-Kickback Statute provided Robinson with fair notice that the paying of fees and commissions . . . for Medicare referrals was prohibited conduct."); United States *ex rel.* Silva v. VICI Mktg., LLC, 361 F. Supp. 3d 1245, 1254, 1256 (M.D. Fla. 2019) (denying the defendant's motion to dismiss because the defendant "knew that paying commissions per prescription to marketers regarding government-

ABSTRACT

For three decades, the federal agency charged with administrative oversight of the Federal Health Care Programs Anti-kickback statute, the Office of the Inspector General of the Department of Health and Human Services, has advised that paying for marketing and advertising of covered health care items and services should be treated as "at most a technical violation" of the law. OIG has noted that enforcement should be limited to cases where certain "suspect characteristics" are present and has issued several advisory opinions declining enforcement in the case of commission-type payments to independent sales agents. In contrast, in the last twenty years, *obiter dicta* in a number of judicial decisions upholding criminal convictions have described such commissions as a *per se* violation of the law. Left unchallenged, this rhetorical inflation presents unjustified risks of enforcement to medical device makers for nothing more nefarious than selling their products in accordance with widespread industry norms that do not implicate any of the purposes underlying the Anti-kickback statute. More important, these decisions have the potential to distort the health care economy through economically disadvantageous allocations of resources: the wastefulness of unwarranted enforcement on the one hand, and on the other, discouraging innovation by imposing additional costs on medical product makers, especially the often small, entrepreneurial, one-product companies that dominate the medical device industry, and do not have the resources to use a fully-employed sales force. This article attempts to remedy these risks by showing that, *dicta* in the opinions notwithstanding, the *facts* in those cases track the agency's guidance, upholding convictions only when suspect characteristics—chiefly that the sales personnel are not truly independent sales representatives but are in a position to exercise undue influence over referral decisions—have been present. Presenting an independent but parallel argument, the article also examines a recent Supreme Court case narrowing the meaning of the term "induce" in an analogous criminal statute, and shows how this new authority also (perhaps even more strongly) supports the conclusion that the Anti-kickback law may not be used to prosecute ordinary commissions. In the hope that it also will influence courts and lead to a more fair, accurate and pragmatic Anti-kickback law jurisprudence, the article concludes with an Appendix containing recommendations for joint OIG/Department of Justice guidance that aligns the rules for enforcement discretion with this reality, instructing the bringing, or joining, of enforcement cases only when the presence of suspect characteristics creates a genuine risk of the fraud and abuse

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funded claims was illegal because of his research into anti-kickback statutes and his experience in the healthcare industry"). *Cf.* People v. Duz-Mor Diagnostic Lab'y Inc., 68 Cal. App. 4th 654, 671 (1998) (similarly-worded Medi-Cal anti-kickback law "prohibits payment of a commission to someone who arranges, through marketing activities, for services to be furnished to Medi-Cal beneficiaries.").

evils that the statute was designed to prohibit.

TABLE OF CONTENTS

I. INTRODUCTION

The language first quoted above represents the longtime policy of the Office of the Inspector General of the Department of Health and Human Services ("OIG") towards commission arrangements with independent contractors for the sale of medical devices used in the diagnosis or treatment of Medicare and other Federal Health Care Program ("FHCP") patients.[3] As reflected in the

3. This article focuses on medical device makers because unlike in the pharmaceutical industry—which is dominated by large companies with extensive in-house R&D capabilities—medical device innovation and development takes place mostly in small, entrepreneurial, often

quoted preamble to the FHCP Anti-kickback statute ("AKS")[4]—safe harbor regulations, OIG has long held that while certain marketing and advertising arrangements may constitute "at least a technical violation" of the AKS, they are often "innocuous" and merit AKS enforcement in only a subset of cases involving particular "suspect characteristics."[5] Probably at least in partial reliance on this position, as further set forth in several OIG advisory opinions issued over the years, commissioned sales agents have remained one of the main ways in which makers of medical devices market and sell their products.[6]

Expressing a very different sentiment, the second quote comes from a 2013 federal appeals court decision upholding a criminal conviction for violations of the AKS. The decision, whose *commission=kickback* conclusion is echoed in several others from the last two decades (detailed *supra* note 2), involved the

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one-product companies. *See, e.g.*, Alan Kahn, *The Dynamics of Medical Device Innovation: An Innovator's Perspective*, *in* 2 THE CHANGING ECONOMICS OF MEDICAL TECHNOLOGY, 89, 90 (Annetine C. Gelijns & Ethan A. Halm eds., 1991)("The development of new medical devices generally takes place in small, entrepreneurial companies. . . . A small company can bring a new product to market in a fraction of the time required by a large company. In the small company the innovator usually is also a key decision maker and can take risks based upon his first-hand knowledge of the technology and its applications."). Because of the nature of the industry, fully-employed sales representatives are an expensive luxury that many innovators cannot afford. Likely, in part, to remain competitive in hiring the best-qualified personnel, even larger device makers adhere to this industry norm. Accordingly, throughout the U.S. medical device industry, sales representatives typically work off commission in promoting products to the health care providers who prescribe and use them in diagnosis or treatment (mostly physicians and nurse practitioners), and who purchase directly—chiefly hospitals and ambulatory surgery centers, but also doctors' offices. They are either solo 1099 independent contractors, or employees of a sales agent entity that is a 1099 independent contractor, which the industry calls a "distributor," although such entities do not take title, and usually are paid solely on commission. This article will use the term "sales agent" to refer to all of these: individual 1099 contractors, employees (or contractors) of 1099 "distributors," and the "distributors" themselves.

4. Social Security Act § 1128B(b) (codified at 42 U.S.C. § 1320a-7b(1)(b) (2010)).

5. *See, e.g.*, Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952, 35974 (Jul. 19, 1991) (to be codified at 42 C.F.R. pt. 1001). *Cf.* U.S. Dep't of Health & Hum. Servs., Off. of Inspector Gen., Advisory Op. No. 98-10 (Aug. 31, 1998) (approving a low risk of fraud and abuse commission arrangement that "would technically fall within the prohibition of the anti-kickback statute if the requisite intent were present").

6. Another reason for the independent sales agent model may be that device reps develop an expertise in the medical use of the products in which they specialize, giving them "a dual role: functioning as commissioned sales representatives at the same time as providing advice on approaches to treatment." Quinn Grundy et al., *Device Representatives In Hospitals: Are Commercial Imperatives Driving Clinical Decision-Making?*, 44 J. MED. ETHICS 589, 589 (2018). It is "likely that these practices are global." *Id. See also* Bonnie O'Connor et al., *Salespeople in the Surgical Suite: Relationships Between Surgeons and Medical Device Representatives*, 11 PLOS ONE 1, 8 (2016) ("Medical device representatives ('device reps') have become an integral part of operating room personnel. . . . Device reps earn as commission a percentage of every sale they make. The moment the sterile packaging is opened in the OR—both items previously selected and those that may be enlisted on the spot during the surgery—the rep earns the commission."). *See also supra* note 3.

sale of medical devices for which payment was made under Medicare.[7] Manufacturers of medical devices can only take notice and wonder which advice to follow. Can OIG's longstanding approach—commissions to ordinary independent sales agents are generally okay, subject to avoiding the "suspect characteristics"—be relied upon? Or are device makers and their commissioned sales agents at serious AKS risk for nothing more than selling a product that is used in the treatment of a Medicare patient?

The courts' inflated rhetoric in these cases (e.g., "*[t]here is no distinction . . . between a commission and a kickback*"), even in *dicta*, presents serious, and unwarranted, risks to medical device makers and, by extension, to a healthcare economy that has to account for increased costs that may result from the likely inducement of unnecessary enforcement and inefficient allocation of industry compliance resources . At the risk of "we told you so," now-Professor Joan Krause and I warned in an article twenty-five years ago that OIG's failure to issue guidance or otherwise address this issue more directly could led to a proliferation of AKS cases in otherwise "innocuous" circumstances.[8] A rise in the number of criminal AKS cases of this kind that have reached the federal courts of appeal in the last several years is a disturbing indicator.[9]

Fortunately, at least so far, the news is not all bad and lends itself to a solution that would not disrupt sensible enforcement practices. This article will show that although these *dicta* may lead to some cases being brought when they shouldn't have been, the *holdings* in those cases actually align with OIG's historic guidance. That is, *dicta* aside, a close reading of the *facts* demonstrates that AKS liability continues to be imposed not where the recipient of the commission is truly an independent sales agent, but instead where they are persons in a position to exercise "undue influence" on the patient or the health

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7. Medicare payment for medical devices is generally indirect. Except for durable medical equipment and certain prosthetic and orthotic devices ("DMEPOS"), and certain new technologies granted temporary passthroughs, payment for devices is deemed to be built into Medicare's rates of payment for the patient care services in which they are used. *See, e.g.*, MEDICARE PAYMENT ADVISORY COMM'N, REPORT TO THE CONGRESS: MEDICARE AND THE HEALTH CARE DELIVERY SYSTEM 208 (2017), *available at* https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun17_reporttocongress_sec.pdf.

8. Thomas N. Bulleit & Joan H. Krause, *Kickbacks, Courtesies, or Cost-Effectiveness: Application of the Medicare Antikickback Law to the Marketing and Promotional Practices of Drug and Medical Device Manufacturers*, 54 FOOD & DRUG L.J. 279, 323 (1999) ("There is perhaps no other area in which manufacturers currently face a greater potential for antikickback law liability than for commissions paid to independent sales agents . . . ."). *See also* 56 Fed. Reg. at 35954; *supra* note 1 (language cited). An associate at our then-law firm when this article was published, Prof. Krause has gone on to a distinguished career in legal academia, including much scholarship on health care "fraud and abuse" in general, and the AKS in particular. *See generally Joan H Krause*, UNC SCH. L., https://law.unc.edu/people/joan-h-krause/ [https://perma.cc/WR5X-Q2W5] (last visited Oct. 19, 2024).

9. *See infra* Section IV.B. By the author's count, there were only four reported federal court of appeals decisions dealing with commissions as criminal AKS violations as of 2000, while since then there have been over thirty such cases.

care provider making the decision to purchase or order. So new enforcement guidance should serve only to discourage unwarranted enforcement, and not lead to any wholesale revision of well-considered compliance measures. Still, such guidance is appropriate to guard against unjustified cases being brought by over-aggressive False Claims Act ("FCA")[10] *qui tam* relators or over-ambitious prosecutors. Zooming out a bit further, OIG should team with the Department of Justice to make clear that buyers and sellers of medical products should not be forced by inflated prosecutorial and judicial rhetoric to abandon non-abusive, economically efficient, and industry-normative business practices due to an unnecessary and misleading fear of compliance risk. Accordingly, the article advocates deflating this at best misleading, and at worst harmful, rhetoric by making changes to enforcement guidelines and industry guidance to better reflect actual fraud and abuse risk to FHCPs.

Following this Introduction, Part I and Part II of the article frame the discussion by providing an overview of the AKS, especially the overlooked legislative history that indicates Congress did *not* intend for ordinary sales agent commissions to be treated as kickbacks. Part III summarizes OIG's longstanding interpretation of the law as applied to sales commissions, showing that in both regulatory preambles and advisory opinions, OIG consistently has declined to treat commissions as *per se* kickbacks, or otherwise meriting sanctions. In Part IV, the article dissects judicial opinions in which the language of *per se* violation is used, demonstrating that the *facts* in those cases instead actually track OIG's guidance. Part V concludes that because the courts' rhetoric in their opinions often not only is inconsistent with OIG's interpretation and unnecessary to their own holdings, but it may create an undue and unfair risk to medical device makers who are merely following industry norms and selling their products on commission through legitimate, independent sales agents. OIG and the U.S. Department of Justice ("DOJ") should adopt internal enforcement guidelines, and issue additional external guidance, that would grant more express protection to sales commissions that involve nothing more than arm's-length selling of medical devices.[11] An Appendix presents a proposal for joint DOJ/OIG enforcement guidelines that would incorporate the principles fairly reflected in OIG's guidance and in the reported judicial decisions.

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10. The False Claims Act, 31 U.S.C. §§ 3729–3733 (2021).

11. Although the Supreme Court's recent expunging of Chevron deference from Administrative Procedure Act jurisprudence might in some circumstances lead to an undoing of problematic HHS regulations, that pathway seems not available here. Loper Bright Enterprises v. Raimondo, 144 S. Ct. 2244, 2273 (2024) (overruling Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984)). As discussed *infra* notes 22–30 and accompanying text, although the agency may have departed from congressional intent in not protecting independent sales representative commissions in its initial safe harbor regulations, Loper Bright seems to provide only an avenue for undoing agency regulations, not compelling the promulgation of new ones. Moreover, here the agency's guidance is the more appropriate interpretation of the law. Accordingly, absent the unlikelihood of statutory reform, joint agency guidance seems the best hope.

II. BACKGROUND

A. The FHCP Anti-Kickback Statute

The AKS makes it unlawful for individuals or entities knowingly and willfully to offer, pay, solicit, or receive remuneration in order to induce or reward the referral of business reimbursable under FHCPs, such as Medicare, Medicaid, and the CHAMPUS/Tricare program for dependents of active-duty military personnel. As interpreted by federal regulators and the courts, the statute has broad application to a range of arrangements in which benefits are offered or received to induce the referral of FHCP business (including, in pertinent part, the order or purchase of medical devices used in the diagnosis or treatment of FHCP patients). Simplifying numerous judicial decisions over the years, OIG summarizes the principal purposes of the law as preventing (1) overutilization, (2) increased program costs, (3) corruption of medical judgment, (4) patient steering, (5) unfair competition.[12]

As to the party offering the benefit, the law states in pertinent part:

> Whoever knowingly and willfully *offers or pays any remuneration* (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person *to induce such person . . . to* purchase, lease, order, or *arrange for or recommend* purchasing, leasing, or ordering *any good*, facility, service, or item *for which payment may be made* in whole or in part *under a Federal health care program*, shall be guilty of a felony . . . .[13]

The section that applies to the recipient of the benefit provides in pertinent part:

> Whoever knowingly and willfully *solicits or receives any remuneration* (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind . . . *in return for* purchasing, leasing,

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12. *See, e.g.*, *Fraud & Abuse Laws*, U.S. DEP'T HEALTH & HUM. SERV'S. OFF. INSPECTOR GEN.: COMPLIANCE A ROADMAP FOR NEW PHYSICIANS, https://oig.hhs.gov/compliance/physician-education/fraud-abuse-laws/ [https://perma.cc/B93S-CEN7] (last visited Oct. 19, 2024); *see also e.g.*, United States v. Ruttenberg, 625 F.2d 173, 177 n.9 (7th Cir. 1980) ("[T]he law does not make increased cost to the government the sole criterion of corruption. In prohibiting 'kickbacks,' Congress need not have spelled out the obvious truisms that while unnecessary expenditure of money earned and contributed by taxpaying fellow citizens may exacerbate the result of the crime, kickback schemes can freeze competing suppliers from the system, can mask the possibility of government price reductions, can misdirect program funds, and, when proportional, can erect strong temptations to order more drugs and supplies than needed.").

13. Social Security Act § 1128B(b)(2) (codified at 42 U.S.C. § 1320a-7b(b)(2)) (emphasis added).

> ordering, or *arranging for or recommending* purchasing, leasing, or ordering *any good*, facility, service, or item for *which payment may be made* in whole or in part *under a Federal health care program*, shall be guilty of a felony . . . .[14]

The civil administrative penalty provisions of the law (which include monetary penalties of $100,000 per violation plus three times the amount of prohibited remuneration and potential exclusion from FHCP participation)[15] are enforced by OIG, while the law's criminal felony provisions (which under the Federal Alternative Fines law can yield penalties of up to $250,000 per violation for individuals and $500,000 per violation for organizations, or twice the gain to the defendant, plus imprisonment for no more than ten years)[16] are handled by the DOJ. In addition, courts generally have permitted cases brought under the "*qui tam*" provisions of the FCA—that is, cases brought not by the government, but by private whistleblowers (or "relators") that the government may or may not decide to join—to proceed, opening up the potentially much larger penalties of treble damages and assessments under that law.[17] Thus, the enforcement risk under the AKS comes not only from OIG and DOJ, but also from disgruntled employees and competitors who may bring *qui tam* cases. Based on analysis y of publicly-reported settlement data conducted by the author and team in researching this article, the author believes that in the last fifteen years, medical device makers have paid out at least $1.1 billion in settlements in FCA cases.[18]

The AKS has been broadly interpreted to apply where just one purpose of a business transaction is to induce FHCP business, even if there are other

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14. *Id.* § 1128B(b)(1) (codified at 42 U.S.C. § 1320a-7b(b)(1)) (emphasis added).

15. *Id.* § 1128A(a)(7) (codified at 42 U.S.C. § 1320a-7a(a)(7)); § 1128(b)(7) (codified at 42 U.S.C. § 1320a-7(b)(7)).

16. *See* 18 U.S.C. § 3571 (fines); 42 U.S.C. § 1320a-7b(b) (imprisonment). The AKS's criminal fine of not more than $100,000 essentially has been rendered obsolete by the Federal sentencing law. *Compare* 18 U.S.C. § 3571, *with* 42 U.S.C. § 1320a-7b(b).

17. *See generally* cases cited *supra* note 2; *see also infra* Section IV. Under 42 U.S.C. § 1320a-7b(g), any claim filed pursuant to an unlawful kickback is necessarily a false claim.

18. DOJ's publicly-available statistics do not break down penalties by type of defendant, but this appears to represent a plausibly modest percentage of overall FCA collections in the health care industry. For example, in 2021 alone, over $5 billion in settlements related to matters involving the health care industry as a whole. *Justice Department's False Claims Act Settlements and Judgments Exceed $5.6 Billion in Fiscal Year 2021*, U.S. DEP'T JUST.: PRESS RELEASE (Feb. 1, 2022), https://www.justice.gov/opa/pr/justice-department-s-false-claims-act-settlements-and-judgments-exceed-56-billion-fiscal-year [https://perma.cc/5MDB-3PZX]. *See also False Claims Act Settlements and Judgments Exceed $2 Billion in Fiscal Year 2022*, U.S. DEP'T JUST.: PRESS RELEASE (Feb. 7, 2023), https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-2-billion-fiscal-year-2022 [https://perma.cc/8CPU-YFKK]; *False Claims Act Settlements and Judgments Exceed $2.68 Billion in Fiscal Year 2023*, U.S. DEP'T JUST.: PRESS RELEASE (Feb. 22, 2024), https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-268-billion-fiscal-year-2023 [https://perma.cc/NXA3-TD5E].

legitimate business purposes.[19] The government also takes the position that even remuneration that is earned solely on products or services that are not paid under FHCPs may violate the law, if one purpose of the arrangement is to induce the "spillover" purchase, lease or use of other FHCP-covered products or services.[20]

B. Legislative History: Rostenkowski on "Conventional Chain of Sale"

Medical device sales agents, commissioned or otherwise, do not refer patients, nor purchase, order, or lease products, for which FHCP payment may be made. Rather, they interact with health care professionals and institutional providers (and less frequently, patients) to provide the opportunity for those persons or entities to purchase, order, or lease the covered products.[21] Accordingly, this analysis of the AKS commission question focuses on the "arranging for or recommending" prong of the statute.

Treatment of commission-based sales and marketing arrangements under the AKS has a long, and somewhat ambiguous, history. In the legislative history of amendments to the AKS passed in 1977, then-House Ways and Means Committee Chairman Dan Rostenkowski commented that the law's exception for payments to employees would protect "a distributor of equipment or supplies [who] pays a retailer on a commission basis for the use of his store to sell a product, [since] such payment would represent a legitimate payment to a legitimate agent employed in a traditional manner to sell a product. That is a simple extension of the conventional chain of sale."[22]

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19. United States v. Greber, 760 F.2d 68, 72 (3d Cir. 1985) ("If the payments were intended to induce the physician to use [defendant's] services, the statute was violated, even if the payments were also intended to compensate for professional services."), *cert. denied*, 474 U.S. 988 (1985). *See also* United States v. LaHue, 261 F.3d 993, 1002 n.10, 1003–04 (10th Cir. 2001) (finding that *stare decisis* effect of prior precedent adopting the "one purpose" test precluded defendant's challenge to a lower court's jury instruction that stated "[t]he intent to gain such influence must, *at least in part*, have been the reason the remuneration was offered or paid") (emphasis in original); United States v. Kats, 871 F.2d 105, 108 (9th Cir. 1989) (adopting the "one purpose" test articulated in *Greber* because "[e]ven if the physician performs some service for the money received, the potential for unnecessary drain on the Medicare system remains." (alteration in original) (quoting *Greber*, 760 F.2d at 71)).

20. *See, e.g.*, U.S. Dep't Health & Hum. Servs., Off. of Inspector Gen., Advisory Op. No. 00-01, (Mar. 9, 2000) ("The mere 'carve-out' of Federal health care program billing, however, does not end our inquiry, since such arrangements could have a 'spillover' effect on billing or coding for Federal health care program items or services. Where such effect occurs and is intended by one or both parties, the statute may be implicated.").

21. Though contact with patients is more rare, typically limited to DMEPOS, *supra* note 7, that are billed directly to patients and their payors, OIG has often stated that targeting elderly and often ill Medicare patients is a concerning suspect characteristic. *See, e.g.*, U.S. Dep't Health & Hum. Servs., Off. of Inspector Gen., Advisory Op. No. 99-08 (July 6, 1999) (finding that a suspect characteristic is present if "the activity is specifically directed at senior citizens, Medicaid beneficiaries, or other particularly vulnerable populations.").

22. 123 CONG. REC. H30280 (daily ed. Sept. 22, 1977) (statement of Rep. Dan Rostenkowski).

Chairman Rostenkowski went on to note, unsurprisingly, that on the other hand, payments from a laboratory to a physician or clinic that were made to induce referrals should not be protected merely because they are structured in the "guise" of an employment relationship. He stated the committee's belief that "the substance rather than simply the form of a transaction should be controlling."[23] Thus, Rostenkowski seems to have made clear that where the "substance" of a transaction is a commission "to a legitimate agent employed in a traditional manner to sell a product," the transaction should be protected from AKS liability.

III. OIG INTERPRETATION OF COMMISSION SALE ARRANGEMENTS

A. Regulatory History: Rostenkowski v. OIG

Despite this legislative history, many years later, when promulgating the first final "safe harbor" regulations in 1991, OIG rejected the argument that commission sale arrangements should be covered under the employment exemption and the suggestion to create a separate safe harbor for such arrangements.[24] OIG noted that Chairman Rostenkowski's remarks had been made with respect to the House version of the bill (exempting payments "by an employer to an employee for employment in the provision of covered items or services"),[25] which differed from the Senate version ultimately adopted by the conference (exempting payments "by an employer to an employee (who has a *bona fide* employment relationship with the employer) for employment in the provision of covered items and services").[26] Explaining its reasoning, OIG went on to note that it would not extend the employment exception to commission sales agents because it was aware of "the existence of widespread abusive practices by salespersons who are independent contractors and, therefore, who are not under appropriate supervision and control."[27]

With this reasoning, OIG rejected Chairman Rostenkowski's remarks and created a distinction between commission-based payments to "bona fide employees" (which under the statutory exception are not restricted by any "fair

23. *Id.*

24. Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35971, 35981(July 29, 1991).

25. *See* H.R. REP. No. 95-393, pt. 2, at 8–12 (1977), *as reprinted in* 1977 U.S.C.C.A.N. 3039, 3056.

26. *See* H.R. REP. No. 95-673, at 6–10 (1977) (Conf. Rep.), *as reprinted in* 1977 U.S.C.C.A.N. 3113, 3115.

27. Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. at 35981. There is good reason to doubt this conclusion. *See infra* note 29.

market value" or "volume or value of referrals" language)[28] and payments to anyone else. The legal distinction seems of dubious merit. One may wonder what is the legal difference between an "employment" relationship (which by definition is not an independent contractor relationship), and a "bona fide" (or "real") employment relationship. Read honestly, OIG's decision was based instead on a policy choice. Relying, it seems, on a belief that sales conduct is better regulated in an employment situation,[29] OIG established a bright line rule

28. *See* 42 U.S.C. § 1320a-7b(b)(3)(B). The AKS employment exception therefore should protect commission arrangements for employees, and in the pharmaceutical industry, sales representatives typically are the employees of the pharma company, where comparable kickback cases do not seem to have been brought. *See, e.g.*, *A Day in the Life of a Pharmaceutical Sales Representative*, MEDREPS (Jan. 27, 2022), https://www.medreps.com/medical-sales-careers/what-do-pharmaceutical-sales-reps-do [https://perma.cc/E2ST-43CL]. As noted above, this is generally not true in the medical device industry, where the sales agent often has a more hands-on role in working with health care professionals during the procedures in which the products are used, and the medical device industry encompasses a vastly larger number of product makers, most of which are much smaller and would lack the revenue to provide the full range of employment benefits to a sales force sufficiently large to reach the desired market. *See* Kahn, *supra* note 3; O'Connor, *supra* note 6. Whatever the reason, the dominant sales rep model in medical devices is the commissioned, independent sales agent. *Id.*

29. *See, e.g.*, 56 Fed. Reg. at 35981; Off. of Inspector Gen., Advisory Opinion No. 98-10, *supra* note 5 ("[B]ecause such agents are independent contractors, they are less accountable to the Seller than an employee. For these reasons, this Office has a longstanding concern with independent sales agency arrangements." (citations omitted)). While, as a technical legal matter, employees may be more closely regulated than independent agents, there is good reason to doubt that independent medical device sales agents are, in fact, less regulated for AKS purposes than they might be as employees. Medical device makers largely adhere to the AdvaMed Code of Ethics, which specifically imposes supervision requirements on both employed and contracted sales personnel. *See* ADVAMED, ADVAMED CODE OF ETHICS 1, 35 (2023), https://www.advamed.org/wp-content/uploads/2023/06/2023-AdvaMed-Code-of-Ethics.pdf. [https://perma.cc/VQA6-G9YH]. Consistent with the Code, contracts between device makers and their "distributors" (*see supra* note 3) routinely require the agents to adhere to the maker's compliance policies and undergo training. *See id.* Further, OIG's Program Guidance for Pharmaceutical Manufacturers (made applicable to medical device makers in footnote 4) emphasizes the importance of "[c]onducting [e]ffective [t]raining and [e]ducation" of "officers, directors, employees, contractors, and agents" as part of a successful compliance program. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23740 (May 5, 2003). OIG directs pharmaceutical and medical device manufacturers to "(i) Develop a regular and comprehensive training program for its sales force, including refresher and updated training on a regular basis, either in person or through newsletters, memoranda, or the like; (ii) familiarize its sales force with the minimum PhRMA Code standards and other relevant industry standards; (iii) institute and implement corrective action and disciplinary policies applicable to sales agents who engage in improper marketing; (iv) avail itself of the advisory opinion process if it has questions about particular practices used by its sales force; and (v) establish an effective system for tracking, compiling, and reviewing information about sales force activities, including, if appropriate, random spot checking." *Id.* at 23739. The industry also is only too aware that mandatory conditions for supervision may be imposed under Corporate Integrity Agreements and Deferred Prosecution Agreements, including activities of both employees and agents. *See, e.g.*, OFF. OF INSPECTOR GEN., U.S. DEP'T HEALTH & HUM. SERVS., CORPORATE INTEGRITY AGREEMENT

that avoids the need to closely examine whether the relationship between a medical device maker and its contracted sales agent fits within the context of a "legitimate" and "conventional" agency relationship.

B. Regulatory Guidance 1: "Technical Violations" v. "Requisite Intent to Induce"

Although arguably inconsistent with pertinent legislative history (and therefore potentially vulnerable to attack),[30] OIG's position on commission sales/marketing arrangements is at least fairly clear: virtually all arrangements of this kind "may involve at least technical violations of the statute."[31] This has

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BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH OF HUMAN SERVICES AND AMGEN (2019) (requiring that Amgen develop policies on how to ensure promotional functions, such as marketing by sales representatives, meet all health care laws); OFF. OF INSPECTOR GEN., U.S. DEP'T HEALTH & HUM. SERVS., CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH OF HUMAN SERVICES AND AVANIR (2019) (requiring Avanir create policies to control "the materials and information that may be distributed by Avanir sales representatives" and "the development, implemental and review of all plans for sales representatives"); U.S. ATT'Y'S OFF., DEP'T OF JUST., DEFERRED PROSECUTION AGREEMENT - ZIMMER ¶¶ 10, 42 (2007) (stating that Company shall adhere to AdvaMed Code of Ethics and mandatory training and education of sales force "shall cover, at a minimum, all relevant federal health care laws and regulations, . . . and the obligations assumed by, and responses expected of, the [sales personnel] upon learning of improper, illegal, or potentially illegal acts relating to the Company's sales and marketing of hip and knee reconstruction and replacement products").

30. While the often-stated "general rule" of statutory construction is that extrinsic evidence is used only in the case of a statutory ambiguity, an ambiguity need not be obvious in order to permit extrinsic evidence, and courts still go beyond even clear statutory language where the extrinsic evidence shows a different congressional intent. *See, e.g.*, SHAMBIE SINGER & NORMAN J. SINGER, SUTHERLAND STATUTES AND STATUTORY CONSTRUCTION § 48.1 (Clark Boardman Callaghan ed., 8th Ed. 2022). Moreover, federal courts generally give the same weight to floor statements by a committee chair in introducing and defending a bill that has been passed by their committee as to formal committee reports. *See id.* § 48.14. However, it would be a broad reading of Loper Bright to conclude that these principles of statutory construction would provide a basis for an Administrative Procedure Act challenge that could compel OIG to give any kind of "safe harbor" protection to "legitimate" and "traditional" commission sales/marketing arrangements. *See supra* note 11.

31. Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. at 35974. Indeed, in another advisory opinion, OIG makes the chilling observation that "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 anti-kickback statute, *irrespective of the methodology used to compensate the agent.*" U.S. Dep't of Health & Hum. Servs., Off. of Inspector Gen., Advisory Op. No. 99-03, at 4–5 (Mar. 16, 1999) (emphasis added). Although OIG has never relied on this broad a statement of the law in any enforcement proceeding that our research has located, the possibility that *any* payment to a sales agent—if the language is to be believed, even a fair market value payment *not* based on volume or value—may implicate the AKS emphasizes the importance of separating out ordinary commissions to what Rep. Rostenkowski referred to as" conventional" sales agents from abusive arrangements utilizing persons with the ability to exercise "undue influence."

been a consistent theme in OIG's analysis of such arrangements.[32] However, in public guidance OIG also has consistently (i) declined to impose sanctions in situations where commissions are paid to *bona fide* independent sales agents, and (ii) qualified its views with the observation that the law "may" or "might" be violated.[33] Together, these suggest not only that some commission sales/marketing arrangements do not warrant prosecution—because, in OIG's words, they amount, at most, only to "technical violations" *and* present a low risk of fraud and abuse—but also form the basis for an argument that there might be some instances where even a straightforward commission sales/marketing arrangement might not have the "requisite intent to induce referrals."[34]

Before moving on to the "suspect characteristics, the absence of which OIG has indicated warrants abjuring sanctions,[35] let us explore the important analysis that not every commission sales/marketing arrangement even has the "requisite intent to induce referrals" that is a prerequisite to even a "technical violation" of the AKS.

In a 1999 Advisory Opinion, OIG considered whether payments from podiatrists to a shoe store where their services would be advertised (and where they would be authorized to make periodic appearances to consult with customers and sales associates) constituted prohibited remuneration under the AKS.[36] The podiatrists would provide these services at no charge, would pay an

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32. *See, e.g.*, Off. of Inspector Gen., Advisory Op. No. 98–10, *supra* note 5 (declining to prosecute an arrangement under which a manufacturer of disposable medical supplies paid a commission to an independent sales agent based on a percentage of the manufacturer's sales to hospitals or group purchasing organizations with which the sales agent had negotiated a contract for the manufacturer).

33. *Id.*

34. Another way of framing this analysis is to observe that the purpose of the AKS is to prohibit payments to influence decision-making around orders of products/services, and not to prohibit payment for legitimate services. With that in mind, the question then becomes whether the mere fact that payment—not to the purchaser, but to the person performing a legitimate sales/marketing function—is calculated based on the number of sales ordered, sold or used is sufficient to demonstrate that prohibited intent? Positing the answer to be "no," this leads to the question of when is the sales agent's service not "legitimate," in turn leading to the "suspect" characteristics and especially to whether the sales agent is in a position to exercise "undue influence." *Cf.* United States v. Miles, 360 F.3d 472, 474 (5th Cir. 2004).

35. *See, e.g.*, Off. of Inspector Gen., Advisory Op. No. 98-10, *supra* note 5 (listing "suspect characteristics" in sales/marketing arrangements). The terminology of "suspect" or "questionable" "characteristics" or "features" or "factors" goes back to the preamble to the original safe harbor regulations, *infra* text accompanying note 41 (there are "many *factors* which are part of the decision-making process regarding case selection for investigation and prosecution") (emphasis added); the first of OIG's Special Fraud Alerts, 59 Fed. Reg. 65372, 65377 (Dec. 19, 1994) (on Joint Venture Arrangements, citing "*questionable features* of these *suspect* joint ventures" (emphasis added); and has been repeatedly used to indicate the presence (or absence) of the "requisite intent to induce referrals" in many OIG Advisory Opinions. *See, e.g.*, Off. of Inspector Gen., Advisory Op. No. 98-10, *supra*; Off. of Inspector Gen., Advisory Op. No. 99-03, *supra* note 31 ("suspect characteristics" in sales/marketing).

36. Off. of Inspector Gen., Advisory Op. No. 99-08, *supra* note 21.

annual fixed fee to participate in the network of in-store podiatrists, and would be assigned on a rotating basis if a customer requested referral to a podiatrist.

OIG had little trouble determining that "in-store signs, special promotions, and authorized presence of the podiatrists" in the shoe department amounted to an "implied recommendation of the podiatrists" by the store, and therefore "come within the plain language of the statute, which prohibits payments to a person to 'arrange for or recommend' the purchasing or ordering of a good or service payable by a Federal health care program."[37] In characterizing these activities, OIG also stated that "*[i]f* the requisite intent to induce or reward referrals . . . is present, the [AKS] is violated."[38]

The "if" language here is noteworthy. "If" the signs and promotions amount to an implied recommendation, "within the plain language of the statute," why is there any question about intent? Is there any doubt that both the podiatrists and the store had an affirmative intent that the signs would imply a recommendation? Accordingly, although OIG does not characterize its analysis in this way, the "if" and "may" language in OIG's pronouncements suggests the basis for an argument that, at least in the case of payments to persons or entities with no status that would give them the ability to actually make or unduly influence ordering or buying decisions (*e.g.*, persons who are not healthcare providers or other purchasing/ordering decisionmakers), applying the "arranging for or recommending" prong of the statute, the "requisite intent to induce referrals" *must* be demonstrated by the presence of "suspect" facts and circumstances. As we shall see, this is most commonly the ability to exercise "undue influence" over the purchase or order of the product or service. In other words, evidence that the parties' intent is merely to compensate an independent sales agent to arrange for or recommend purchase of the covered product or service by itself arguably may not be sufficient *scienter* to violate the law in the first place.[39]

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37. *Id.*

38. *Id.* (emphasis added).

39. A recent Second Circuit decision, concluding that unlawful intent under the AKS need not be a "corrupt" intent, is not to the contrary, and its procedural posture makes it wholly inapplicable. Pfizer, Inc. v. U.S. Dep't of Health & Hum. Servs., 42 F.4th 67, 74 (2d Cir. 2022). Pfizer sought an advisory opinion from OIG to the effect that a proposed patient co-pay assistance program for an expensive drug would not be an AKS violation. The OIG's opinion concluded that the arrangement squarely implicated the law, offering "remuneration (the Subsidy Card) to a person (the Medicare beneficiary) to induce that person to purchase an item (the Medications) reimbursable under a Federal health care program (Medicare)." U.S. Dep't of Health & Hum. Servs., Off. of Inspector Gen., Advisory Op. No. 20-05, at 14–16 (Sept. 23, 2020). Pfizer sued in federal district court under, in pertinent part, the Administrative Procedure Act, arguing that the OIG's opinion should be set aside as "contrary to law," asserting that as a matter of law an AKS violation requires a "corrupt" intent, and that no facts could be presented under which the program could be shown to be motivated by such intent. *Pfizer*, 42 F.4th at 69. The district court held, and the court of appeals affirmed, that "corrupt" intent is not an AKS requirement. *Id.* Since the case involved benefits to beneficiaries that were plainly designed to induce them to purchase Pfizer's

A recent Supreme Court decision also supports this conclusion. In *United States v. Hansen*, the Court held that when Congress criminalized activity that "encourages or induces an alien to come to, enter, or reside in the United States [when such entrance or residence would be illegal]"[40] it used the terms "encourages or induces in their specialized, criminal law sense—that is, as incorporating common law liability for solicitation and facilitation [with a corrupt intent]."[41] Applying that decision to the use of the term "induce" in the AKS leads to the conclusion that merely paying an incentive to a legitimate sales representative to make a sale of a lawful product to a lawful purchaser would not provide the payer or the recipient with the requisite *mens rea* to violate the law.

C. Regulatory Guidance 2: "Suspect" Characteristics and Factors

Putting aside whether commission sales/marketing arrangements lacking suspect characteristics might not even constitute "technical" violations of the AKS—a case that, in light of *Hansen*, likely soon will be made in defense of future AKS enforcement proceedings—it is clear that, in the articulation of its enforcement posture, OIG's consistent approach to commission arrangements that might constitute "at least technical" violations is *not* to treat them as *per se* violations, but to assess them on a case-by-case basis under "the many factors which are part of the decision-making process regarding case selection for investigation and prosecution."[42] In the specific context of commission

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products—and not commissions to sales agents to compensate them for their sales services—on its face it has no application to the latter. Moreover, the cases cited by Pfizer on "corrupt" intent that were rejected by the courts held that under different statutes, an intent to induce had to have a criminal or otherwise nefarious element. *Id.* at 75. In contrast, the argument that a device maker's intent to induce sales agents to "arrange for or recommend" its products is not a kickback need not depend on whether that intent is "corrupt" or not; but rather may depend on whether that intent must be coupled with other "suspect characteristics" to constitute unlawful intent. Furthermore, the *holding* of the Second Circuit case was simply that it was not contrary to law for OIG to refuse to issue a favorable advisory opinion. *Id.* at 73 ("Pfizer filed this action . . . challenging, in relevant part, HHS OIG's advisory opinion on the Direct Program as contrary to law under the Administrative Procedure Act. . . . [and] the district court granted summary judgment to the government on the APA claim. . . ."); *see also id.* at 80 ("We therefore affirm the judgment of the district court."). It did not *hold*, because it was not presented with the question, that the intent to offer beneficiary remuneration in the proposed program *did* violate the AKS. Finally, the Supreme Court's recent decision in United States v. Hansen, 599 U.S. 762 (2023) and accompanying text, casts doubt on whether the Second Circuit's reading of the AKS in Pfizer itself was correct in concluding that the intent to "induce" need not be a "corrupt" intent. For all of these reasons, *Pfizer* does not shed any light on the question of whether paying a commission to induce a recommendation of a covered product constitutes even a "technical" violation of the AKS.

40. 599 U.S. 762, 770 (2023).

41. *Id.* at 774.

42. Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. at 35954.

sales/marketing arrangements, OIG has stated that "[w]e, of course, recognize that many of these advertising and marketing activities do not warrant prosecution in part because (1) they are passive in nature, i.e., the activities do not involve direct contact with program beneficiaries, or (2) the individual or entity involved in these promotions is not involved in the delivery of health care."[43]

1. Oft-cited "Suspect Characteristics"

In its advisory opinions, OIG has incorporated two principles (respectively, in numbers 1 and 2 below) into additional guidance as to what arrangements carry heightened fraud and abuse risk. These opinions identify a number of "suspect" characteristics that, if present, would cause it concern about a sales arrangement; however, in all six advisory opinions that address commission sales/marketing arrangements that, importantly, involve payments to truly independent sales personnel—not to persons in a position to exercise "undue influence" on a purchaser's or patient's ordering decision—OIG *always* has found a low risk of fraud and abuse, and *always* has declined to impose any sanctions, *even when some of the other suspect characteristics are present*.[44] For pedagogical convenience, this article groups these characteristics into four categories (and skips the first characteristic—payment on a percentage of sales—because commission payment is the trigger for all of the potential violations in the commission advisory opinions):

2. Suspect Characteristics Based on the Nature of the Sales Agent

a. "Undue influence." Use of sales agents who are health professionals or persons in a similar position to exert undue influence on purchasers or patients.[45]

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43. *Id.* at 35974.

44. The one commission advisory opinion that was negative fits the "undue influence" paradigm. *See infra* note 60 and accompanying text.

45. Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. at 35954. *See also* Off. of Inspector Gen., Advisory Op. No. 99-08, *supra* note 21 (finding a suspect characteristic where the "party engaged in the marketing or promotional activity . . . . is involved in the delivery of health care (e.g. a doctor, a nurse, a home health aide, or the like) and whether the party is otherwise in a position to exert undue influence on potential purchasers or patients."); U.S. Dep't Health & Hum. Servs., Off. of Inspector Gen., Advisory Op. No. 08-19 (Oct. 29, 2008) ("Marketing by health care providers and suppliers . . . . is subject to closer scrutiny, since health care providers and suppliers are in a position of trust and may exert undue influence when recommending health-care related items or services, particularly to their own patients."). Significantly, *none* of the favorable advisory opinions involve a person in this position, while the one unfavorable advisory opinion and the judicial decisions finding an AKS commission violation *uniformly* involve persons in a position to exercise "undue influence." *See infra* notes 54–59 (favorable advisory opinions), 60, 80–85 (undue influence found), and accompanying text.

3. Suspect Characteristics Based on the Nature of the Audience

a. Targeted to the vulnerable. The target audience is the activity "specifically directed at senior citizens, Medicaid beneficiaries, or other particularly vulnerable populations."[46]

b. Contact with the vulnerable. Direct contact between the sales agent and FHCP beneficiaries prior to the prescribing or dispensing of the product.[47]

c. Physicians and HCPs. Direct contact between the sales agent and physicians in a position to order items or services that are then paid for by a FHCP.[48]

4. Suspect Characteristics Based on the Nature of the Activity

a. Passive or non-coercive v. coercive. The nature of the marketing or promotional activity, "to what degree the activity may be coercive . . . . For example, [with respect to patients] door-to-door marketing, telephone solicitations, and direct mailings are more intrusive, and typically pose a greater potential for abuse than truthful passive advertising in general circulation newspapers or on television."[49]

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46. Off. of Inspector Gen., Advisory Op. No. 99-08, *supra* note 21.

47. *See, e.g.*, Off. of Inspector Gen., Advisory Op. No. 98-10, *supra* note 5. (Importantly, OIG clearly views the potential for *contact* with vulnerable patient populations as less problematic than arrangements that "specifically target" such arrangements.); *see also, e.g.*, Off. of Inspector Gen., Advisory Op. No. 99-08, *supra* note 21 (approving marketing arrangement that, "while it involves direct patient contact, the Arrangement is not *targeted* at Federal health care program beneficiaries." (emphasis added)).

48. *See, e.g.*, *id.* In practice, evidence suggests that the importance of this characteristic is to be doubted. Although OIG has named direct contact between sales agents and *physicians* as a suspect characteristic, it not only has declined to impose sanctions where such direct contact was present, *see, e.g.*, Off. of Inspector Gen., Advisory Op. No. 99-03, *supra* note 31 (declining to impose sanctions despite there being contact between sales agents and physicians), but has affirmatively cited the "less vulnerable" nature of HCPs as a reason not to impose sanctions even when marketing is targeted at HCPs. *See, e.g.*, U.S. Dep't Health & Hum. Servs., Off. of Inspector Gen., Advisory Op. No. 99-10 (Oct. 25, 1999) (declining to impose sanctions despite marketing activities that would directly target physicians, respiratory therapists, and other health care professionals because this was a "less vulnerable audience" to inappropriate inducement than the patient population.).

49. Off. of Inspector Gen., Advisory Op. 99-08, *supra* note 21. *See also* Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. at 35954 ("We, of course, recognize that many of these advertising and marketing activities do not warrant prosecution in part because (1) they are passive in nature, i.e., the activities do not involve direct contact with program beneficiaries . . . ."); U.S. Dep't Health & Hum. Servs., Off. of Inspector Gen., Advisory Op. No.19-04 (Sept. 5, 2019) ("The advertising activity under the Proposed Arrangement is essentially passive in nature because any contact with Requestor must be initiated

5. Suspect Characteristics Based on the Nature of the Product

a. Direct billing of a FHCP by the seller for the item or service sold by the sales agent.[50]

b. Marketing of items or services that are separately reimbursable by a FHCP (e.g., items or services not bundled with other items or services covered by a DRG payment), whether on the basis of charges or costs. [51]

c. Whether the item or service is one for which there is a likelihood of overutilization based on the historical experience of FHCPs, reimbursement methodology, or other reason.[52]

As discussed below, OIG's own advisory opinions support an interpretation of the statute concluding that while a percentage commission may be the *trigger* for the inquiry, it is only the presence of other suspect characteristics that even call for closer scrutiny. Although OIG has noted that "the more factors that are present, the greater the scrutiny we ordinarily will give an arrangement,"[53] except in one instance, discussed below, involving DMEPOS sales (therefore potentially implicating the suspect factors of undue influence on a "vulnerable" patient population),[54] no combination of suspect factors has ever resulted in a negative advisory opinion about ordinary commissions to independent sales agents.

Most important, as discussed more fully in Section IV, despite sometimes inconsistent rhetoric and *dicta*, it is really only the presence of one such characteristic—"undue influence" on a purchaser's or patient's ordering decision—a characteristic almost unique to selling to vulnerable rather than sophisticated audiences that, based on OIG's advisory opinions and the facts in the decided cases, turns a commission into a kickback.

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by a Federal health care program beneficiary. Unlike more direct forms of advertising, such as emails, mailings, or text messages, Requestor's advertisements for Providers would be visible to Federal health care program beneficiaries only if they visit the Marketplace . . . .').

50. *See, e.g.*, Off. of Inspector Gen., Advisory Op. No. 98-10, *supra* note 5. As discussed *supra* note 7, this characteristic almost never is present for medical devices used in Medicare patients except for DMEPOS, which, since such items are sold direct to patients, means that this characteristic nearly always also implicates the undue influence/vulnerable audience factors (#s 1, 2a and 2b above).

51. *See* Off. of Inspector Gen., Advisory Op. No. 98-10, *supra* note 5 (As with direct billing by the seller, this factor is almost never present in medical device sales except DMEPOS). *See supra* note 48.

52. Off. of Inspector Gen., Advisory Op. No. 99-08, *supra* note 21.

53. Off. of Inspector Gen., Advisory Op. No. 99-03, *supra* note 31.

54. *See infra* note 60.

6. Application of "Suspect Characteristics" in Advisory Opinions

As noted, except in one DMEPOS ("vulnerable audience") case, OIG has never issued a negative advisory opinion in a commission sale-type situation. In all six of its other commission opinions—despite the existence of a sales-based payment to the sales agent and despite the presence of one or more of the potentially "suspect" characteristics—OIG found a low risk of fraud and abuse and determined that it would not impose sanctions.

a. The Rule: no combination of suspect factors sufficient to warrant enforcement

(i) Nature of sales agent: Commission to independent sales agent allowed.

The simplest example involved a commission to an independent sales agent where OIG found no suspect factors (other than the percentage commission itself). Here, a manufacturer of disposable medical supplies paid a commission to an independent sales agent based on a percentage of the manufacturer's sales to hospitals or group purchasing organizations ("GPOs") with which the sales agent had negotiated a contract for the manufacturer. Hospitals and GPOs are not vulnerable audiences, and the ordinary sales rep had no other relationship giving rise to the potential for undue influence. The products were not separately paid for, and OIG saw no coercive tactics.[55]

(ii) Nature of audience: contact with persons in a position to order the services or beneficiaries allowed.

(1) Direct contact with ordering persons insufficient for enforcement.

In one advisory opinion that involved contact with HCPs, OIG declined to prosecute an arrangement in which a manufacturer of therapeutic air mattresses used to treat and prevent pressure ulcers would pay an independent supplier a commission on sales of the air mattresses to skilled nursing facilities.[56] As with hospitals and GPOs, nursing facilities are not vulnerable audiences, so the sales agent had no relationship that would provide undue influence, no coercive tactics were noted and the products were not separately paid for.

(2) Direct contact with beneficiaries insufficient for enforcement.

Even *contact* with a vulnerable audience, by itself, has not been enough absent other suspect factors. The podiatrist/shoe store advisory opinion did not

55. Off. of Inspector Gen., Advisory Op. No. 98-10, *supra* note 5.
56. Off. of Inspector Gen., Advisory Op. No. 99-03, *supra* note 31.

involve a sales-based fee, but it did involve direct contact between the sales agents and beneficiaries, and potentially separately reimbursable podiatrist services. OIG concluded this posed a low risk of fraud and abuse because the marketing did not *target* FHCP beneficiaries—though the patient "targets" were anyone in the shoe store who might need a podiatry evaluation, suggesting that a likely focus on the elderly was deemed insufficient—and involved patient education that was not "coercive" in nature.

(iii) Nature of activity: passive advertising and non-coercive patient education allowed.

Similar to the independent sales agent situation, OIG favorably examined a technology company's proposal to allow FHCP beneficiaries to use its online healthcare directory to search for providers and book medical appointments through the technology platform.[57] Health care providers—here, the "product" being sold was appointments for their professional services—would pay the company a "per-click" or per-booking fee to be listed in the directory and could purchase sponsored advertisements on the website.[58] Distinguishing these circumstances from "white coat" marketing to beneficiaries, surely the paradigm of "undue influence," OIG concluded that enforcement was not warranted given the technology company was not a healthcare provider and the advertising was accessible only after proactive searches by potential patients.[59]

(iv) Nature of the product: Separately reimbursable service directly billed by the seller allowed.

(1) Podiatrists redux

As noted above, the services of the podiatrists in that advisory opinion would be separately reimbursable and billed by the selling podiatrists, who would have direct contact with beneficiaries, yet OIG concluded that such contact was neither targeted at beneficiaries nor coercive, thus finding that the separately reimbursable and directly billed "product" did not warrant enforcement.[60]

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57. Off. of Inspector Gen., Advisory Op. No. 19-04, *supra* note 48.

58. *Id*. OIG also noted that by scheduling appointments on behalf of FHCP beneficiaries, the company would be "arranging for the furnishing of federally reimbursable items and services in exchange for the payment of fees," and by displaying search results, as well as providers' sponsored advertisements, the company engages in "advertising activities meant to induce the use of an item or service." *Id.* at 7-8.

59. *Id.* at 8-9; *see also* Off. of Inspector Gen., Advisory Op. No. 08-19, *supra* note 44 (finding that a similar Internet advertising arrangement where chiropractors would pay a per-call or per-lead fee in exchange for being listed on the website's platform, which potential patients could use to search for chiropractors in their area, would present minimal risk of abuse).

60. Off. of Inspector Gen., Advisory Op. No. 99-08, *supra* note 21.

(2) Overutilization

None of these commission advisory opinions found a risk of overutilization, despite potentially separate reimbursement being available in the podiatrist case and the medical technology case.

b. The exception: DMEPOS, no-charge loaner products, and unsafeguarded risks warrant enforcement.

OIG has only once issued a negative advisory opinion in a commission situation, noting a plethora of suspect characteristics and no safeguards against abuse. Here, the commissioned sales agent was itself a Medicare supplier, thus implicating the nature-of-agent suspect factor, and the products were DMEPOS, thus implicating the direct-contact-with-vulnerable-audience/undue influence suspect factor. In addition, the agent consigned product to customer physician offices for the physicians to dispense as temporary "loaners" while the claims were pending, thus giving the referring physicians the direct financial benefit of a no-charge inventory to use with their patients, and OIG specifically noted that the arrangement had no safeguard against the potential for "improper payments" to the physicians.[61]

What thus emerges from a review of the commission advisory opinions is that although OIG has indicated characteristics where scrutiny is called for, a commission based on market conditions, paid to an ordinary independent sales agent, even where the sales agent would be likely to have contact with persons in a position to order, should not in itself warrant AKS enforcement. Even contact with beneficiaries should not be sufficient absent the specific *targeting* of a vulnerable beneficiary audience, the use of "coercive" marketing tactics like door-to-door solicitation, or (as in the DMEPOS "Exception" discussed above) other unusual circumstances and/or adjacent kickback risks without reasonable safeguards.[62]

As discussed more below, the one suspect characteristic present in nearly all judicial decisions and DOJ enforcement involving sales agent commissions is that the person receiving the commission is *not* an ordinary sales agent, but is

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61. U.S. Dep't Health & Hum. Servs., Off. of Inspector Gen., Advisory Op. No. 98-01 n.6 (Mar. 19, 1998) (highlighting that OIG was also troubled by the fact that the sales agent/supplier would be charging "Medicare Prices" substantially in excess of the product maker's list price. In other words, charging Medicare more than private payers, albeit within the Medicare fee schedule. While not specifically cited by OIG, the "substantially in excess" language indicates that OIG was signaling another abuse; OIG's authority to exclude entities from Medicare participation for submitting bills for charges substantially in excess of the entity's usual charges.); *see also* 42 C.F.R. § 1001.701(a)(1) (2017).

62. The amount of commission is rarely discussed, but in one advisory opinion OIG spoke approvingly of "a fixed percentage, which Company A has represented will be fair market value in an arms-length transaction." Off. of Inspector Gen., Advisory Op. No. 99-03, *supra* note 31.

instead a person who is making use of "undue influence" over a person who is in a position to bring about sales. Although "undue influence" is sometimes found in the relationship with the ordering health care provider, more commonly it has been the key factor in assessing the recommender's relationship to the patient when leveraged in the sales/marketing process.

IV. JUDICIAL INTERPRETATION

A. The Classic View: Arranging for or Recommending Has to be Done by a Relevant Decisionmaker

As noted above, in the context of commission sales, it is the "arranging for or recommending" prong of the AKS that is at issue. Although there were not many cases at the turn of the millennium parsing the meaning of "arranging for" or "recommending" under the AKS, it is clear that case law did *not* support the idea of a criminal AKS violation for mere sales/marketing activity, and courts always required something more to support a conviction.[63] Two cases illustrate this classic judicial approach, which turned on whether the recipient of the remuneration was the relevant decisionmaker.

In *United States v. Miles*, the government prosecuted the principals and employees of a home health care agency, for allegedly paying kickbacks to a "public relations firm" for referral of Medicare patients.[64] Under the arrangement at issue, the agency hired the firm to distribute information about its home health care services, including literature and business cards, to doctors

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63. *See supra* note 9 and *infra* Section IV.B. Easily distinguished is a line of *private contract avoidance* cases, voiding commission contracts as against public policy. It is notable that none of these cases has ever been cited as precedent in any of the AKS commission enforcement cases, suggesting that courts do not find them applicable. There are several good reasons for this. Perhaps most important, these decisions are inapplicable to AKS enforcement because they were civil breach-of-contract cases, subject only to the preponderance of evidence standard and calling for different elements of proof. As the trial judge reasoned in one such case, it is not necessary to establish all elements of an AKS criminal (or even civil monetary penalty) violation in order to determine that a contract may be void as against public policy. MedPricer.com v. Becton, Dixon & Co., 240 F. Supp. 3d 263, 274-75 (D. Conn. 2017). Moreover, three of the five cases lacked binding precedential value for a judicial circuit or a state: two were federal district court cases, *see id.*; *see also* Zimmer, Inc. v. Nu Tech Med., Inc., 54 F. Supp. 2d 850 (N.D. Ind. 1999), and another one was decided by an intermediate state court. *See* Med. Dev. Network, Inc. v. Pro. Respiratory Care/Home Med. Equip. Servs., Inc., 673 So. 2d 565 (Fla. Dist. Ct. App. 1996). Finally, in each of the remaining two cases, which a federal court of appeals affirmed, it does not appear that the courts were presented with arguments based on OIG's suspect characteristic analysis but rather applied the language of the law and/or precedent from non-commission AKS cases to reject technical arguments on the applicability of a safe harbor. *Compare* Joint Tech., Inc. v. Weaver, No. CIV-11-846-M, 2013 WL 257075, at *2-3 (W.D. Okla. Jan. 23, 2013) (employment safe harbor not available to independent contractor), *aff'd*, 567 F. App'x 585 (10th Cir. 2014), *with* Nursing Home Consultants, Inc. v. Quantum Health Servs., Inc., 926 F. Supp. 835, 844 (E.D. Ark. 1996) (personal services safe harbor not available where compensation not fixed in advance), *aff'd*, 112 F.3d 513 (8th Cir. 1997).

64. 360 F.3d 472, 474 (5th Cir. 2004).

in the area. When a doctor determined that home health care services were needed for a patient, the doctor could contact the firm with the patient's information. The firm, in turn, provided the patient's information to the home health agency, which would deliver the necessary services ordered by the physician to patients. The agency paid the public relations firm $300 for each client it received this way.[65]

Despite these payments, the Fifth Circuit reversed the defendant's AKS convictions, noting that the referring physicians did not receive any remuneration under the arrangement that could affect their referral decision-making and that the arrangement "did not unduly influence the doctors' decisions."[66] That the PR firm received a payment seems not even to have been relevant to the court's decision, because the firm was not the relevant decisionmaker, nor in a position to exert undue influence on the relevant decisionmaker.

The *Miles* court contrasted its conclusion with another circuit's decision to affirm AKS convictions, where the court concluded that the sales representative *was* the relevant decisionmaker. In *United States v. Polin*, the Seventh Circuit affirmed the AKS convictions of employees of a pacemaker monitoring service, which paid the sales representatives of a pacemaker medical device maker $50 in cash for each Medicare patient that was referred to their monitoring center.[67] In this case, the sales representatives were responsible for patient follow-up after implantation, including arranging for ongoing monitoring of the implanted device.[68] As such, the court concluded that the sales agent effectively was the decisionmaker as to which monitoring service would receive the business and that the agent's recommendation amounted to a selection since the suggestion was never once refused.[69]

The critical issue in both of these cases was *who* made the decision to refer a patient for services reimbursed by Medicare: "[u]nder our reading of the statute, 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 correctly upheld the conviction of the individuals who paid the salesman. . ."[70] In contrast, in *Miles*,

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65. *Id.* at 479.

66. *Id.* at 480.

67. 194 F.3d 863, 864 (7th Cir. 1999).

68. *Id.* at 864-65.

69. *Id.* at 866 ("Once it was decided that the patient would be sent to an outside service for monitoring, [the sales representative] would suggest [defendants] or a similar service to the physician. Never in his fourteen year career was [the sales representative's] suggestion rebuked by a physician. Indeed, after his recommendation was made, he would call [the monitoring service] and arrange for the patient's follow-up himself. Of course, [the monitoring service] would have to receive the physician's authorization before commencing service, but that permission seemed to be more of a formality or rubber stamping of [the sales representative's] referral.").

70. *Miles*, 360 F.3d at 480–81 (emphasis added).

the "relevant decisionmakers" were the physicians who determined that a patient required home health care services, and because those physicians were *not paid to influence* their choice of home health care providers, the payments to the marketing firm for advertising the home health agency's services did not violate the statute.[71]

B. Variation: The Recipient with "Undue Influence"

As noted above, research did not locate any AKS enforcement cases holding that commissions to independent sales representatives were kickbacks until the turn of the current century.[72] Since then, a number of federal appeals courts have upheld AKS criminal convictions based on commission-type payments for arranging for or recommending covered products to be used in the care of Medicare patients, and several of those decisions have also described those commissions as, or as equivalent to, *per se* AKS violations.[73]

However, as discussed further below, a close reading of these decisions results in the conclusion that they are consistent with OIG's historical guidance and the *Miles* court's rationale: commissions are a kickback only when paid to a decisionmaker, or someone in a position to exercise "undue influence" over that decision.

1. "[G]arden Variety" Undue Influence: Payments to Doctors and Buyer Employees

The Second Circuit has characterized payments to the referring physicians as a "garden-variety kickback scheme."[74] In another recent decision, the Fourth

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71. *Id.* at 479-80.

72. *See supra* note 62 (citing note 9 and contract avoidance cases).

73. *See* cases cited *supra* note 2.

74. *See, e.g.*, United States v. Krikheli, No. 09-CR-725, 2009 WL 4110306 (E.D.N.Y. Nov. 24, 2009) (physicians personally, or through intermediaries, arranged for patients to be referred to a radiological testing facility operated in exchange for payments to the referring doctors and the physicians), *aff'd*, 461 F. App'x 7 (2d Cir. 2012) (non-precedential); *see also* United States v. Medoc Health Servs., LLC, 470 F. Supp. 3d 638, 645 (N.D. Tex. 2020) (physicians were made owners of management services organizations for pharmacies and received "profits" based on their referrals to those pharmacies). *See also Press Release: Seven Texas Doctors and a Hospital CEO Agree to Pay over $1.1 Million to Settle Kickback Allegation*s, DEP'T OF JUST. (Jan. 20, 2022), https://www.justice.gov/usao-edtx/pr/seven-texas-doctors-and-hospital-ceo-agree-pay-over-11-million-settle-kickback [https://perma.cc/MJ38-WUVS]; *Press Release: Ten Texas Doctors and a Healthcare Executive Agree to Pay over $1.68 Million to Settle Kickback Allegations*, DEP'T OF JUST. (Mar. 22, 2022), https://www.justice.gov/usao-edtx/pr/ten-texas-doctors-and-healthcare-executive-agree-pay-over-168-million-settle-kickback [https://perma.cc/38LA-VTAN]; *Press Release: McAllen Woman Pleads Guilty to Multi-Million Dollar Kickback Conspiracy*, DEP'T OF JUST. (Mar. 7, 2019), https://www.justice.gov/usao-sdtx/pr/mcallen-woman-pleads-guilty-multi-million-dollar-kickback-conspiracy [https://perma.cc/VR4D-

Circuit upheld criminal AKS convictions of the owners of a clinical laboratory for paying, and independent sales representatives for receiving, commissions; but the facts make the result consistent with OIG's principles, because the lab (through the involvement of the sales representatives) was also paying the physicians a per test-order "process and handling fee."[75] Likewise, courts have had little difficulty finding kickbacks in payments made to employees of the referring provider.[76] In these cases, there is no need for the court to articulate the presence of "undue influence" because direct payment to those in a position to influence or select the product or service makes it obvious.[77]

2. Further Articulating the "Undue Influence" Standard

Putting aside the low-hanging fruit of payments to the referring doctors and the doctors' employees, courts have applied the concept to other insiders who are deemed to be either in a position to make directly, or as a practical matter bring about, the decision as to whether the product or service should be

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VWV3] (Texas pharmacy marketer pleaded guilty when she paid physicians to write expensive compound drugs).

Payments to providers have also been a common theme in FCA settlements with compounding pharmacies who paid physicians for prescribing pain creams that would be filled at specific pharmacies which they controlled. *See, e.g., Press Release: Three Physicians and Five Marketers Charged for Violations to Federal Anti-Kickback Statutes*, DEP'T OF JUST. (June 13, 2019), https://www.justice.gov/usao-ndok/pr/three-physicians-and-five-marketers-charged-violations-federal-anti-kickback-statutes [https://perma.cc/XC2C-U7LN]; *Press Release: Compounding Pharmacy, Two of Its Executives, and Private Equity Firm Agree to Pay $21.36 Million to Resolve False Claims Act Allegations*, DEP'T OF JUST. (Sept. 18, 2019), https://www.justice.gov/opa/pr/compounding-pharmacy-two-its-executives-and-private-equity-firm-agree-pay-2136-million [https://perma.cc/JA7P-EJ2Z] (payments from compounding pharmacy to telemedicine prescribing doctors, including copayment waivers and sham charitable foundation).

75. United States *ex. rel.* Lutz v. Mallory, 988 F.3d 730, 735 (4th Cir. 2021). In upholding the conviction of one of the sales reps for receiving unlawful remuneration, the *Mallory* court specifically noted that in communicating with the physicians, rep "emphasized [their] ability to profit from P&H fees, a key component of the [g]overnment's case." *Id.* at 740. Of course, even this case does not stand for the proposition that all payments to physicians for services to a business that benefits from their referrals are kickbacks. Not only were the physicians not defendants in the appeal, the court emphasized that the profit-motive discussions, and repeated warnings from counsel about the arrangement, showed an intent by the sales agents to exercise undue influence by using the P&H payments as a kind of bribe. *Id.* at 739-40.

76. *See, e.g.*, United States v. St. Junius, 739 F. 3d 193, 215 (5th Cir. 2013); United States v. Robinson, 505 F. App'x 385, 388 (5th Cir. 2013) (unpublished). In both cases, kickback convictions were upheld for commission-type payments to employees or contractors of healthcare providers for mining their employer's databases and passing the information on to product sellers.

77. Similarly, it is easy to see that payments to patients are also low-hanging fruit. *See Press Release: Houston Nurse Guilty in East Texas Health Care Kickback Scheme*, DEP'T OF JUST. (Mar. 6, 2020), https://www.justice.gov/usao-edtx/pr/houston-nurse-guilty-east-texas-health-care-kickback-scheme [https://perma.cc/82JY-L9NG]. *See also* United States v. Lobe, No. 18-CR-00040-RWS, 2020 U.S. Dist. LEXIS 40874, at *1 (E.D. Tex. Mar. 6, 2020).

prescribed or used, or who should supply it. The Fifth Circuit's decision in *Miles* summarizes this "undue influence" rule succinctly:

> 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 mere fact that the good or service provider compensates the advertiser following each purchase is insufficient to support the provider's conviction for making a payment "to refer an individual to a person" under [the AKS].[78]

3. Undue Influence Absent: Ordinary Sales Calls on Providers

As discussed above, *Miles* itself applied this rule to vacate an AKS conviction for per-patient payments when the recipients were, in effect, just independent sales agents, with no ability to exert "undue influence."[79] The court's description of the "professional marketers" tracks that of an independent sales agent. The marketers working for the home health agency would visit physicians and provide them with their contact information and promotional materials about their client. Physicians who wanted to make a referral to the agency for which the marketers worked would send a patient's contact information to the marketers, and the marketers would pass along the referral. The court observed that the marketers had no decision-making authority and "did not unduly influence the doctors' decisions."[80] Without evidence of undue influence on the purchasing decisionmaker or patient, or other suspect characteristics, the commissions paid to the public relations firm, although based on each patient referred, did not meet the definition of a prohibited referral within the meaning of the AKS.[81]

4. "Undue Influence" Found

There would be little reason to write this article if the *Miles* rule were a free pass for all cases involving commissions, and in other cases, the court has found, sometimes expressly, sometimes implicitly, that "undue influence" was present. However, in each such case, it is evident that, unlike the situation of a legitimate independent sales agent, the recipient of the payment was in a position to make or bring about the referral.

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78. United States v. Shoemaker, 746 F.3d 614, 628 (5th Cir. 2014) (quoting United States v. Miles, 360 F.3d 472, 480 (5th Cir. 2004)).

79. *See* United States v. Miles, 360 F.3d 472, 479-81 (5th Cir. 2004).

80. *Id.* at 480.

81. *See id.*

a. Pressuring the boss

In *United States v. Shoemaker*, the Fifth Circuit upheld the conviction of the owner of a nurse staffing business, who paid the board chair of a community hospital five dollars for every hour of work his contract nurses billed at the hospital, and the board chair, in turn, pressured the hospital CEO to increase the hospital's use of the business's contract nurses.[82] The facts of *Shoemaker* presented an "archetypal example of the undue influence prohibited by the [AKS]," as the evidence clearly showed that the chair received payments not to distribute a brochure about the nursing company to hospital staff or engage in any form of traditional marketing, but rather to exploit his relationships with hospital executives to steer business towards the company.[83]

b. Vulnerable audiences

These cases all involve "undue influence" resulting from the unique vulnerability of elderly and disabled patients.

(i) "Patient recruiters"

In two related cases, the Fifth Circuit upheld AKS convictions for "patient recruiters" who exerted undue influence by seeming to befriend and even bribe patients to join a partial hospitalization program. The recruiters visited group homes and assisted living facilities to recruit patients by giving residents gifts, including cigarettes, paying their co-payments, and driving patients to the program. One patient recruiter owned a boarding house and required her residents to attend the partial hospitalization program, while other recruiters made payments to the owners of group homes they visited based on the number of beneficiaries from that home who attended the program.[84]

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82. United States v. Shoemaker, 746 F.3d 614, 616, 627 (5th Cir. 2014).

83. *See id.* at 629.

84. *See* United States v. Gibson, 875 F.3d 179, 186-89 (5th Cir. 2017). The *Gibson* court made a point of distinguishing the benign marketing services in *Miles*. *Id.* at 190-91; *see also* United States v. Ricard, 922 F.3d 639, 641 (5th Cir. 2019) (affirming the conviction of a patient "recruiter" who received a flat fee for each home health referral, all of whom came from the behavioral health center where her fiancé worked). *See also* United States v. George, 900 F.3d 405 (7th Cir. 2018) *aff'g* 171 F. Supp. 3d 810 (N.D. Ill. 2016) (affirming the conviction of the defendant who, according to the government's brief, "went directly to Medicare beneficiaries, got their information, and made the decision herself to refer those patients to [the agency], rather than having doctors or patients make those decisions themselves."); United States v. Williams, 218 F. Supp. 3d 730, 738-39 (N.D. Ill. 2016) (defendant, a patient "recruiter", called Medicare beneficiaries to collect information that was transmitted to a home health agency in exchange for a per-patient referral fee). The Ninth Circuit affirmed an AKS conviction in United States v. Adebimpe, 649 F. App'x 449, 455 (9th Cir. 2016) (affirming the conviction of a recruiter who

(ii) Deceitful offers of "free" DMEPOS and coercive marketing

DMEPOS suppliers are particular favorites for "undue influence" convictions, both because such products are separately paid for by FHCPs, and marketed directly to patients, who are perceived as more vulnerable to undue influence than health care providers.[85] In these cases, the "undue influence" often consists of outright deception and violation of other patient protection rules in the sales/marketing process. In *United States v. Turner*, for example, the court upheld the AKS conviction of a "recruiter" of Medicare beneficiaries for DME arthritis kits in exchange for a per-beneficiary fee.[86] The court found that the recruiter used telemarketers to contact beneficiaries before a device had been prescribed or dispensed to falsely inform them that they were entitled to free arthritis kits (ignoring the 20% co-insurance for DME supplies, and potentially in violation of the prohibition on DME telemarketing).[87]

c. Effective Decisionmaker

As discussed above, in *Polin*, the court upheld the conviction of employees of a cardiac pacemaker monitoring service for paying a per-patient fee to the pacemaker manufacturer sales representatives whom the court found effectively controlled the decision as to which monitoring service would be used.[88]

In sum, while not always using OIG's term "undue influence," in each of these cases the court's finding of a violation (or, as occasionally reflected in the footnotes, the government's allegations in bringing or joining or settling the

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collected information directly from Medicare beneficiaries and sent it to a medical supply company).

85. *Compare* Off. of Inspector Gen., Advisory Op. No. 99-08, *supra* note 21 (stating that senior citizens and Medicaid beneficiaries are "particularly vulnerable" populations), *with* Off. of Inspector Gen., Advisory Op. No. 99-10, *supra* note 5 (stating that health care professionals are a "less vulnerable audience"). *See supra* notes 45-46 and accompanying text.

86. 561 F. App'x 312, 316-17 (5th Cir. 2014).

87. *Id.; see also* United States v. Brown, 871 F.3d 352, 354-55 (5th Cir. 2017) (obtaining Medicare numbers directly from beneficiaries, selling the information to DME and home health companies, and arranging with specific doctors to "rubber stamp" orders); Second Amended Complaint, United States *ex rel.* Herman v. Coloplast Corp., No. 11-cv-12131-RWZ (D. Mass. June 1, 2015), ECF No. 40 (intervened False Claims Act case alleging that suppliers and marketers of DME ostomy and continence care products used pre-existing relationships with patients to switch to defendants' products). *Cf.* United States *ex rel* Silva v. VICI Mktg., LLC, 361 F. Supp. 3d 1245, 1248-49 (M.D. Fla. 2019) (excerpting Complaint at 2, United States *ex rel.* Silva v. Z Stat Med., LLC, No. 15-cv-00444, ECF No. 39 (M.D. Fla. Oct. 18, 2018)) (intervened False Claims Act case involving direct marketing to patients of pain cream products).

88. United States v. Polin, 194 F.3d 863, 866 (7th Cir. 1999); *see also* United States v. Vernon, 723 F.3d 1234, 1254 (11th Cir. 2013) ("patient advocate" was "effectively responsible for deciding which pharmacy to use for the filling of patients' prescriptions"); United States v. George, 171 F. Supp. 3d 810, 815 (N.D. Ill. 2016) ("like the defendants in *Vernon*, defendant [whom the court noted was also a "Certified Homemaker"] was effectively responsible for deciding which home health service the patients used" (citing United States v. Vernon, 723 F.3d 1234, 1254 (11th Cir. 2013)).

case) relied on facts that support a high degree of "undue influence" over the referral. "Undue influence" has been the crux of the violation where the recipient has authority over the decisionmaker,[89] or is found to be the effective decisionmaker,[90] and most often when the recipient of the remuneration is dealing with a vulnerable (usually elderly, usually ill) beneficiary population: bearing gifts, free transportation, untrue offers of "free" products, door-to-door solicitation.[91] These decisions highlight the need for enforcement and sanction where the recipient of the commission is in a position to engage in, and has engaged in, the use of "undue influence" to bring about sales. Conversely, they do not support the conclusion that a commission to a truly independent sales agent, not in such a position, should be the basis for an AKS violation.

V. CONCLUSION

In light of the law's purposes and legislative history, administrative guidance and the results of these enforcement actions, together with the Supreme Court's recent interpretation of "induce" in *Hansen*, the best reading of the AKS is that commission-based arrangements with independent sales agents should be protected from AKS enforcement or liability so long as the relationship with those agents represents "a legitimate payment to a legitimate agent employed in a traditional manner to sell a product."[92] OIG's advisory opinions describe the suspect characteristics that help identify whether the arrangement is in fact a legitimate payment to a legitimate agent.[93]

There can be no serious argument that this would conflict with any of the AKS's purposes. Legitimate sales agents do not control the ordering of the products they sell. Those decisions are made by health care professionals and providers, so merely incentivizing the sales agent cannot reasonably contribute to overutilization, increased program costs, corruption of medical judgment, patient steering, or unfair competition.[94] The legislative history supports an exemption for commission sales agents. OIG's advisory opinions support this conclusion and describe the suspect characteristics that help identify whether the arrangement is in fact a legitimate payment to a legitimate agent. Despite

89. United States v. Shoemaker, 746 F.3d 614, 629 (5th Cir. 2014).

90. *See* United States v. Tuner, 561 F. App'x 312, 316-17 (5th Cir. 2014).

91. *Id.*

92. 123 CONG. REC. H30280 (1977) (statement of Rep. Rostenkowski). Whether protection should arise from the employment exception, as Chairman Rostenkowski stated, or in some other way, is a technical point that could be resolved in any number of ways. *See* Appendix (suggesting joint DOJ/OIG guidance as a potential pathway).

93. *See supra* Section III.

94. *See supra* note 12 and accompanying text. For the prospect that the incentive of the commission alone might lead to other abuses, *see supra* note 29 (discussing the ubiquity of device industry compliance practices) and *infra* note 100 (exploring the utility of OIG's existing "suspect characteristics" analysis).

inflated language, the judicial decisions track the OIG's guidance and this result.

Moreover, despite the *dicta* in some opinions, *all* of the commission enforcement cases finding a violation include facts that show that persons or entities receiving payments were not a "legitimate agent employed in a traditional manner to sell a product," but instead were in a position to exert "undue influence" on the treatment decision, most frequently on the patient.[95] Cases have found "undue influence" when sales-based payments for sales/marketing activities are made to physicians and other health care professionals and their employees,[96] to so-called "recruiters" who actually have formed some close and influential relationship with the patient,[97] to a board member exercising influence over the CEO,[98] and in cases, especially DME cases, involving direct sale to beneficiaries.[99]

And yet, inflation in the language represented in this growing body of case law suggests otherwise. So what, if anything, is to be done about the independent sales agent commission issue?

On the one hand, one would hope that there is little reason to think that responsible OIG or DOJ enforcement authorities will bring, or join, AKS cases based simply on a percentage commission to an independent sales agent, without other suspect facts. Nothing in the authorities discussed above—whether OIG's guidance, the holdings of the opinions, or the facts underlying

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95. *See supra* Section IV. Although its rhetoric about commissions as kickbacks is among the more extreme examples—and more evidence that corrective guidance from DOJ and OIG is called for—the recent decision in U.S. *ex rel.* Lutz v. Mallory, 988 F.3d 730 (4th Cir. 2021), is not to the contrary. In that case, the sales agents not only received commissions but used the laboratory's payments of P&H fees to the physicians—which were also found to be unlawful kickbacks—as inducements to the physicians. *See Mallory*, 988 F. 3d at 735-36. The AKS convictions of the sales agents thus may be understood to have been as much for the agents offering or paying kickbacks to the doctors, as for receiving commissions, or alternatively, as empowering the sales agents with "undue influence" in the form of the payments to the doctors.

96. *See* United States v. Krikheli, No. 09-CR-725, 2009 WL 4110306 (E.D.N.Y. Nov. 24, 2009), *aff'd*, 461 F. App'x 7 (2d Cir. 2012) (physicians, personally or through intermediaries, arranged for patients to be referred to a radiological testing facility in exchange for payments to referring doctors); United States v. Medoc Health Servs., LLC, 470 F. Supp. 3d 638, 645 (N.D. Tex. 2020) (physicians were made owners of management services organizations for pharmacies and received "profits" based on their referrals to those pharmacies); United States *ex rel.* Lutz v. Mallory, 988 F.3d 730, 735, 739-40 (4th Cir. 2021). *See also* sources cited *supra* note 74 and accompanying text.

97. *See* United States v. Shoemaker, 746 F.3d 614 (5th Cir. 2014).

98. *See* United States v. Miles, 360 F.3d 472, 479-81 (5th Cir. 2004). *See also* 56 Fed. Reg. at 35974; U.S. Dep't of Health & Hum. Servs., Off. of Inspector Gen., Advisory Op. No. 99-03, *supra* note 31, at 4-5 (noting the broad potential application of the anti-kickback statute to sales agents).

99. *See* United States v. Shoemaker, 746 F.3d 614, 629 (5th Cir. 2014); United States v. Gibson, 875 F.3d 179, 190-91 (5th Cir. 2017); United States v. Ricard, 922 F.3d 639, 641 (5th Cir. 2019); United States v. George, 900 F.3d 405 (7th Cir. 2018), aff'g 171 F. Supp. 3d 810, 815 (N.D. Ill. 2016); United States v. Williams, 218 F. Supp. 3d 730, 738-39 (N.D. Ill. 2016); United States v. Adebimpe, 649 F. App'x 449, 455 (9th Cir. 2016). *See also* Off. of Inspector Gen., Advisory Op. No. 99-08, *supra* note 21; Off. of Inspector Gen., Advisory Op. No. 99-10, *supra* note 5 and accompanying text.

the settlements—suggests that would be a well-founded action, nor one consistent with decades of experience under the AKS.

On the other hand, the existing state of the law and guidance—including OIG's continuing guidance stating that virtually every independent commission may be "at least [a] technical violation"[100] of the AKS—coupled with the *dicta* quoted in too many of the more recent AKS enforcement cases, gives the government, or a *qui tam* relator, an unfair advantage in commission cases: a free pass beyond a motion to dismiss. Moreover, at trial, instead of needing to prove the presence of "undue influence," the government may be able to count on a jury instruction advising that is not an element of the offense. And where sufficient government-funded healthcare is present, FCA relators (or their counsel) may be incented to proceed. Prudent allocation of government enforcement and industry compliance resources dictates that medical device makers who daily provide medically necessary products for patient diagnosis and treatment, and often are not large enterprises with the resources to fully employ a sales force[101]—should not have to live with that risk.

In sum, OIG and DOJ should provide clear guidance to the medical products community that articulates the principles set forth in OIG's advisory opinions and in the actual facts of AKS enforcement cases. Such guidance should preclude the possibility of sales-based commission arrangements resulting in AKS enforcement (or conviction), without a demonstrable presence of undue influence on a relevant decisionmaker, or some other combination of aggravating suspect characteristics at least as severe as those that have been present in the adverse decisional law discussed. The Appendix sets forth proposed joint DOJ/OIG enforcement guidelines that would incorporate the principles recognized in OIG's guidance and in judicial precedent.

It is true that this is not a perfect solution, because joint agency guidance will not be binding on courts, or on FCA *qui tam* relators. However, in the absence of statutory reform—unlikely because there is always bipartisan antagonism for anything that, however unjustifiably, could be characterized as soft on "waste, fraud and abuse"—there seems no way to force these changes. But in the interests of not allowing the perfect to be the enemy of the good, it is

100. *See, e.g.*, 56 Fed. Reg. at 35974; U.S. Dep't of Health & Hum. Servs., Off. of Inspector Gen., Advisory Op. No. 99-03, *supra* note 31, at 4-5 (noting the broad potential application of the anti-kickback statute to sales agents).

101. *See supra* note 3 (discussing the dominance of small, entrepreneurial companies in medical device innovation and the reliance on independent sales agents); *supra* note 6 (noting the dual role of device reps as sales agents and advisors, with practices extending globally); *supra* note 28 (highlighting the AKS employment exception and contrasting the pharmaceutical and medical device industries' sales models).

to be hoped that the weight of agency interpretation, bolstered by the analysis set forth in this article, will also lead courts to dismiss from FCA cases counts that are based on no more than "a legitimate payment to a legitimate agent employed in a traditional manner to sell a product."[102]

102. *See supra* note 22 (highlighting Rep. Rostenkowski's statement on conventional sales agents). To be sure, there is always a risk of misbehavior by the sales agents themselves. They could pay kickbacks to the ordering professionals or providers or otherwise find ways to exercise "undue influence." That appears to be the underlying rationale for the *Mallory* decision, *see* U.S. *ex rel.* Lutz v. Mallory, 988 F.3d 730 (4th Cir. 2021). But that is precisely why the OIG has identified "suspect characteristics" to guide enforcement. *See* Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. at 35954. *See also supra* note 45 (noting the OIG's analysis of suspect characteristics and undue influence in marketing arrangements); *see supra* notes 46-49 (providing examples of OIG advisory opinions related to marketing practices and vulnerable populations); *see also supra* notes 50-53 (analyzing characteristics typically absent in medical device sales except in DMEPOS cases). There is no reason to think that the industry's compliance apparatus would be any less effective if enforcement were limited to cases involving those "suspect characteristics." *See supra* note 29.

APPENDIX

Proposed DOJ/OIG Enforcement Guidelines

Joint DOJ/OIG Guidelines for initiating enforcement proceedings under the Federal Health Care Programs ("FHCP") anti-kickback statute ("AKS") for payment of commissions to independent sales agents of medical devices.

The AKS[103] is criminal statute prohibiting the offer, payment, solicitation or receipt of any remuneration for, among other things arranging for or recommending the purchase, order or lease of any item or service for which payment may be made under a FHCP. The Department of Justice ("DOJ") has responsibility for criminal enforcement, and the Department of Health and Human Services Office of Inspector General ("OIG") has responsibility for enforcement of various administrative sanctions, including civil monetary penalties and exclusion from FHCP participation. Because AKS cases are often brought under the False Claims Act ("FCA"), DOJ also has responsibility for AKS enforcement in those cases as well.

Under current law, questions may be raised as to whether the statute is implicated when a maker of medical devices pays an independent sales agent for promoting (by hypothesis, "arranging for or recommending") the sale of a product that may be used in the diagnosis or treatment of a FHCP patient. The personal services "safe harbor" may be available for certain such arrangements, but may not be available for traditional commission-type payments: compensation that is based directly or indirectly on the amount of product sold. OIG is aware that in many sectors of the medical device industry, such compensation is the norm and, accordingly, has consistently advised that, such arrangements generally merit enforcement only when certain "suspect characteristics" are present. OIG's analysis of recent judicial opinions in AKS cases supports the conclusion that DOJ is cognizant of these characteristics in exercising prosecutorial discretion over which cases to bring, including which relator-initiated False Claims Act cases to join.

However, *obiter dicta* in more than one judicial opinion rendered in such cases seems to equate all commission-type arrangements with kickbacks. OIG and DOJ are concerned that such language may encourage prosecutions or FCA cases in circumstances where suspect characteristics are not present, that do not warrant the use of federal resources in enforcement, and that do not, in fact, involve violations of the AKS.

For this reason, OIG and DOJ have jointly adopted these guidelines, to encourage AKS enforcement against payment or receipt of commission-type payments to independent sales agents of medical devices only in circumstances where the totality of the circumstances show that enforcement is necessary to prevent patient or FHCP abuse, which may be the case when there is strong evidence that one or more of the following suspect characteristics is present.

1. Nature of the sales agent
   a. Undue Influence. Use of sales agents who are health professionals or

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103. Social Security Act § 1128B(b) (codified at 42 U.S.C. § 1320a-7b(1)(b) (2010)).

persons in a similar position to exert undue influence on purchasers or patients.

i. Commentary: Along with targeting a vulnerable audience (see #2 below), this is one of the two most important factors. Ordinary sales agents, whose only relationship with the person ordering or purchasing is that of an independent promoter of the product, generally should not be in a position to exercise any "undue influence." Most of the cases in which AKS commission convictions have been upheld have involved persons who are in a position to exercise "undue influence."[104] In addition to health care professionals (HCPs) (when communicating with patients), "undue influence" has been found where the person receiving the remuneration is in a position of authority over, or is effectively, the decisionmaker,[105] and where the recipient of the commission has used deception, bribes or gifts to influence a healthcare professional or beneficiary.[106]

2. Nature of the audience

a. Targeted to the vulnerable. Is the sales/marketing activity specifically directed at senior citizens, Medicaid beneficiaries, or other particularly vulnerable populations.

i. Commentary: Neither OIG's advisory opinions nor the reported cases cite this factor except in its absence, e.g., OIG gave

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104. *See, e.g.*, United States v. Shoemaker, 746 F.3d 614, 627-29 (5th Cir. 2014) (presenting an "archetypal example of the undue influence prohibited by the [AKS:]" payments to board chair of local hospital, not to distribute a brochure about the nursing company to hospital staff or engage in any form of traditional marketing, but rather to exploit his relationships with hospital executives to steer business towards the company).

105. *See, e.g.*, United States v. Miles, 360 F.3d 472, 480-81 (5th Cir. 2004) ("[B]ecause 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 [in *Polin*] correctly upheld the conviction of the individuals who paid the salesman."), (citing with approval United States v. Polin, 194 F.3d 863, 866 (7th Cir. 1999) ("Once it was decided that the patient would be sent to an outside service for monitoring, [the sales representative] would suggest [defendants] or a similar service to the physician. Never in his fourteen-year career was [the sales representative's] suggestion rebuked by a physician. Indeed, after his recommendation was made, he would call [the monitoring service] and arrange for the patient's follow-up himself. Of course, [the monitoring service] would have to receive the physician's authorization before commencing service, but that permission seemed to be more of a formality or rubber stamping of [the sales representative's] referral."). S*ee also* United States v. Vernon, 723 F.3d 1234, 1254 (11th Cir. 2013) (noting that "patient advocate" was "effectively responsible for deciding which pharmacy to use for the filling of patients' prescriptions").

106. *See, e.g.*, Off. of Inspector Gen., Advisory Op. No. 98-1, (Mar. 19, 1998) (free inventory of loaner products to referring physicians); United States v. Turner, 561 F. App'x 312, 316-17 (5th Cir. 2014) (telemarketers falsely informed beneficiaries that they were entitled to free arthritis kits, and did not collect the twenty percent co-insurance for DME supplies, potentially also in violation of the prohibition on DME telemarketing).

favorable treatment to an advertising campaign by podiatrists in a shoe store because although there would be contact with FHCP beneficiaries, the store sold to all kinds of customers and beneficiaries therefore were not a special target.[107]

b. Contact with the vulnerable. Direct contact between the sales agent and FHCP beneficiaries prior to the delivery or dispensing of the product.
    i. Commentary: As noted immediately above, OIG has given favorable advisory opinion treatment where there was contact with Medicare beneficiaries when those beneficiaries were not the exclusive or even primary targets of the sales activity.[108] However, most cases of suspect commission sales activity have been found in situations where sales/marketing activity was directed at patients, who are deemed not to be sophisticated purchasers, and to be particularly "vulnerable" to aggressive sales tactics.[109] It is important to note that the danger is of inappropriate sales/marketing activity. Where the sales agent's role is limited to fitting or training of a device that has already been prescribed and dispensed prior to the agent's appearance, this generally should not be an issue.
c. Physicians and other HCPs. Direct contact between the sales agent and physicians in a position to order items or services that are then paid for by a FHCP
    i. Commentary: Although this factor may be considered, it would be the unusual case where contact *itself* with physicians or other product decisionmakers by independent sales agents represents an abusive situation. Subsequent OIG guidance recognizes that, in general, physicians and other health care professionals "such as DME suppliers, physicians, and respiratory therapists" are "a less vulnerable audience" than patient customers.[110]

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107. Off. of Inspector Gen., Advisory Op. No. 99-08, (July 6, 1999) (finding that a suspect characteristic is present if "the activity is specifically directed at senior citizens, Medicaid beneficiaries, or other particularly vulnerable populations," but approving marketing arrangement that, "while it involves direct patient contact, the Arrangement is not targeted at Federal health care program beneficiaries.").

108. *See* Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952, 35974 (Jul. 19, 1991) (to be codified at 42 C.F.R. pt. 1001). *Cf.* U.S. Dep't of Health & Hum. Servs., Off. of Inspector Gen., Advisory Op. No. 98-10 (Aug. 31, 1998) (discussing the approval of a low risk of fraud and abuse commission arrangement that "would technically fall within the prohibition of the anti-kickback statute if the requisite intent were present").

109. *See, e.g.*, United States v. Turner, 561 F. App'x 312, 316-17 (5th Cir. 2014) (defendant "used . . . teenagers . . . to solicit Medicare beneficiaries by telephone, then used information gathered during those calls to bill . . .").

110. *See, e.g.*, Off. of Inspector Gen., Advisory Opinion No. 98-10, *supra* note 5 ("There was no contact between Sales Agent A and patients or physicians. [He] was not in a position to

3. Nature of the activity
   a. Coercive. The nature of the marketing or promotional activity, the degree to which it may be coercive, or perceived to be coercive.[111]
      i. Commentary: For marketing by independent sales agents to HCPs, this should rarely be an issue. With respect to consumers, door-to-door marketing, telephone solicitations, and direct mailings are more intrusive, and typically pose a greater potential for abuse than truthful passive advertising in general circulation newspapers or on television.
4. Nature of the Device
   a. Direct billing of a FHCP by the seller for the item or service sold by the sales agent.
      i. Commentary: For medical devices, this is rarely the case in Medicare except for items paid for under the durable medical equipment, prosthetics or orthotics (DMEPOS) benefit. DMEPOS also often involve direct contact with patients, who are recognized to be "vulnerable" to inappropriate sales/marketing activity. Direct billing thus generally should not be an issue absent this connection of the sales agent to vulnerable patients, and again, excluding situations where the product has already been prescribed and dispensed.
   b. Marketing of items or services that are separately reimbursable by a FHCP (e.g., items or services not bundled with other items or services covered by a DRG payment), whether on the basis of charges or costs.
      i. Commentary: As noted, except for DMEPOS (and certain passthrough devices) this is rarely the case for medical devices. Like billed by the seller, for DMEPOS, separately reimbursable should be connected with inappropriate/coercive sales/marketing activity to the beneficiary in order to deserve scrutiny.
   c. Whether the item or service is one for which there is a likelihood of over-utilization based on the historical experience of FHCPs, reimbursement methodology, or other reason.

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exert undue influence on medical decision-making . . . [and his] direct contacts were sophisticated purchasers, either [GPOs] or . . . multi-hospital systems . . .").

111. *See, e.g.*, Off. of Inspector Gen., Advisory Op. No. 99-08, *supra* note 21 ("One relevant factor is whether and to what degree the activity may be . . . perceived to be coercive by the party to whom the activity is directed. For example, door-to-door marketing, telephone solicitations, and direct mailings [to beneficiaries] are more intrusive, and typically pose a greater potential for abuse, than truthful passive advertising in general circulation newspapers or television.").

i. Commentary: This factor has been mentioned, but never found to be present in a commission Advisory Opinion. In other non-commission cases, diagnostics and other non- or minimally-invasive services have been noted as most subject to over-utilization.[112]

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112. *See, e.g.*, U.S. Dep't Health & Hum. Servs., Off. of Inspector Gen., Advisory Op. No. 12-10 (Aug. 30, 2012) (noting that advanced imaging services may be subject to over-utilization); U.S. Dep't Health & Hum. Servs., Off. of Inspector Gen., Advisory Op. No. 11-15 (Oct. 3, 2011) (profit distributions to physician investors in laboratory business pose "considerable risks of overutilization"); U.S. GOV'T ACCOUNTABILITY OFF., GAO-12-966, HIGHER USE OF ADVANCED IMAGING SERVICES BY PROVIDERS WHO SELF-REFER COSTING MEDICARE MILLIONS (2012).