Under the Meat Axe: Application of the Antikickback Statute to Price Concessions by Pharmaceutical Manufacturers

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Pharmaceutical manufacturers are under mounting political pressure to reduce prices. Unfortunately, however, offering price concessions is fraught with significant risk under the federal healthcare antikickback statute (the "Statute"). 42 U.S.C. § 1320a-7b. The purpose of this article is to provide an overview of the Statute in order to assist manufacturers to make informed decisions about the implications under the Statute of offering price concessions and to argue for a more rational application of the Statute.

The federal healthcare antikickback Statute was enacted in 1972.[2] This Statute is vast in its sweep and ambiguous in its language, and was recently described as "simply a meat axe", not a "scalpel." United States v. Anderson, 85 F.Supp. 2d 1047, 1075 n.25 (D. Kan. 1999), rev'd in part, *sub nom*. United States v. McClatchey, 217 F. 3d 823 (10th Cir. 2000). It has, however, never been successfully challenged on vagueness or overbreadth grounds.[3] The Statute makes it a criminal offense knowingly

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[2] Pub. L. No. 92-603, 86 Stat. 1419 (1972) (codified as amended 42 U.S.C. § 1320a-7b(b)(1994)). The Statute amends the Social Security Act (SSA), Ch. 531, 49 Stat. 620 (1935) (codified as amended 42 U.S.C. §§ 300 et seq.).

[3] See, e.g., United States v. Bay State Ambulance & Hosp. Rental Serv., Inc., 874 F.2d *id*. 20, 32 (1st Cir. 1989). Notwithstanding judicial decisions to the contrary, Congress and the Office of Inspector General of the Department of Health and Human Services, the agency charged with civil and administrative enforcement of the Statute, have explicitly acknowledged and sought to cure the overbreadth and vagueness of the Statute by creating numerous exceptions and "safe harbors." See Medicare & Medicaid Patient and Program Protection Act of 1987, Pub.L. No. 100-93, § 14, 101 Stat. 697-698; 56 Fed. Reg.

and willfully to offer, pay, solicit, or receive any "remuneration"[4] to induce referrals of items or services reimbursable by any Federal health care program. The Statute was designed to address evils similar to those which underlie commercial bribery statutes. The latter statutes are intended to punish self-dealing by agents at the expense of their principals. Agents are not permitted to solicit or retain benefits that rightfully belong to their principals. For example, an agent may not accept remuneration from a vendor to induce the agent to purchase goods and/or services from the vendor. By accepting such remuneration, the agent is deemed to violate her fiduciary duty to the principal.

These same concepts underpin the federal healthcare antikickback Statute, although they have largely been overlooked by courts, prosecutors and defense counsel. The overriding goal of the Statute is to prevent pharmaceutical manufacturers and others from providing economic incentives which could affect the medical judgment of doctors.[5] It was thought that such conduct was unethical and would increase costs to

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35,952 (July 29, 1991).

[4] Despite the presence of the phrase "remuneration…to induce" referrals in the Statute, it is arguable that in order to obtain a conviction the government need not establish that all or a portion of the payment exceeded the fair market value of the non-referral services provided by the recipient of the monies. See, e.g., United States v. Anderson, supra, at 1069-70 (not necessary for government to establish the payment exceeded fair market value of consulting services from referral source; "evidence was overwhelming that the [consulting] services…on their face, were not grossly disproportionate with the fees paid."; conviction affirmed.); Bay State, supra. In that respect, the concept of "remuneration" for referrals may have been read out of the Statute.

[5] The legislative report accompanying the enactment of the Statute states that the purpose of the Statute was to

> Provide penalties for certain practices which have long been regarded by professional organizations as unethical, as well as unlawful in some jurisdictions, and which contribute appreciably to the cost of the Medicare and Medicaid programs. Thus…the criminal penalty provision would include such practices as the soliciting, offering or accepting of kickbacks or bribes…involving providers of health care services.

H.R.Rep. No. 92-231, at 1 (1972), reprinted in 1972 U.S.C.C.A.N. 4989, 5093. It was understood at the time (and thereafter) that although the legislative history and the Statute itself spoke in broader terms, the overriding purpose of the Statute was to "ensure that medical decisions are not influenced by financial rewards from third parties." H.R. Rep. No. 104-236(I), 1195 (to accompany H.R. 2425 [Medical

federal healthcare programs. In this construct, doctors were seen as agents for both their patients and the federal government. Congress believed it was important that doctors not put their own economic interests ahead of the health and welfare of their patients or the economic interests of the entity paying for the doctor's services, namely the federal government.[6] It is against this backdrop that price competition in the pharmaceutical industry must be analyzed for purposes of determining compliance with the Statute.

Price competition between pharmaceutical manufacturers typically consists of offering discounts or other economic favors to physicians or other buyers (collectively "price concessions"). Although these price concessions come in many forms, their primary, if not sole, purpose is to induce the physician or other buyer to select products and/or services from one manufacturer over the products and/or services of competitor manufacturers. On its face, such conduct would implicate, but not necessarily violate, the Statute.

Courts have generally held that the Statute is violated if one purpose, rather than the primary or sole purpose, of the payment is to induce referrals. See

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Preservation Act of 1995.]).

[6] The legislative concerns which prompted enactment of the Statute were a response to perceived evils associated with the fee-for-service modality which predominated the healthcare delivery system when the Statute was first enacted in 1972. Paradoxically, one year later, in 1973, Congress passed its first managed care legislation, which endorsed and encouraged the very conduct which Congress had sought to penalize under the Statute, *viz.*, offering economic incentives to influence the physician's medical judgment. Congress enacted the Health Maintenance Organization Act of 1973, 87 Sta. 914, 42 U.S.C. § 300e et seq., which allowed the formation of HMOs to assume financial risks for the provision of health care services. Pegram v. Herdich, 120 S.Ct. 2143, 2156-2157 (2000). The OIG has indicated that many of the concerns underlying the Statute are either not implicated at all, or only to a significantly reduced degree, in the context of managed care. See 56 Fed. Reg. at 35, 961. While the OIG's view has generally been accepted uncritically by commentators, see e.g. Bulleit & 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 and Drug L.J. 279, 317-321 (1999), ("Bulleit & Krause"), in fact, the perceived evils with which the Statute sought to deal exist to a greater, not lesser, extent in the managed care rather than the fee for service world.

United States v. Kats, 871 F.2d 105, 108 (9th Cir. 1989); United States v. Bay State Ambulance & Hosp. Rental Serv., Inc., 874 F.2d 20, 30 (1st Cir. 1989); United States v. Greber, 760 F.2d 68, 72 (3d Cir.), *cert. denied*, 474 U.S. 988 (1985). I have argued elsewhere that the "one purpose" rule swallows the Statute because it criminalizes virtually every transaction in the healthcare area between a party with power to refer and a party with the capacity to accept referrals. Fabrikant, *The Healthcare Antikickback Statute: The Need for Repeal or Decriminalization*, Health Care Fraud & Abuse Newsletter, October 2000, Volume 3, Number 9.

As one court has recently recognized, "every business relationship between a hospital and a physician is based 'at least in part' on the hospital's expectation that the physician will choose to refer patients." United States v. McClatchey, 217 F.3d 823, 834 (10th Cir. 2000). If this is so, as it indisputably is, then virtually no transaction in the healthcare (or any other commercial) area will be completely devoid of the purpose of generating referrals from a contracting party who is in a position to make referrals of patients or other business. Since virtually no healthcare transaction is referral-purpose free, it is extremely difficult to distinguish between transactions which violate the Statute and those that do not. In order to blunt the force of this argument, courts have fashioned rules which attempt to quantify the amount of purpose necessary to constitute a violation of the Statute. But to state the rules is to document their fundamental unworkability. There is no point in debating how much purpose is too much when there is no objective way of measuring a person's or organization's purpose, and when the purportedly prohibited purpose necessarily accompanies every transaction.

The most recent, and damning, example of this phenomenon is the McClatchey court's pronouncement that liability under the Statute cannot be imposed where the defendant "hope[s] for or expect[s] referrals ... so long as the [defendant] is motivated to enter into the relationship for legal reasons entirely distinct from its collateral hope for referrals." Id. The court's acknowledgement that "it may be difficult for a jury to distinguish between a motivating factor and a collateral hope or expectation," id., understates the impossibility not only for the task of the fact-finder, but also for the actors themselves. A commercial actor cannot know, and cannot be expected to know, whether her "motivating factors" and "collateral hopes and expectations" are lining up correctly for Statute purposes. Nor can a jury or judge know whether a defendant's "collateral hope or expectation" for referrals has become so overarching as to eclipse the non-criminal purpose component of the transaction. The Socratic approach may be a useful teaching tool in a law school environment, but it does not provide a sound basis for determining whether criminal liability should be imposed. Rather than focus on the quantum and content of the actor's purpose, courts should focus on whether the transaction would have effects which contravene the intent of the Statute.

In order to avoid violating the Statute, drug manufacturers and others seek to design their price concessions so as to satisfy either the discount exception to the Statute[7] or the discount safe harbor.[8] This article is not intended to discuss the technical requirements of the Statute's discount exception or the discount safe harbor other than to note that they contain requirements which are complex, artificial and

[7] 42 U.S.C. § 1320a-7b(b)(3).

[8] 42 C.F.R. § 1001.952 (h).

difficult to meet, and that it is precarious to predict the outcome of judicial analyses of transactions crafted to meet the Statute's discount exception or the discount safe harbor. See e.g., United States v. Shaw, 106 F. Supp. 2d 103 (D. Mass 2000). Rather, the purpose of this article is to provide a framework for determining how to make informed decisions about the implications under the Statute of offering price concessions.

A price concession by drug manufacturers should not be prohibited under the Statute unless one of the following two conditions is met:

> First, the price concession results in or poses a substantial risk of a patient receiving lower quality of care. This means that a price concession is not illegal unless it results in potential or actual diminution of quality. If the patient is not put in harm's way, it is difficult to see how the caregiver has breached his/her fiduciary duty to the patient by accepting a price concession. If so, it should not matter what form the "price concession" takes, provided further, that
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> Second, the price concession does not result in or pose a substantial risk of economic loss or financial damage to the federal government in its capacity as the payor. Such loss or damage could come about in at least one of two ways:
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> (1) price concessions which induce overutilization, i.e., more goods and service are, or are likely

to be, prescribed than are necessary. While this is a genuine concern, it is ironic that we prohibit offering economic incentives to caregivers which could result in overutilization, but not the offering of such incentives when they could result in underutilization (in the managed care context), despite the fact that the latter rather than the former poses a greater threat to patient welfare.[9]

(2) price concessions which permit the customer to exploit reimbursement systems and thus obtain reimbursements that would not have been forthcoming. For example, a price concession given on a non-reimbursable item in exchange for purchasing a reimbursable item disguises the true cost for the reimbursable item and is likely to result in receiving improper reimbursement.

In sum, if the price concession does not inflict actual injury or pose a substantial risk of injury to patients or payors, it is difficult to see how the manufacturer or its customer has breached a fiduciary duty by accepting the price concession. In such circumstances, the price concession should not be found to violate the Statute.

In order to maximize the likelihood of avoiding that the evils with which the Statute seeks to deal, the Statute should be amended so as to require physicians to disclose to their patients and to payors, including the federal government, the fact they receive things of value from drug manufacturers and others. Such a disclosure

[9] See Pegram v. Herdich, supra; Fabrikant, supra.

provision would largely vitiate perceived and actual conflicts of interests between physicians on the one hand and their patients and the federal government on the other hand. Upon being advised of the existence and value of such relationships, a patient could select a different physician or have the right to receive an alternate prescription from the physician for a drug not manufactured by the company with whom the physician has an economic relationship. Likewise, a disclosure provision would enable the federal government to monitor and investigate, as appropriate, economic relationships between physicians and third parties.

Unfortunately, the case law frowns on the approach suggested above, and, while the HHS Office of Inspector General has issued advisory opinions occasionally supportive of this approach, it has also wrongly suggesting that factors in addition (or contrary) to those mentioned above ought to govern the analysis under the Statute.

The case law makes clear that in order to obtain a conviction under the Statute, the government need not demonstrate that the conduct in question reduced or threatened to reduce quality of care,[10] or that the conduct caused or threatened to cause economic loss to a federal health plan. See Bay State, supra.[11] Notwithstanding the case law, the HHS Office of Inspector General has issued advisory opinions expressly considering potential or actual patient harm, overutilization and economic loss to the government in declining to impose sanctions on transactions which appear to violate the Statute. See Advisory Opinion 00-10 (released Dec. 28, 2000) (declining to

[10] See, e.g., United States v. Anderson, 85 F.Supp. 20 1047, 1054 (D. Kan. 1999), rev'd sub nom, in part, United States v. McClatchey, 217 F.3d 823)) (10th Cir. 2000); Bay State, supra.

[11] Thus, the McClatchey court declined to "engraft a materiality requirement on the Statute…." 85 F.Supp. 2d at 1075 n. 25.

impose sanctions on the provision of free reimbursement services by pharmaceutical manufacturers; mentioning, *inter alia*, the offering of such services may increase patient access to expensive drugs). While such an approach by the OIG is laudable, it is wholly discretionary and is at odds with the position the Department of Justice has taken in prosecuting cases under the Statute.

The OIG has also relied wrongly upon the following two factors in announcing or suggesting that a transaction violates the Statute: The transaction would have the "practical effect[] of 'locking in' the purchasers for an extended period of time, …and interfering with a purchaser's normal cost/quality considering in ordering specific goods or services." D. McCarty Thornton, Chief Counsel to the Inspector General of HHS, July 17, 2000 letter to David R. Ford and Hope S. Foster (concerning "Prebates," "Signing Bonuses" and "Up-Front Rebates."). If the price concession is otherwise legitimate, it should not matter for antikickback Statute purposes that the buyer finds it attractive enough to warrant entering into a long term or exclusive contract. The propriety of such relationships should be tested under the antitrust and trade regulation laws, not the Statute. It is also a *non sequitur* to argue that price concessions "interfer[e] with a purchaser's normal cost/quality considerations in ordering specific goods or services." To the contrary, legitimate price concessions are at the very heart of a buyer's "normal cost/quality considerations in ordering specific goods or services." The OIG's approach is anticompetitive, and will discourage healthy and routine price competition.

Similarly, in the context of the drug industry (and elsewhere) the OIG has looked to such issues as whether a price concession could have the effect of "steering"

or "switching" patients. Thus, in the Prescription Drug Marketing Alert[12] and in two major settlements,[13] the OIG has adopted the stance that the Statute is violated by payments to pharmacists which cause a patient to purchase one manufacturer's drug rather than another's. This is considered a violation of the Statute regardless of whether the "switching" results in a diminution of quality to the patient or in an increase in cost to a federal payor.

A similar issue has arisen regarding the payment by drug manufacturers to pharmacy benefit managers ("PBM") in order to have the manufacturer's drug be listed on the PBM's formulary or for preferred formulary placement. Arguably, such payments might be construed to violate the Statute insofar as they could constitute a payment for "arranging for" or "recommending" the purchase of the manufacturer's drug. Likewise, it has been reported that a prominent federal prosecutor has suggested that "arrangements with PBMs may violate the antikickback law if they reward the PBM for the volume or market share purchased by the health plan clients. The same prosecutor reportedly also called into question payments made by PBMs to pharmacists to alert patients to the availability of alternative drugs and help arrange for a switch."[14]

Related issues have arisen in the context of payments by manufacturers to commission sales representatives based on a percentage of sales. The OIG has issued several advisory opinions casting doubt on such payments on the grounds that

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[12] Special Fraud Alert on Prescription Drug Marketing Schemes, 59 Fed. Reg. 65, 376 (Dec. 10, 1994) (issued August 1994).

[13] See Commonwealth of Mass., Off. of the Att'y Gen., Drug Company Pays $200,000 to Settle Kickback Claims (June 30, 1994); Settlement Agreement Between Miles Inc. and the Commonwealth of Massachusetts, Dep't of the Att'y Gen. (June 30, 1994); In re Upjohn Company, C7-94-7854, Order Approving Assurance of Discontinuance (Ramsey Cty. (Mass.) Dist. Ct., Aug. 1, 1994).

[14] Bulleit & Krause, supra, at 313 n. 139 (reporting comments of Assistant U.S. Attorney James Sheehan.).

such payments may violate the Statute on the ground that the payments constitute "remuneration" in exchange for "arranging" or "recommending" the purchase, sale or leasing of covered items or services. This position, unfortunately, is consistent with the case law.[15] While the OIG apparently believes that such arrangements "may involve at least technical violations" of the Statute, the OIG refrained from condemning those at issue in the advisory opinions on the ground that there was a low likelihood of abuse. The OIG did, however, identify a number of "suspect characteristics" in such arrangements that are so hopelessly overbroad that they are likely to ensnare many legitimate independent sales arrangements in the drug industry.

CONCLUSION

On its face the Statute precludes many legitimate arrangements which are commonplace outside the healthcare area. Unfortunately, the case law and HHS OIG administrative pronouncements exacerbate the dangers inherent in the Statute. Since it is difficult to structure transactions which genuinely comply with the Statute, the statutory discount exception, or the safe harbor regulations, attention must be paid to the Statute's underlying purposes. Transactions which pose little or no risk to the health of patients or the pocket-books of payors should not be found to violate the Statute, even though the case law and administrative pronouncements from HHS OIG may indicate otherwise.

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[15] Two courts have held that commissions to independent sales representatives represent *per se* violations of the Statute. See Nursing Home Consultants, Inc. v. Quantum Health Serv. Inc., 926 F. Supp. 835, 844 (E.D. Ark. 1996); Medical Dev. Network, 673 So.2d 565 (Fla. App., 4th Dist, 1996). Moreover, a California appellate court held that California's Medicaid antikickback law constitutes a *per se* prohibition on commission sales. People v. Duz-Mor Diagnostic Lab., 68 Cal. App. 4th 654 (2d App. Dist. 1998).