

**VENDOR – HEALTHCARE PROFESSIONAL
GIFT GIVING, MARKETING, AND COMPLIANCE¹**

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A debate has heated up within the healthcare industry involving potential conflicts of interest between healthcare professionals and vendors resulting from gift-giving and other marketing practices.² The issue has been grabbing headlines in prominent publications such as *Newsweek*,³ the *Wall Street Journal*,⁴ *Forbes*,⁵ *USA Today*,⁶ the *N.Y. Times*,⁷ and the *Washington Post*⁸ and is described in a recent article published in the *Journal of the American Medical Association (JAMA)* as “a conflict of interest between physicians’ commitment to patient care and the desire of pharmaceutical companies and their representatives to sell their products.”⁹ While most of the literature and authority on this subject has focused on physicians and the pharmaceutical industry, the issues raised are equally relevant to all medical device and equipment manufacturers, wholesalers and distributors, and other medical service providers (collectively, the “vendors”) and the subjects of their marketing, which include individual practitioners, healthcare entities, providers, and suppliers (collectively, the “healthcare professionals”).

Some studies have shown, and **guidance from professional medical associations, industry trade associations, and the U.S. Department of Health and Human Services’ Office of Inspector General (OIG) reflects concern with, the potential that the promotional efforts by vendors could have a direct and profound effect on physician**

² See Karen Springen, *Saying No to Big Pharma*, NEWSWEEK (Oct. 5, 2006).

³ *Id.*

⁴ A.W. Matthews, B. Martinez., *E-mails Suggest Merck Knew Vioxx’s Dangers at Early Stage*, WALL ST. J. (Nov. 1, 2004).

⁵ Doctors’ Ties to Drug Companies Called Commonplace, FORBES (Apr. 25, 2007); Group Calls for Ban on Drug-Industry Gifts to Doctors, FORBES (Jan. 24, 2006).

⁶ R. Rubin, Most Doctors Get Money and Gifts from Industry, USA TODAY (Apr. 25, 2007).

⁷ A. Berenson & A. Pollack, *Doctors Reap Millions for Anemia Drugs*, N.Y. TIMES (May 9, 2007); A. Zuger, *Medicine and the Drug Industry, A Morality Tale*, N.Y. TIMES (Apr. 24, 2007).

⁸ J.P. Kassirer, *Why Should We Swallow What These Studies Say*, WASH. POST (Aug. 1, 2004)

⁹ T. Brennan et al., Health Industry Practices That Create Conflicts of Interest, 295 JAMA 429 (Jan. 25, 2006).

prescribing practices, which may impact medical judgment.¹⁰ Not only is this conflict of interest receiving considerable attention in the press generally, but it is also making news in the form of enforcement actions and legislation. Considering the staggering costs associated with these marketing practices—approximately 90% of the \$21 billion marketing budget of the pharmaceutical industry is directed at physicians, despite a dramatic increase in direct-to-consumer advertising¹¹—and the seeming inability to control rising healthcare costs,¹² it is not surprising that vendor gift-giving and other marketing practices have come under increasing scrutiny and interest by federal and state enforcement agencies and self-regulation by the vendors, hospitals, and physicians. This paper examines common industry practices, potential legal implications, certain industry guidance, enforcement trends and legislative developments, industry-proposed policies, and compliance planning considerations.

I. The Landscape of Vendor Gift-Giving

This nation's vendors interact with healthcare professional-customers in many different capacities—as customers, students, inventors, consultants, and instructors. Some of these interactions involve value conveyed from the vendors to the healthcare professionals. For example, vendors may provide healthcare professionals with promotional items (such as pens or pads), business courtesies (such as lunches or drinks in connection with business meetings), education on the safe and effective use of

¹⁰ E. Hemminki, Review of Literature on the Factors Affecting Drug Prescribing, 9 Soc. Sci. & Med. 111 (1975).

¹¹ R. Kreber, *Drug Makers Target Consumers with Their Ads*, BOSTON GLOBE (Mar. 10, 2004).

¹² In 2005, U.S. healthcare spending increased 6.9% to almost \$2.0 trillion, or \$6,697 per person. The healthcare portion of gross domestic product was 16%, slightly higher than 15.9% (and fairly dramatically up from 13.2% in 2000). This third consecutive year of health spending growth was largely driven by prescription drug expenditures. A. Catlin et al., *National Health Spending in 2005*, 26 HEALTH AFFAIRS 142 (2007).

products, and consulting fees and royalty payments for services and inventions. Some of these expenditures clearly are appropriate and favored by public policy; for example, the OIG has blessed vendor provision of reimbursement support programs and some charitable giving programs, and the U.S. Food and Drug Administration (FDA) sometimes requires that vendors provide education for some products. However, the government has viewed some of these interactions as improper remuneration under the federal Anti-Kickback Statute (AKS). Indeed, vendors have entered into settlements with the OIG for the provision of improper perks to healthcare professional-customers, allegedly for the improper purpose of inducing subsequent purchases from the vendor, as discussed more fully in Section V herein.

While many of the vendor marketing activities may have a legitimate function, rising healthcare costs have increased scrutiny of these interactions,¹³ calling into question practices that have been part of healthcare's historical landscape but, for the most part, previously occurred unchecked. This trend is reflected in an article published in the January 2006 edition of *JAMA*, which has heralded changes in the professional perception and practices of vendor gift-giving.¹⁴ In the 2006 *JAMA* article, the authors propose a ban or strict limit on even small gifts that vendors distribute to physicians. Citing psychological research showing that the desire to reciprocate even small gifts has a strong influence on behavior, these physicians expressed concern that the vendor marketing campaigns could unduly bias treatment decisions. The physicians advocate a ban on pharmaceutical companies' marketing tactics at medical schools and teaching

¹³ Ashley Wazana, M.D., *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?*, 283 *JAMA* 373 (Jan. 19, 2000). Dr. Wanzana cites an estimated pharmaceutical marketing budget of \$13,000 spent per year per physician.

¹⁴ Brennan, *supra* note 9.

hospitals. The *JAMA* authors postulate that their peers develop a habit of accepting perks from vendors because they develop a sense of entitlement early in their medical training.¹⁵

The *JAMA* article's recommendations are highlighted by recent studies regarding the link between the relationships between vendors and healthcare professionals. A national study published in the *New England Journal of Medicine* on April 26, 2007¹⁶ found that 94% of physicians in the United States reported some type of relationship with the pharmaceutical industry, and most of these relationships involved receiving food in the workplace (83%), or receiving drug samples (78%). The survey also found variations in the physician-pharmaceutical relationship according to specialty, practice type, and professional activities. For example, cardiologists were more than twice as likely as family practitioners to receive payments; family practitioners met more frequently with industry representatives than did physicians in other specialties; and physicians in solo, two-person, or group practices met more frequently with industry representatives than did physicians practicing in hospitals and clinics.

II. Federal and State Laws Governing Vendor - Healthcare professional Relationships

The interest of the federal government in this issue is not new. In the 1960s, congressional hearings exposed questionable healthcare professional-vendor

¹⁵ *Id.* (citing Frederick Sierles et al., Medical Students' Exposure to and Attitudes About Drug Company Interactions, 294 *JAMA* 1034 (Sept. 7, 2005)).

¹⁶ Campbell, E., Gruen, R., Mountford, J., Miller, L., Cleary, P., & Blumentahl, M., *A National Survey of Physician – Industry Relationships*, *N. ENGL. J. MED.* 356:17 (Apr. 26, 2007).

relationships.¹⁷ In the 1970s, a Senate bill was introduced that would have prohibited the transfer of anything of value from a person in the drug industry to any physician or pharmacist “if the purpose of such transfer is to influence the prescribing, administering, or dispensing of any such drug.”¹⁸ The bill died in the House, but the subject was revived in 1990 by the Senate Labor and Human Resources Committee, which showed skyrocketing promotional expenditures since the last survey in the mid-1970s.¹⁹

In the healthcare industry, vendor gift-giving and other marketing initiatives, while acceptable practices in most other industries, can implicate certain federal and state laws, including the AKS²⁰ and the Prescription Drug Marketing Act,²¹ with potential collateral consequences including violations of the federal False Claims Act (FCA),²² the Civil Monetary Penalties Law (CMPL),²³ and the federal healthcare program exclusion provisions.²⁴

A. The Federal Anti-Kickback Statute

The AKS is a criminal prohibition against payments (in any form, whether the payments are direct or indirect) made purposefully to induce or reward the referral or generation of federal healthcare business.²⁵ AKS addresses not only patient referrals, but also the offer or payment of anything of value in return for purchasing, leasing, ordering, or

¹⁷ OIG, *Promotion of Prescription Drugs Through Payment and Gifts at 2* (OEI-01-90-00481) (Aug. 1991), available at <http://oig.hhs.gov/oei/atod.html>.

¹⁸ *Id.* (quoting S. 1831 (1977)).

¹⁹ *Id.* at 1.

²⁰ See 42 U.S.C. § 1320a-7b.

²¹ 21 U.S.C. § 353 *et seq.* The preamble to the federal Physician Self-Referral Law (Stark II) indicates that pharmaceutical manufacturers are not generally subject to Stark II because they do not furnish designated health services. 66 Fed. Reg. 855, 920 (Jan. 4, 2001).

²² 31 U.S.C. §§ 3729, 3730.

²³ 42 U.S.C. § 1320a-7a.

²⁴ *Id.* § 1320a-7.

²⁵ *Id.* § 1320a-7b(b).

arranging for or recommending the purchase, lease, or ordering of any item or service reimbursable in whole or part by a federal healthcare program.²⁶ The OIG has specifically stated:

[O]ne does not have to be a “provider” or make an actual “referral” to be covered by the anti-kickback statute. The statute covers any persons who offer, pay, solicit, or receive any unlawful remuneration. The scope of prohibited conduct includes not only that which is intended to induce referrals, but also that which is intended to induce the purchasing, leasing, ordering or arranging for any good, facility, service or item paid for by Medicare or Medicaid.²⁷

As such, the AKS covers vendors’ offers of remuneration that are given in return for purchasing or ordering an item that is in some way reimbursable by Medicare or Medicaid. The statute extends equally to the solicitation or acceptance of remuneration for referrals. Liability under the AKS is determined separately for each party involved, and penalties include fines of not more than \$25,000 or imprisonment of not more than five years, or both.²⁸

Although liability under the AKS ultimately turns on a party’s intent, it is possible to identify arrangements or practices that present a potential for abuse. Initially, a vendor should identify any remunerative relationship between itself (or its representatives) and

²⁶ See *Id.* § 1320a-7b(b)(2).

²⁷ 61 Fed. Reg. 2122, 2124 (Final Rule, Jan. 25, 1996).

²⁸ 42 U.S.C. § 1320a-7b(b)(2).

persons or entities in a position to directly or indirectly generate federal healthcare business for the manufacturer. Persons or entities in a position to generate federal healthcare business include, for example, benefit managers, formulary committee members, group purchasing organizations, and any healthcare professionals.

In certain jurisdictions, the government can argue that a vendor's gift-giving and marketing practices may violate the AKS if any one purpose of the gift or marketing promotion is to induce the healthcare professional to refer patients for items or services or in return for recommending purchasing or ordering any item or service payable under a federal healthcare program.²⁹ In those jurisdictions, even if the practice includes a legitimate benefit, **any illegal intent will violate the AKS.**

Despite the breadth of the AKS's reach, many healthcare professional-vendor relationships may be legitimate and present little risk of program abuse. Accordingly, in order to avoid violating the AKS, healthcare professionals and vendors should attempt to structure their arrangements so as to satisfy the criteria of an applicable AKS statutory exception or safe harbor.

²⁹ See *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985), cert denied, 474 U.S. 988 (1985); see also *United States v. Katz*, 871 F.2d 105, 108 (9th Cir. 1989); *United States v. Bay State Ambul. & Hosp. Rental Servs., Inc.*, 874 F.2d 20, 30 (1st Cir. 1989).

B. Collateral Consequences of AKS Violation

In addition to the penalties noted above, the OIG can impose civil penalties in the form of treble damages plus \$50,000 for each violation of the AKS.³⁰ The penalties, however, go beyond monetary.

An AKS violation can also lead to exclusion from the federal healthcare programs upon an OIG determination that such a violation has occurred.³¹ It is important for vendors to remember that it is not only entities and individuals that bill the federal healthcare programs that can be excluded—vendors can be excluded as well.

The government also has created the opportunity to “bootstrap” a FCA claim to a AKS claim.³² The FCA prohibits knowingly presenting (or causing to be presented) to the federal government a false or fraudulent claim for payment or approval. A “false claim” is defined to include a claim for payment for services or supplies for which the provider is not otherwise entitled to payment. In AKS cases when the government elects to include a FCA claim, the government’s argument is that if a claim results from an illegal arrangement, then the provider submitting the claim is not entitled to payment and has violated the FCA. The penalty for violating the FCA is a minimum of \$5,500 up to a maximum of \$11,000 for *each* false claim submitted. In addition to the penalty, a health care professional or vendor could be found liable for damages of up to three times the

³⁰ 42 U.S.C. § 1320a-7a(a)(7).

³¹ *Id.* § 1320a-7(a)(7).

³² 31 U.S.C. §§ 3729, 3730; see, e.g., OIG, *Compliance Program Guidance for Individual and Small Group Physicians*, 65 Fed. Reg. 59434, 59450. (Oct 5, 2000) (hereinafter “Physician CPG”).

amount of damages sustained by the federal healthcare program (i.e., treble damages).³³

C. The Prescription Drug Marketing Act

The Prescription Drug Marketing Act (the PDMA)³⁴ was enacted in 1988 to address certain prescription drug marketing practices (e.g., the distribution of free samples, the use of coupons redeemable for drugs at no or low cost, and the sale of deeply discounted drugs to hospitals and healthcare entities). Congress decided that legislation was necessary because the prescription drug distribution system had insufficient safeguards to prevent the introduction and retail sale of substandard, ineffective, or counterfeit drugs and a wholesale drug diversion submarket had developed that prevented effective control over, or even routine knowledge of, the true sources of drugs.

The most simple of the acts prohibited by the PDMA is knowingly selling, purchasing, trading, or offering to sell, purchase, or trade a prescription drug sample.³⁵ This offense is punishable by up to 10 years in prison.³⁶ Several recent enforcement actions, most prominently the TAP Pharmaceuticals investigation and settlement in 2001, have focused on physicians who received drug samples at no or discounted cost and billed Medicare/Medicaid for those pharmaceuticals in violation of the PDMA.

³³ 31 U.S.C. § 3729(a).

³⁴ Pub. L. No. 100-293, 100 Stat. 96 (1988), *codified at* 21 U.S.C. § 353.

³⁵ 21 U.S.C. § 353(c)(1).

³⁶ *Id.* § 333(b)(1)(B).

D. State Laws that Address Vendor—Healthcare Professional Interactions

Maine, Minnesota, Nevada, Vermont, West Virginia, and the District of Columbia all have laws requiring gift reporting by pharmaceutical manufacturers. Vermont's 2002 statute, for example, requires that pharmaceutical manufacturers disclose gifts given to physicians, hospitals, or pharmacists of \$25 or more to the state's attorney general. The state also publishes the aggregate totals given, but not the individual recipients' names. Analysts indicate this legislation is a growing trend and as many as 25 states may have similar proposals in upcoming legislative sessions.

California's statute goes a step beyond disclosure requirements and requires that certain guidance and materials be included in a pharmaceutical manufacturer's compliance program.³⁷ Specifically, SB 1765, which was effective July 1, 2005, requires pharmaceutical companies to adopt and publicly disclose a comprehensive compliance program that is in accordance with the **Final OIG Guidance and the Pharmaceutical Research and Manufacturers of America (PhRMA) Code; establish specific annual dollar limits on gifts or incentives provided to medical or health care professionals; and make an annual declaration of compliance publicly available.** This statute presents a number of implementation challenges that may require manufacturers to develop expensive new systems or expand pre-existing ones. The statute may be difficult to implement because there are many ambiguities and other aspects that raise significant questions. As a result of the broad definition of a "pharmaceutical company," which may

³⁷ Cal. SB 1765 (codified at CAL. HEALTH & SAFETY CODE § 119400 *et seq.*).

or may not include out-of-state pharmaceutical companies doing business in California, it is unclear what the scope of SB 1765 is and to what extent it affects companies based outside of California. In addition, requiring pharmaceutical companies to comply with the Final OIG Guidance and PhRMA Code is difficult because both sources provided recommendations and not “requirements,” which create difficulties in interpretation. Finally, while the statute does not identify a specific enforcement mechanism, there are ways the government and the plaintiff’s bar could attack pharmaceutical companies. Pharmaceutical companies are subject to allegations of unfair business practices under the Unfair Competition Law of the *California Business and Professions Code § 17200*. In addition, False Claims Act liability could arise under the California False Claims Act³⁸ and Section 1871.7 of the California Insurance Code.³⁹ The lesson to take away from the California law is that pharmaceutical manufacturers around the country need to watch what happens in California to see how the federal and state governments and the plaintiff’s bar proceed in making claims against pharmaceutical manufacturers under SB 1765.

III. OIG Guidance Regarding Vendor—Healthcare Professional Relationships

A. 1992 OIG Report and Investigation

Although healthcare professional-vendor relationships have been the subject of recent heightened enforcement initiatives, these relationships have been a long-standing concern of the OIG. In mid-1991, the OIG published findings from a study in a report

³⁸ CAL. GOV’T CODE § 12650 *et seq.*

³⁹ CAL. INS. CODE § 1871.7.

entitled, “Promotion of Prescription Drugs through Payments and Gifts” (the “OIG Report”).⁴⁰ The purpose of the OIG’s study was to (1) describe the range of drug promotion practices that involve physicians receiving money or other items of value from pharmaceutical companies; (2) assess the vulnerabilities such practices present; and (3) examine the responses of government and private groups to inappropriate or illegal practices.⁴¹ The OIG Report concluded that gifts and offers of value to physicians appear to affect physicians’ prescribing decisions. The OIG Report observed that some practices may indeed be illegal, violating the AKS. According to the OIG, acceptance of promotion-related money or other items of value from pharmaceutical companies has, at a minimum, the appearance of impropriety. The OIG notes that this appearance is “damaging to the public’s confidence in the medical profession.”⁴²

In 1992, the OIG conducted a second investigation into pharmaceutical company promotional practices.⁴³ The OIG randomly sampled approximately 1000 physicians to inquire about items of value offered to them by pharmaceutical companies. The OIG found that, for this sample, the pharmaceutical companies offered “gifts”⁴⁴ or “payments”⁴⁵ to 82% of physicians sampled.⁴⁶ The investigation also revealed that many gifts had been offered that would specifically run afoul of the American Medical Association (AMA) guidelines, which also had been adopted by the Pharmaceutical

⁴⁰ OIG, *Promotion of Prescription Drugs through Payment and Gifts* (OEI-01-90-00480) (Aug. 1991), available at <http://oig.hhs.gov/oei/atod.html>.

⁴¹ *Id.*

⁴² *Id.* at 17.

⁴³ OIG, *Prescription Drug Promotion Involving Payments and Gifts: Physicians’ Perspectives* (July 1992) (OEI-01-90-00481), available at <http://oig.hhs.gov/oei/atod.html>.

⁴⁴ Gifts most frequently included pens, notepads, pharmaceutical samples for personal or family use, meals or drinks. *Id.* at 3.

⁴⁵ Payments most frequently included travel expenses and honoraria for attending educational programs and compensation for participation in focus groups. *Id.*

⁴⁶ The OIG mailed surveys to 997 physicians who billed the Medicare program and received 617 usable responses from physicians from a wide variety of specialties and locations. *Id.* at 1 and ii.

Manufacturers of America (PMA),⁴⁷ because they bore no relation to the physician’s work and did not benefit any patient.⁴⁸ The investigation also uncovered offers of samples for use by the physicians or their families and compensation for physician involvement in focus groups and studies – some of those offers may have been gifts with strings attached or token consulting arrangements.⁴⁹

The OIG’s investigation concluded that pharmaceutical companies were more likely to offer gifts and payments to physicians who were frequent prescribers of those companies’ products than to those who were infrequent prescribers.⁵⁰ This investigation, in turn, led the OIG to recommend that the Public Health Service (PHS), through FDA, produce final guidelines that would distinguish clearly promotional activity from “scientific interchange.”⁵¹ The OIG also recommended that AMA and PMA work closely to eliminate gray areas in their guidance.⁵² Several groups commented on the OIG’s investigation and its recommendations. One of them—the Public Citizen Health Research Group—recommended legislation to ban gifts and payments because guidelines alone had proved ineffective.⁵³

⁴⁷ PMA was the precursor to the Pharmaceutical Research and Manufacturers of America (PhRMA).

⁴⁸ *Id.* at ii.

⁴⁹ *Id.*

⁵⁰ *Id.* at 4.

⁵¹ *Id.* at iii.

⁵² *Id.*

⁵³ *Id.* at iv.

B. 1994 OIG Special Fraud Alert

In 1994, the OIG issued a Special Fraud Alert⁵⁴ that focused on “product conversion” by pharmacies, “frequent flier campaigns” aimed at physicians, and “research grant” programs in which physicians were given *de minimis* recordkeeping tasks. The Fraud Alert explained: “Traditionally, physicians and pharmacists have been trusted to provide treatments and recommend products in the best interest of the patient”; however, “[p]hysicians, suppliers and, increasingly, patients are being offered valuable, non-medical benefits in exchange for selecting specific prescription drug brands.”⁵⁵ The OIG noted that “[i]f one purpose of any of these marketing schemes is to induce the provision of a prescription drug item reimbursable by Medicaid, then the criminal AKS is implicated. There is no statutory exception or ‘safe harbor’ to protect such activities.”⁵⁶ The OIG also stated that a marketing program that violates the AKS “may pose a danger to patients because the offering or payment of remuneration may interfere with a physician’s judgment in determining the most appropriate treatment for a patient.”⁵⁷ The OIG explained:

A gift or payment may be illegal under the AKS if it:

- **is made to a person who can generate business for the paying party;**
- **is related to the volume of business generated; and**

⁵⁴ OIG, Special Fraud Alert, *How Does the Anti-kickback Law Relate to Prescription Drug Marketing Schemes?* (Aug. 1994, reprinted Dec. 19, 1994), available at www.oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html.

⁵⁵ *Id.*

⁵⁶ *Id.*

⁵⁷ *Id.*

- exceeds the fair market value of any legitimate service rendered to the payer.⁵⁸

The OIG set forth the following circumstances that would compel it to investigate a physician/vendor relationship:

- If a gift is offered to physicians and/or suppliers in exchange for prescribing or providing specific prescription products.
- If the offer of materials bestows benefits upon pharmacists (or others in a position to recommend prescription drug products) in exchange for performing marketing tasks related to Medicare or Medicaid.
- If grants are made to physicians and clinicians for studies of prescription products when the studies are of questionable scientific value and require little or no actual scientific pursuit.
- If any benefit is given to a patient, provider or supplier for recommending or requesting a change of prescription, from one product to another, unless the payment is consistent with a “safe harbor” regulation, 42 CFR 1001.952, or other federal provision governing the reporting of prescription drug prices.⁵⁹

⁵⁸ *Id.*

⁵⁹ *Id.*

Since this Special Fraud Alert, the OIG, through voluntary guidelines described below, has made further efforts to shape policies on healthcare professional-vendor interactions.

C. OIG Compliance Program Guidance for Physicians

On October 5, 2000, the OIG published its *Compliance Program for Individual and Small Group Physician Practice Guidance* (“Physician Compliance Guidance”).⁶⁰ The Physician Compliance Guidance provides the OIG’s views on the fundamental components of physician practice compliance programs, as well as the principles that a physician practice might consider when developing and implementing a compliance program.

Identifying relationships between physicians and “durable medical equipment suppliers, pharmaceutical manufacturers and vendors” as areas of potential concern, the OIG recommends that physicians avoid establishing illegal arrangements with the pharmaceutical industry by (i) ensuring that all arrangements are made on a fair market value basis; (ii) establishing standards and procedures to address arrangements with other providers and suppliers; (iii) implementing measures to avoid offering inappropriate inducements to patients; and (iv) ensuring that all arrangements are reviewed by legal counsel familiar with the AKS. The OIG further recommends that physicians address in their compliance measures, “the soliciting, accepting or offering of any gift or gratuity of more than nominal value to or from those who may benefit from a

⁶⁰ See 65 Fed. Reg. 59434 (Oct. 5, 2000).

physician practice's referral of federal health care program business,"⁶¹ in their compliance measures, highlighting the importance of compliance efforts for physicians on this issue, as discussed in greater detail herein, not just academic medical centers.

D. OIG Compliance Program Guidance for Pharmaceutical Manufacturers

In an effort to encourage pharmaceutical manufacturers to use internal controls to efficiently monitor relationships with healthcare providers with whom they conduct federal healthcare program business, the OIG issued the *Compliance Program Guidance for Pharmaceutical Manufacturers* ("Pharmaceutical CPG") in April 2003.⁶²

According to the OIG, any remuneration from a manufacturer provided to a purchaser that is expressly or impliedly related to a sale potentially implicates the AKS and should be carefully reviewed.⁶³

The Pharmaceutical CPG identified a number of pharmaceutical industry practices that could result in kickbacks and other illegal remuneration under the AKS. In particular, the OIG identifies three potential risk areas for pharmaceutical manufacturers: (1) integrity of data used by state and federal government; (2) kickbacks and other illegal remuneration; and (3) compliance with laws regulating drug samples. In assessing pharmaceutical manufacturers' relationships with physicians, the OIG recommends that manufacturers examine whether they are providing a valuable tangible benefit to the physician with the intent to induce or reward referrals any time something of value is provided to the physician. "Any time a pharmaceutical manufacturer provides anything

⁶¹ *Id.* at 59441.

⁶² 68 Fed. Reg. 23731 (May 5, 2003) (hereinafter "Pharmaceutical CPG"). (Note: The OIG issued the Pharmaceutical CPG on April 28, 2003, but it was published in the *Federal Register* on May 5, 2003.)

⁶³ *Id.* at 23745.

of value to a physician who might prescribe the manufacturer's product, the manufacturer should examine whether it is providing a valuable tangible benefit to the physician with the intent to induce or reward referrals."⁶⁴

The Pharmaceutical CPG advises manufacturers to review all arrangements for physician services to ensure that: (1) the arrangement is set out in writing; (2) there is a legitimate need for the services; (3) the services are provided; (4) the compensation is at fair market value; and (5) all of the preceding facts are documented prior to payment.⁶⁵ In addition, whenever possible, pharmaceutical manufacturers should structure the arrangement to fall within a safe harbor and, if not possible, review the arrangement in light of the totality of all facts and circumstances, bearing in mind the following factors:

- *Nature of the relationship between the parties.* What degree of influence does the physician have, directly or indirectly, on the generation of business for the manufacturer?
- *Manner in which the remuneration is determined.* Is the remuneration conditioned in whole or in part on referrals or other business generated?
- *Value of remuneration.* Does the remuneration exceed the fair market value of any legitimate, reasonable, and necessary services rendered by the physician to the manufacturer?

⁶⁴ *Id.*

⁶⁵ *Id.* at 23738.

- *Potential federal program impact of the remuneration.* Can the remuneration increase costs to any of the federal health care programs or lead to over utilization?
- *Potential conflicts of interest.* Would acceptance of the remuneration appear to diminish the objectivity of professional judgment? If the remuneration relates to the dissemination of information, is the information complete, accurate, and not misleading?⁶⁶

In particular, the OIG identifies five problematic relationships between manufacturers and prescribers:

1) ***Switching Arrangements.*** Switching arrangements, suspect under the federal AKS,⁶⁷ involve pharmaceutical manufacturers offering benefits to physicians each time a patient's prescription is changed from a competing product to the manufacturer's product.⁶⁸ These programs may be permissible in certain managed care arrangements, but manufacturers must review "switching" payments in connection with products reimbursable under federal healthcare programs.⁶⁹

2) ***Consulting and Advisory Payments.*** The OIG recognized that fair market value payments to a few physicians for *bona fide* consulting or advisory services do not raise significant concern under the federal AKS. But paying physicians as "consultants" to attend meetings primarily in a passive capacity is suspect as are

⁶⁶ *Id.*

⁶⁷ *Id.* at 23738 (citing OIG, Special Fraud Alert, 59 Fed. Reg. at 65372).

⁶⁸ *Id.*

⁶⁹ *Id.*

compensation relationships with physicians for services directly or indirectly connected to a manufacturer's marketing and sales activities, e.g., speaking; certain research, preceptor or "shadowing" services; and ghost writing of papers or speeches.⁷⁰

3) *Payments for Detailing.* Some manufacturers pay physicians for time spent listening to sales representatives market their products.⁷¹ Other companies pay physicians for time spent accessing websites or listening to marketing information. According to the Pharmaceutical CPG, these payments are highly suspect under the federal AKS.

4) *Business Courtesies and Other Gratuities.* Pharmaceutical companies sometimes offer benefits to physicians or others in a position to make or influence referrals, e.g., entertainment, recreation, travel, meals or other benefits in association with information or marketing presentations; and gifts, gratuities, and other business courtesies. These arrangements potentially implicate the federal AKS if any purpose of the arrangement is to generate business for the pharmaceutical company.

The OIG states that "compliance with the PhRMA Code with respect to these arrangements should substantially reduce a manufacturer's risk."⁷²

5) *Educational and Research Funding.* Payments for research services should be "fair market value for legitimate, reasonable, and necessary

⁷⁰ *Id.* The OIG recommends that in addition to structuring these arrangements to comply fully with the personal services safe harbor under the federal Anti-Kickback Statute, consulting and advisory arrangements meet the following requirements: (1) such arrangements must be set out in writing; (2) there is a legitimate need for the services; (3) the services are provided; (4) the compensation is at fair market value; and (5) all of the preceding facts are documented prior to payment.

⁷¹ *Id.*

⁷² *Id.*

services.”⁷³ Sales and marketing functions should be kept separate from the awarding of research contracts. The OIG considers research contracts that originate through the sales or marketing functions to be particularly suspect.⁷⁴

The manufacturer must determine whether the funding is based, in any way, on the physician’s referral of the manufacturer’s product.⁷⁵ Further, the manufacturer must determine whether the funding is for a *bona fide* educational or research purpose.

Grants or support for educational activities that are sponsored and organized by medical professional organizations raise little risk of fraud, provided that the grant or support is not restricted or conditioned with respect to content or faculty.⁷⁶

Manufacturers sometimes provide funding to other sponsors of continuing medical education (CME) programs. Again, the OIG warns manufacturers against using the funding of CME as a way to provide remuneration to healthcare professionals who are in a position to generate business for the manufacturer, or to influence the content of the CME programs.⁷⁷

IV. Industry Guidance on Establishing Appropriate Vendor—Healthcare Professional Relationships

In addition to guidance from the OIG, the increased scrutiny of vendor marketing practices with physicians has led medical professional associations and industry trade

⁷³ *Id.*

⁷⁴ *Id.* Examples of questionable research arrangements include: (1) research initiated or directed by marketers or sales agents; (2) research that is not transmitted to, or reviewed by, a manufacturer’s science component; (3) research that is unnecessarily duplicative or is not needed by the manufacturer for any purpose other than the generation of business; and (4) post-marketing research used as a pretense to promote product.

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ *Id.*

organizations to issue guidelines to shed light and guidance on appropriate physician-vendor relationships. While most of this guidance deals directly with physician relationships with pharmaceutical companies, the guidelines are still applicable to other vendors as there are little substantive differences in these relationships with physicians and with the federal healthcare programs (i.e., as indirect providers).

A. Guidance for and Action by Academic Medical Centers

The authors of the January 2006 *JAMA* article propose that academic medical centers must take the lead in regulating common practices that may create conflicts of interests with vendors.⁷⁸ The recommendations of the *JAMA* article are as follows:

- All gifts from vendors to physicians be prohibited;
- The provision of pharmaceutical samples to physicians should be prohibited and replaced with a system of vouchers for low-income patients;
- Committees establishing drug formularies or charged with purchasing medical devices should exclude physicians with financial relationships with those vendors;
- Vendors should not be allowed to directly or indirectly support Accreditation Council for Continuing Medical Education (ACCME)

⁷⁸ Brennan, *supra* note 9.

accredited programs, but should be required to make any such contributions through a central repository that would distribute the funds;

- Vendors interested in having faculty or fellows attend meetings should provide grants through a central office at the academic medical center;
- Academic medical center faculty should not serve as members of speakers bureaus for vendors nor should they be able to publish articles and editorials that are ghostwritten by industry employees;
- Consulting and honoraria should require a written contract with specific scientific deliverables, research grants should be made on a general basis, and information regarding consulting agreements and unconditional grants should be publicly available.⁷⁹

A growing number of academic medical centers and hospitals are prohibiting many of the arrangements identified in the *JAMA* article, which suggests that these institutions are the appropriate initial sites for these new policies and procedures. According to the *JAMA* article, “[b]ecause gifts of even minimal value carry influence and because disclosure is an inadequate safeguard, the guidance presently provided by the medical profession, the pharmaceutical industry, and the federal government fails to protect the best interests of patients and the integrity of physician decision making.”⁸⁰

After the *JAMA* article was published, in February 2006, the Association of American Medical Colleges (AMC) formed a task force to determine how to eliminate conflicts of

⁷⁹ *Id.*

⁸⁰ Brennan, *supra* note 9, at 431.

interest between physicians and pharmaceutical and medical device companies. A report from that task force was expected within a year, but to date nothing has been released. In the interim, a number of academic medical centers have been busy.

Below are some recent trends reflecting how many of the nation's top academic medical centers and healthcare systems are reacting to the challenge presented by the *JAMA* authors.

- In February of 2006, Yale University (Yale) rolled out a policy banning all gifts and on-campus meals from drug representatives. Under the policy, members of the medical staff are urged to use discretion in participating in off-campus industry-sponsored meals. Yale also limits participation in pharmaceutical industry-sponsored conferences.
- On July 1, 2006, the Hospital of the University of Pennsylvania (Penn) banned all gifts. However, the rules apply only to activities during work hours. Doctors and other staff will still be free to do as they choose in their free time, although accepting gifts or meals from drug representatives is strongly discouraged. Penn would appear to have adopted many of the more restrictive policies recommended in the *JAMA* article.⁸¹
- On October 1, 2006, Stanford University Medical Center (Stanford) prohibited its physicians from accepting even small gifts like pens and mugs from pharmaceutical sales representatives under a new policy intended to limit

⁸¹ D. Fallik, *Penn Bans Gifts From Drug Reps*, PHILADELPHIA INQUIRER (May 3, 2006).

- industry influence on patient care and doctor education.⁸² The Stanford policy also prohibits physicians from accepting free drug samples and publishing articles in science journals that were ghost written by corporate authors.
- As of January 1, 2007, Henry Ford Health Center (Henry Ford) banned no-cost lunches, gifts, and other incentives to physicians from medical equipment and pharmaceutical company representatives. Under the Henry Ford policy, representatives will be required to schedule appointments before visiting physicians and obtain a certification with the health system to conduct business with a healthcare provider, which includes payment of a \$100 annual certification fee by the pharmaceutical company.
 - The medical staff executive committee of the University of California (UC)-Los Angeles and UC-Davis approved a proposal that bans doctors from receiving any free gifts from pharmaceutical companies, medical device manufacturers, or sales representatives of any kind. These policies are effective July 1, 2007.

Some of the more specific policies and procedures, listed/grouped by subject matter, implemented by AMCs and hospitals in response to the *JAMA* article include the following:

⁸² See Paul Elias, *Stanford Won't Let Doctors Accept Gifts*, ASSOCIATED PRESS (Sept. 12, 2006), available at <http://abcnews.go.com/Health/print?id=2426004>. Stanford's "Industry Interactions Policy" is available at <http://med.stanford.edu/coi/siip/>.

1. Gifts and Compensation

Many AMCs' and hospitals' policies have adopted the *JAMA* suggestion and prohibit all personal gifts (e.g., pens, meals, and other food) from vendors on any institution site—and discourage acceptance of such gifts off-site as well (e.g., at professional meetings or events).

In addition, under these policies, compensation may not be accepted, including the defraying of costs, for simply attending a CME or other activity or conference (unless the individual is speaking or otherwise actively participating or presenting at the event).

2. Banning of Free Samples

Many institutions' policies treat free samples in the same manner that they view all other gifts and include an outright ban of free samples. Because one of the uses of free samples is to provide access to necessary drugs to those who may not be financially able to afford such medications, many institutions have adopted a voucher system. Under the voucher system, patients who meet the medical center's financial need criteria are given a voucher to be tendered at the center's pharmacy in exchange for the particular drug, which the manufacturer then replaces without charge.

One of the drawbacks of handing out free drug samples is the difficulty in tracking patients who were provided free samples. Some argue that, under the voucher system, better screening and follow-up may occur in case of adverse drug events (ADE) and patients may receive better instructions. The voucher system may be helpful for tracking purposes and reducing vendor-healthcare professional contact at institutions. The

practicalities of how the voucher system would or could work in the physician practice setting were not addressed by the *JAMA* authors.

3. Site Access Restrictions

Many institutions have developed policies and procedures that limit vendor representative access to physicians and others who are in a position to order goods or services within the AMC or hospital. Appointments to obtain information about new drugs in the formulary are issued by the hospital pharmacy department or by certain designated committees. Sales and marketing representatives are generally not permitted in any patient care areas except to provide in-service training on devices and other equipment and then only by appointment.

In addition, many institutions have restricted the forms of information that vendors may disseminate within the medical center. For example, an institution may permit distribution of reprints of primary literature from peer-reviewed journals and promotional materials that are deemed unbiased and are approved for distribution by the medical center.

4. Scholarships and Other Funds

Some of the academic medical centers' policies indicate that vendor scholarship support and contributions should be free of any actual or perceived conflict of interest and must comply with guidelines specified in the policy that will mitigate these types of potential conflicts.

5. **Support of Educational Activities**

Educational and professional activities must be compliant with the ACCME Standards for Commercial Support regardless of whether or not formal CME credit is being granted. As discussed above, **meals or other types of food *directly* funded by vendors are strictly prohibited by academic medical centers' policies in most cases,** unless the food is provided as part of an educational program that meets certain criteria, including ACCME compliance. **Many institutions will accept unrestricted educational grants, which are made without stipulation regarding the content of the educational program.**

6. **Implementation and Enforcement of Conflicts of Interest Policy**

Many institutions' policies require physicians to disclose any financial relationships with any vendor doing business with the institution. In addition, many policies require physicians who have a financial interest with a vendor may not serve on the drug formulary committee or will be required to recuse themselves from making decisions regarding drug/product purchases from vendors if they have a financial interest with the vendor. These policies also include a requirement that speakers disclose any financial interest or conflict of interest they may have related to the materials they are presenting.

B. Guidance for Physicians

Social research reveals that promotional efforts by vendors have a direct effect on physician prescribing practices, which may impact medical judgment.⁸³ Consider the following physician responses regarding the impact of physician/vendor interaction:

Promotions don't affect my practice⁸⁴—61%

Promotions don't affect my colleagues' practice⁸⁵—16%

Several physician organizations have developed guidelines for physicians on accepting gifts and other types of remuneration from vendors. Most widely recognized among these guidelines are: the ethical opinion “Gifts to Physicians from Industry” found in the AMA’s Code of Medical Ethics,⁸⁶ the American College of Physicians-American Society of Internal Medicine position statement on “Physicians and the Pharmaceutical Industry”,⁸⁷ and the American Osteopathic Association’s Guidelines to Industry Gifts to Physicians.⁸⁸ The American Association of Orthopaedic Surgeons recently adopted Standards of Professionalism.⁸⁹

⁸³ E. Hemminki, Review of Literature on the Factors Affecting Drug Prescribing, 9 Soc. Sci. & Med. 111 (1975).

⁸⁴ M.A. Steinman et al., Of Principles & Pens: Attitudes of Medicine Housestaff Toward Pharmaceutical Industry Promotions, 110 AM. J. MED. 551-557 (2001).

⁸⁵ *Id.*

⁸⁶ AMA, Council on Ethical and Judicial Affairs, Gifts to Physicians from Industry (E-8.061) (2001), available at www.ama-assn.org/ama/pub/article/4001-4236.html.

⁸⁷ S.L. Coyle, American College of Physicians-American Society of Internal Medicine, Ethics & Human Rights Committee, *Physician—Industry Relations, Part 1: Individual Physicians*, 136(5) ANN. INTERN. MED. 396-402 (Mar. 2002); S.L. Coyle, American College of Physicians-American Society of Internal Medicine, Ethics and Human Rights Committee, *Physician—Industry Relations, Part 2: Organizational Issues*, 136(5) ANN. INTERN. MED. 403 (Mar. 2005).

⁸⁸ AOA, Guidelines on Industry Gifts to Physicians, available at www.osteopathic.org/index.cfm?PageID=aoa_ethics.

⁸⁹ American Academy of Orthopaedic Surgeons, Standards of Professionalism: Orthopaedist-Industry Conflicts of Interest, Guide to the Ethical Practice of Orthopaedic Surgery (7th ed. 2007), available at www5.aaos.org/industryrelationships/pdf/standards.

1. American Medical Association

AMA first published its Opinion E-8.061, Gifts to Physicians from Industry,⁹⁰ which sets forth guidelines for physicians regarding promotional gifts. Since its adoption and subsequent amendments, Opinion E-8.061 has played a central role in establishing norms of conduct for physicians' interactions with industry representatives.

More specifically, AMA Opinion E-8.061 provides:

(1) Any gift accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value. Accordingly, textbooks, modest meals, and other gifts are appropriate if they serve a genuine educational function. The use of drug samples for personal or family use is permissible as long as these practices do not interfere with patient access to drug samples. It would not be acceptable for non-retired physicians to request free pharmaceuticals for personal use or use by family members.

(2) Individual gifts of minimal value are permissible as long as the gifts are related to the physician's work (e.g., pens and notepads).

⁹⁰ The AMA guidance is available at www.ama-assn.org/ama/pub/category/4001.html; it was issued June 1992 based on the AMA report "Gifts to Physicians from Industry," adopted December 1990 (265 JAMA 501 (1991); 56 Food & Drug L. J. 27-40 (2001)). The AMA has updated these guidelines through 2004.

(3) The [AMA's] Council on Ethical and Judicial Affairs defines a legitimate "conference" or "meeting" as any activity, held at an appropriate location, where (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering), and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented. An appropriate disclosure of financial support or conflict of interest should be made.

(4) Subsidies to underwrite the costs of CME conferences or professional meetings can contribute to the improvement of patient care and, therefore, are permissible. Since the giving of a subsidy directly to a physician by a company's representative may create a relationship that could influence the use of the company's products, any subsidy should be accepted by the conference's sponsor who in turn can use the money to reduce the conference's registration fee. Payments to defray the costs of a conference should not be accepted directly from the company by the physicians attending the conference.

(5) Subsidies from vendors should not be accepted directly or indirectly to pay the costs of travel, lodging, or other

personal expenses of physicians attending conferences or meetings, nor should subsidies be accepted to compensate for the physicians' time. Subsidies for hospitality should not be accepted outside of modest meals or social events held as a part of a conference or meeting. It is appropriate for faculty at conferences or meetings to accept reasonable honoraria and to accept reimbursement for reasonable travel, lodging, and meal expenses. It is also appropriate for consultants, who provide genuine services, to receive reasonable compensation and to accept reimbursement for reasonable travel, lodging, and meal expenses. Token consulting or advisory arrangements cannot be used to justify the compensation of physicians for their time or their travel, lodging, and other out-of-pocket expenses.

(6) Scholarship or other special funds to permit medical students, residents, and fellows to attend carefully selected educational conferences may be permissible as long as the selection of students, residents, or fellows who will receive the funds is made by the academic or training institution. Carefully selected educational conferences are generally defined as the major educational, scientific or policy-making meetings of national, regional or specialty medical associations.

(7) No gifts should be accepted if there are strings attached.

For example, physicians should not accept a gift if they are given in relation to the physician's prescribing practices.

AMA guidance, like other industry guidance, finds cash gifts unacceptable. The AMA Guidelines apply to all forms of gifts, whether they are offered in person, through intermediaries, or through the Internet. While affirming the belief that certain gifts to physicians by companies serve an important and beneficial function for both physicians and patients, the AMA Working Group for the Communication of Ethical Guidelines on Gifts to Physicians from Industry notes that “gifts that don’t adhere to the AMA’s Code—or other similar guidelines—may create the perception of unethical behavior. That perception undermines our credibility with patients and the public.”⁹¹ The AMA Guidelines seek to foster and promote an ongoing interaction and relationship between physicians and the pharmaceutical industry; however, physicians are urged to “ensure that those interactions are always ethically based.”⁹²

2. American College of Physicians-Internal Medicine

In March 2002, the American College of Physicians-Internal Medicine (ACP)⁹³ updated its 1990 position paper, “Physicians and the Pharmaceutical Industry,” which offered advice to physicians on accepting gifts and entering into other financial relationships with pharmaceutical manufacturers. ACP essentially sets forth a test for its physician

⁹¹ See Letter from the AMA (Aug. 2001), *available at* www.ama-assn.org/ama/pub/category/5765.html.

⁹² *Id.*

⁹³ ACP is the nation's largest medical specialty organization and the second-largest physician group. Its membership comprises more than 115,000 internal medicine physicians and medical students. Internists are specialists in the prevention, detection, and treatment of illnesses that primarily affect adults.

members, encouraging them to avoid all relationships and gifts that (1) might diminish their objectivity; and (2) are detrimental to the patient's best interest. While the position paper indicates that it may be acceptable for physicians to accept inexpensive gifts for office use (e.g., pens and notepads); low cost gifts for educational or patient care purposes (e.g., medical books); and modest meals at legitimate educational programs, ACP strongly discourages physicians from accepting gifts, hospitality, trips, and subsidies from pharmaceutical manufacturers. However, rather than prohibiting acceptance of any gifts, the organization encourages physicians to make decisions on a case-by-case basis.

3. American Osteopathic Association

The American Osteopathic Association (AOA), in its "Guidelines on Industry Gifts to Physicians" also provides guidance to physicians relating to gifts and subsidies offered by pharmaceutical and medical equipment companies.⁹⁴ The AOA Guidelines provide that gifts to physicians should be related to patient care or medical practice and of modest value. According to AOA, unacceptable gifts include cash, subsidies for travel, lodging or personal expenses, or compensation for time spent by physicians attending conferences or meetings; payment for token focus groups, token consulting and advisory services; and gifts with "strings attached," such as those given in relation to a physician's prescribing practices. Acceptable gifts include textbooks and other educational gifts not of substantial value; work-related gifts of minimal value (e.g., pens, notepads and penlights); scholarships for medical students and residents to attend

⁹⁴ The AOA Guidelines are available at www.osteopathic.org/index.cfm?PageID=aoa_ethics.

educational conferences if selection and payment is made by the academic institution; reasonable compensation and reimbursement of expenses sustained by consultants; and modest meals, usually in conjunction with educational programs.

4. American Association of Orthopaedic Surgeons

On April 18, 2007, the American Association of Orthopaedic Surgeons (AAOS) adopted Standards of Professionalism on Orthopaedist-Industry Conflicts of Interest providing guidance on the appropriate relationship between orthopaedic surgeons and the pharmaceutical and medical device industry. To enable implementation of educational programs on the guidelines, the standards will not be effective until January 1, 2008. Acceptable gifts include modest gifts (under \$100), medical textbooks, or other patient educational materials. The standards also allow for surgeons to accept reimbursement for reasonable costs associated with participating in clinical research trials and consulting services. In terms of educational events, surgeons may accept financial support, tuition, and modest hospitality for non-CME educational events for themselves but not for their guests. Further, the standards allow for financial grants to medical residents to attend CME events as long as the selection of the recipients and payments are made by the resident's academic institution or CME sponsor. Unacceptable gifts include compensation for attending non-educational, industry-related events and the "string attached" gifts for using a particular medication or device or for "switching" arrangements. Similar to the AMA guidance, AAOS requires appropriate disclosure of financial arrangements or conflicts of interest. Although the AAOS standards provide some guidance for orthopaedic surgeons on accepting gifts and compensation from vendors, the standards are far less stringent than the

recommendations of the *JAMA* article even though these standards were adopted subsequent to the *JAMA* article's publication date.

C. Pharmaceutical Manufacturers' Guidance

To promote ethical relationships with physicians, trade organizations in the pharmaceutical industry, like PhRMA and, more recently, the International Federation of Pharmaceutical Manufacturers Associations (IFPMA), have issued codes that address vendor marketing practices. As a result of these codes and OIG guidance, federal enforcement and state disclosure laws, the old model of interactions between healthcare professionals and pharmaceutical manufacturers has changed from expensive trips, gifts, and entertainment to contracted consulting services and more patient and practice-centered "gifts."

1. PhRMA Code

PhRMA is an association that represents research-based pharmaceutical and biotechnology companies. In July 2002, it adopted the PhRMA Code on Interactions with Healthcare Professionals to govern the marketing of pharmaceutical products (the "PhRMA Code").⁹⁵ PhRMA's stated objective was to emphasize that interactions with healthcare professionals must benefit patients and enhance the practice of medicine.⁹⁶ Specifically, according to the PhRMA Code, pharmaceutical manufacturers' interactions with healthcare professionals enable manufacturers to—

- Inform healthcare professionals about the benefits and risks of products;

⁹⁵ PhRMA Code (July 1, 2002), available at www.phrma.org.

⁹⁶ *Id.* at 3 & 5.

- Provide scientific and educational information;
- Support medical research and education; and
- Obtain advice about products through consultation with medical experts.⁹⁷

The PhRMA Code states the general rule that no grants, scholarships, subsidies, support, consulting contracts, or educational or practice-related items should be provided or offered to a healthcare professional in exchange for prescribing products or for continuing to prescribe them.⁹⁸ Assuming there is no quid pro quo arrangement based on prescriptions, the PhRMA Code lays out the following guidelines:

*a. Informational Presentations by or on Behalf of a Pharmaceutical Company.*⁹⁹

Occasional meals (but no entertainment or recreational events) may be offered by pharmaceutical companies during informational presentations by or on behalf of a pharmaceutical company as long as such meals are “modest as judged by local standards” and “occur in a venue and manner conducive to informational communication and provide scientific or educational value.” Inclusion of a healthcare professional’s spouse or other guests is inappropriate, as is offering meals to be eaten without a company representative present.

*b. Third-Party Educational or Professional Meetings:*¹⁰⁰

⁹⁷ *Id.* at 3.

⁹⁸ *Id.* at 19.

⁹⁹ *Id.* at 7.

Financial support for CME should be given to the conference's sponsor, who can use the money to reduce the overall conference registration fee for all attendees.

Responsibility for the selection of content, faculty, educational methods, materials, and venue belongs to the organizers of CME conferences. It is not appropriate to pay travel, lodging, or other personal expenses of non-faculty healthcare professionals attending CME conferences. Neither is it appropriate to compensate for the time spent by healthcare professionals attending the conference or meeting.

Financial support for meals or receptions may be provided to the CME sponsors, who, in turn, can provide meals or receptions for all attendees. Such meals and receptions should be "modest" and "conducive to discussion among faculty and attendees," and the "amount of time at the meals or receptions should be clearly subordinate to the amount of time spent at the educational activities of the meeting."¹⁰¹

Financial assistance for scholarships or other educational funds to allow medical students, residents, fellows, and other healthcare professionals in training to attend carefully selected educational conferences may be offered as long as the selection of the fund recipients is made by the academic or training institution.¹⁰²

*c. Consultants.*¹⁰³

Pharmaceutical companies may pay reasonable compensation and expenses for consulting and advisory services; however, token consulting or advisory arrangements

¹⁰⁰ *Id.* at 9.

¹⁰¹ *Id.*

¹⁰² *Id.* at 15.

¹⁰³ *Id.* at 11.

should not be used to justify payments. Pharmaceutical companies should not pay honoraria or travel or lodging expenses to non-faculty and non-consultant attendees at company-sponsored meetings, including attendees who participate in interactive sessions.

The following factors support the existence of a *bona fide* consulting arrangement:

- A written contract specifying the nature of the services to be provided and the basis for payment;
- A legitimate need for the services has been clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants;
- The selection of consultants should be performed using criteria related to the identified purpose by individuals competent to evaluate whether the particular healthcare professionals meet those criteria;
- The number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified purpose;
- Records should be maintained by the company concerning the use of services provided by consultants; and
- Meeting with consultants should take place in circumstances conducive to the consulting services, and any social or entertainment events should be clearly subordinate in terms of time and emphasis.

d. *Speaker Training Meetings*.¹⁰⁴

Pharmaceutical companies may offer healthcare professionals who recruit and train speakers for speakers bureaus to be offered reasonable compensation and reimbursement for reasonable expenses, as long as (1) the participants receive extensive training on the company's drug products and on compliance with FDA regulatory requirements for communications about such products, (2) this training will result in the participants providing a valuable service to the company, and (3) the participants meet the criteria for consultants (discussed above).

e. *Educational and Practice-Related Items*.¹⁰⁵

Items primarily for the benefit of patients may be offered to healthcare professionals if they are valued at \$100 or less. Items should not be offered on more than an occasional basis, even if each individual item is appropriate. Providing samples for patient use in accordance with the Prescription Drug Marketing Act is acceptable.

Items of minimal value may be offered if they are primarily associated with a healthcare professional's practice (such as pens, notepads, and "reminder" items with company or product logos).

Items for the personal pleasure of healthcare professionals (e.g., tickets to a sporting event) should *not* be offered. Payments in cash or cash equivalents should not be offered, except as compensation for *bona fide* services.

¹⁰⁴ *Id.* at 13.

¹⁰⁵ *Id.* at 17.

2. IFPMA Code of Pharmaceutical Marketing Practices

In January 2007, the revised IFPMA Code of Pharmaceutical Marketing Practice (“IFPMA Code”) came into effect, requiring pharmaceutical companies to ensure the ethical promotion of their products to healthcare professionals.¹⁰⁶ “IFPMA” stands for the International Federation of Pharmaceutical Manufacturers Association, a non-profit organization, representing industry associations and companies from sixty developed and developing countries. Member companies include major global research-based pharmaceutical companies like Pfizer, GlaxoSmithKline, Sanofi-Aventis, Eli Lilly, AstraZeneca, Schering-Plough, and Bristol-Myers Squibb. Member associations include PhRMA. Conditions of membership in IFPMA are a commitment to good manufacturing practices and acceptance of the provisions of the IFPMA Code.

In addition to PhRMA Code-like rules, the IFPMA Code includes rules that are not covered under the PhRMA Code, but are covered under FDA laws, e.g., rules regarding advertising and the sale of samples. Some differences exist between the PhRMA Code and the IFPMA Code. For example, unlike the PhRMA Code, the IFPMA Code allows payment directly to healthcare professionals for travel expenses related to CME, whereas the PhRMA Code only allows sponsorship indirectly through the third-party conference sponsor. The other IFPMA Code rules regarding gifts to healthcare professionals are similar to the PhRMA Code, including the allowance of certain promotional aids of minimal value, items of medical utility of modest value, and free samples of a pharmaceutical product to enhance patient care.

¹⁰⁶ The IFPMA Code of Pharmaceutical Marketing Practices (eff. Jan. 1, 2007), *available at* www.ifpma.org/pdf/IFPMA-TheCode-FinalVersion-30May2006-EN.pdf.

The IFPMA Code has a reporting and enforcement mechanism that is missing from the PhRMA Code:

- Complaints related to infringements of the IFPMA Code are reported to IFPMA;
- IFPMA investigates if the complaint relates to a member company (unless already being investigated by a member organization);
- The IFPMA Director General refers complaints to an ad hoc group of three individuals “experienced in the application of national codes and selected from member associations” for adjudication, and decisions are made by simple majority;
- There is a right to appeal the IFPMA decision to an ad hoc group of five individuals again “experienced in the application of national codes and selected from member associations” (but not the original group of three), and decisions are made by simple majority;
- When a complaint is upheld and a breach of the IFPMA Code is found, or not disputed by the company, information about the case will be made public on IFPMA’s website.

3. Adoption of Other Industry Guidance

Apart from its industry guidance, the pharmaceutical manufacturers have also recognized guidance applicable to physicians. As discussed above, in 1992, the AMA

issued Opinion E-8.061, “Guidelines on Gifts to Physicians from Industry,” which was intended to provide ethical guidance to physicians.¹⁰⁷ PMA, now PhRMA, also adopted those guidelines. Physician associations, although they may have adopted their own codes or guidance, have not specifically adopted the PhRMA or IFPMA codes.

D. Guidance for Medical Device Manufacturers/Suppliers

In 2003, AdvaMed, the world’s largest medical technology association, representing over 1300 of the world’s leading medical technology innovators and manufacturers of medical devices, diagnostic products and medical information systems,¹⁰⁸ drafted a “Code of Ethics on Interactions with Health Care Professionals” (“AdvaMed Code”) that became effective January 1, 2004.¹⁰⁹ The AdvaMed Code specifies the parameters for furnishing gifts to healthcare professionals, the circumstances under which it is appropriate for manufacturers to pay for expenses incurred during member-sponsored product training and education, third-party educational conferences, sales and promotional meetings, and arrangements with consultants.¹¹⁰ It also addresses the circumstances under which manufacturers may give charitable contributions to healthcare professionals.

¹⁰⁷ AMA, Ethical Opinion E-8.061, *available at* www.ama-assn.org/ama/pub/category/4001.html.

¹⁰⁸ See www.advamed.org.

¹⁰⁹ See AdvaMed, Code of Ethics on Interactions with Health Care Professionals and its associated list of Frequently Asked Questions Regarding the Code, *available at* www.advamed.org/publicdocs/coe_with_faqs_4-15-05.pdf (last updated Apr. 2005).

¹¹⁰ AdvaMed Code, *available at* www.advamed.org/publicdocs/coe.html. There are several other codes of ethics relevant to the device industry that cover similar territory to the AdvaMed Code, for example, National Electronic Manufacturers Association (NEMA), Code of Ethics on Interactions with Health Care Providers (adopted Nov. 30, 2004), *available at* www.nema.org; Eucomed, Ethics – Guiding Principles, *available at* www.eucomed.be/about_us/ethics.aspx; MEDEC, Code of Conduct (Canada), *available at* www.medec.org/code_of_conduct.

1. Identifying and Managing Potential Conflicts of Interest

The first step in assessing the potential for a conflict of interest is to identify the value being transferred between the parties (the “remuneration,”) in connection with any particular arrangement. After the remuneration has been identified, the next step is to identify the intent of the transfer. Manufacturers interact with providers in many different capacities, including for example, as students, inventors, and investors. All of the relationships involve the transfer of value from the manufacturer to the customer: students receive valuable education; inventors are paid for their inventions; and investors receive an opportunity to invest and receive a return on their investment. When the providers are also customers, the transfer of value can be, or appear to be, an improper payment for referrals or utilization. In response to this concern, the AdvaMed Code, like the AKS safe harbors, and OIG industry guidance, focuses on limiting the value transferred and restricting the purpose of the underlying interactions.

Limiting the value transferred between manufacturers and their provider-customers may be helpful in dispelling the notion that the intent of the transfer is improper. A very low value transfer is unlikely to be seen as creating a conflict of interest, or as capable of inducing an improper referral or recommendation. The fact that remuneration is of low value does not entirely negate the possibility of an allegation of impropriety, however. Indeed, the Civil Monetary Penalties Act suggests that gifts of more than \$10.00 (in any given instance, and \$50 per annum) could be expected to influence beneficiary provider selection.¹¹¹ Indeed, the term “remuneration” has been

¹¹¹ 42 U.S.C. § 1320a-7a(a)(5).

interpreted to apply to anything of value,¹¹² and the magnitude of the value per item appears to be irrelevant to the determination of whether remuneration exists. While a \$10 item by itself will not likely draw the government's attention (although the government could theoretically prosecute on the same), a pattern or practice of \$10 kickbacks will draw the government's attention and enforcement activity.

The AdvaMed Code mirrors the other authorities in the area, when it promotes transfers of value that are related to purposes other than inducement, and then, only in contexts where a proper purpose is evident. So, for example, support of product-related training and education is explicitly permitted by the AdvaMed Code. The legitimate purpose of this type of training and education is self-evident: to increase product familiarity, thereby enhancing patient safety and promoting appropriate use. In other words, it is unlikely that the provision of training and education is a pretext for conveying value to customers in order to exert improper influence, especially when the AdvaMed Code requires that the programs be bona fide and that the value of any ancillary travel or other hospitality be constrained.

2. Business Courtesies

Business courtesies, such as offering to pick up the cost of a meal over which business was discussed, are a common feature of commercial relationships. When they are of relatively low value, they are generally accepted as courtesies, and not thought of as being capable of creating, or designed to create, a conflict of interest. When they are of significant value, for example, when a manufacturer pays for travel to a resort

¹¹² See *United States v. Bay State Ambul. & Hosp. Rental Servs.*, 874 F.2d 20 (1st Cir. 1989).

location, luxury lodging, and entertainment for attendees and their spouses during a business meeting, suspicions can be raised as to the whether the underlying motivation is benign.

The AdvaMed Code does provide guidance with respect to business courtesies. It recognizes that a degree of hospitality is accepted business practice designed to facilitate business interactions, but implicitly acknowledges that at some point the expenses may be so extraordinary or extravagant as to function or appear to function as an illegal inducement. Thus, the AdvaMed Code counsels against business courtesies with a high value, those that are given too frequently, as well as those that are given in a context unlikely to facilitate business. This approach is consistent with many authorities, including those governing government lobbyists and members of Congress.¹¹³

The AdvaMed Code addresses business courtesies arising in a number of contexts, including those extended by manufacturers in connection with sales and promotional meetings. In particular, the AdvaMed Code instructs:

It is appropriate for Members to meet with Health Care Professionals to discuss product features, contract negotiations, and sales terms. Often, these meetings occur close to the Health Care Professional's place of business. It is appropriate for Members to pay for occasional hospitality only in the form of modest meals and receptions for Health Care

¹¹³ See, e.g., Lobbying Disclosure Act of 1995 at 2 U.S.C. § 1601 *et seq.*; Ethics Reform Act of 1989, 18 U.S.C. § 207 *et seq.*

Professional attendees that are conducive to the exchange of information. It is also appropriate to pay for reasonable travel costs of attendees when necessary (e.g., for plant tours or demonstrations of non-portable equipment). However, it is not appropriate to pay for meals, hospitality, travel, or lodging of guests of Health Care Professionals or any other person who does not have a bona fide professional interest in the information being shared at the meeting.

This approach seeks to distinguish true courtesies from improper inducements by: (1) establishing that there is a legitimate need for the interaction in order to discuss product features, contract negotiations, or sales terms—thereby assuring that the purpose of the undertaking seems to be appropriate; (2) limiting the value of the courtesy to occasional hospitality only in the form of modest meals and receptions and reasonable travel costs of attendees when necessary—as the limited value of the courtesy makes it unlikely to function as an improper inducement; and 3) ensuring that the courtesies are extended only to persons with a real reason to be at the meeting, and not, for example, to their spouses or significant others—thereby underscoring the first two objectives.

The AdvaMed Code also addresses business courtesies extended in connection with third-party conferences. In particular, the AdvaMed Code instructs:

Members may provide funding to the conference sponsor to support the conference's meals and hospitality. Also, Members themselves may provide meals and receptions for all Health Care Professional attendees, but only if provided in a manner that is also consistent with the sponsor's

guidelines. Any meals, receptions, and hospitality should be modest in value and should be subordinate in time and focus to the purpose of the conference.

Again, the focus is on limiting the contexts in which the support is provided and the value of the support.

3. Training and Education

Manufacturers also provide training and education on the safe and effective use of their products. This activity undoubtedly has public utility, but could be construed as involving the provision of remuneration in the form of valuable training to customers. Also, training and education is often accompanied by business courtesies (e.g., coffee breaks and lunch provided during a training session) and also may involve the subsidy of travel (e.g., to a centralized training point, picked so that the company can efficiently deliver training to many customers at one site). Since the allocation of limited resources may result in the favorable treatment of “big” customers, it also may appear that the training is being provided as a reward for prior purchases or as an inducement for subsequent purchases.

With respect to the provision of training and education to customers, the AdvaMed Code provides:

- Members have a responsibility to make product education and training available to Health Care Professionals. In fact, the U.S. Food and Drug

Administration mandates training and education to facilitate the safe and effective use of certain medical technology. Such programs often occur at centralized locations (necessitating out-of-town travel for some participants), and may extend to more than one day. With regard to Member programs focused on the education and training in the safe and effective use of Member products:

- Programs and events should be conducted in clinical, educational, conference, or other settings, including hotel or other commercially available meeting facilities conducive to the effective transmission of knowledge.
- Programs requiring “hands on” training in medical procedures should be held at training facilities, medical institutions, laboratories, or other appropriate facilities. The training staff should have the proper qualifications and expertise to conduct such training.
- Members may provide Health Care Professional attendees with hospitality only in the form of modest meals and receptions in connection with these programs. Any such meals and receptions should be modest in value and subordinate in time and focus to the educational or training purpose of the meeting.
- Members may pay for reasonable travel and modest lodging costs incurred by attending Health Care Professionals.

- It is not appropriate for Members to pay for the meals, hospitality, travel, or other expenses for guests of Health Care Professionals or for any other person who does not have a bona fide professional interest in the information being shared at the meeting.

The approach taken in this section is similar to the approach taken by the PhRMA Code to business courtesies. Implementation of this guidance should reduce the possibility that manufacturer sponsored training and education will be seen as an excuse to provide high value vacations to customers and their significant others. The implementation challenge is in establishing an objective interpretation of the term “modest” as it applies to accommodations, and ensuring that manufacturers’ impetus for the training and education session is indeed training and education. With respect to the latter, manufacturers must pay attention to the context of the program and the selection criteria for attendees. In other words, they must establish a process for assuring and documenting that the content is robust and that the attendees are likely to benefit from the training and education. As the vacation-like qualities of the venue increase, this process becomes more critical.

4. Value-Added Services

Manufacturers often provide customers with free product related assistance and support, either as part of their regular customer service program or as a negotiated term of sale. For example, assistance in installation, operation, troubleshooting, and correct billing for services performed with the particular manufacturer’s equipment may all be supplied without additional charge. In addition, manufacturers of implanted devices

often provide technical assistance in customer's facilities at the time of implant.¹¹⁴ It is well established that the provision of some of these "value-added" services do not implicate compliance-related concerns, and, indeed, that it may be desirable to encourage the provision of these services. However, at some point, the value-added service may become so attenuated from the product, that it may appear to be "something of value" given to "induce" business rather than an integral part of the purchased product with no independent value.

In this regard, the OIG has explained that:

Drug manufacturers often offer free assistance to physicians and other providers by serving as a clearinghouse for information regarding insurance coverage criteria and reimbursement levels for their products. Since these services have no independent value to providers apart from the products, they are properly considered part of the products purchased and their cost is already included in the products' price. Therefore, standing alone, these services have no substantial independent value and do not implicate the federal anti-kickback statute.

However, the federal anti-kickback statute may be implicated when drug manufacturers combine these types of reimbursement support services with other services or programs which do confer an independent financial benefit upon referring providers. For example, coupling a reimbursement

¹¹⁴ John J. Hayes et al., *The Role(s) of the Industry Employed Allied Professional*, 24 J. OF PACING & CLINICAL ELECTROPHYSIOLOGY 398 (2001).

support service with a program either requiring payment for ordered products *only if* the referring provider is paid or guaranteeing a minimum “spread” between the purchase price and third party reimbursement levels would implicate the anti-kickback statute. Such programs eliminate the normal financial risks facing providers, potentially raising the risk of over utilization and increased Federal health care program costs.¹¹⁵

From this explanation, we gather that value-added services are permissible if “they are properly considered part of the products purchased and their cost is already included in the products’ price” and do not confer an independent financial benefit upon referring providers. This suggests that value-added services may be provided without charge if they are of a type that would normally be provided ancillary to a product without additional charge, are provided to all purchasers without charge, and do not have the capacity to be resold by the recipient.¹¹⁶ Accordingly, the AdvaMed Code’s focus with regard to value-added services is on ensuring that they are product-related and of a type not commonly thought of as having independent value. In this respect, the AdvaMed Code states:

Members may support accurate and responsible billing to Medicare and other payors by providing reimbursement information to Health Care Professionals regarding Members’ products, including identifying appropriate coverage, coding, or billing of Member products, or of

¹¹⁵ OIG Advisory Opinion No. 00-10 (Dec. 15, 2000), *available at* www.oig.hhs.gov/fraud/docs/advisoryopinions/2000/ao00_10.pdf.

¹¹⁶ See OIG bulletin on free computers, 56 Fed. Reg. 35978 (July 29, 1991); Kevin G. McAnaney Letter (July 3, 1997), *available at* <http://oig.hhs.gov/fraud/docs/safeharborregulations/freecomputers.htm>.

procedures using those products. Members may also provide information designed to offer technical or other support intended to aid in the appropriate and efficient use or installation of the Member's products. However, it is inappropriate for Members to provide this technical or other support for the purpose of unlawfully inducing Health Care Professionals to purchase, lease, recommend, use, or arrange for the purchase, lease or prescription of Members' products.

The AdvaMed Code does not tackle, however, the more difficult question of when services should be viewed as having independent value. Nor does it take on the elusive question of when support should be viewed as constituting an unlawful inducement. These concepts are not well developed in the authorities, and it is often difficult, particularly in light of the dynamic nature of the market, where, for example, a new service may have independent value when it is initially offered, but seemingly lose it when all competitors offer the same service without charge, to determine with certainty when a product related service or feature should be considered as having independent value.

5. Consulting Arrangements

Among the common relationships between manufacturers and providers, perhaps consulting arrangements have received the most attention and criticism.¹¹⁷ Manufacturers have a legitimate need to contract with customers to provide personal services. For example, manufacturers may need healthcare professionals to train and

¹¹⁷ Reed Abelson, *Surgeons Invest in Makers of Hardware*, N.Y. TIMES (Dec. 30, 2006).

educate on the safe and effective use of their products, to act as principal investigators in connection with manufacturer-sponsored clinical trials, or to consult in the development of product. Even so, critics worry that the relationships may be subterfuges for illegal kickbacks, or that even legitimate arrangements can create unacceptable conflicts of interest.

The compliance risk posed by these arrangements stems from a number of factors. Generally, only persons who are familiar with the manufacturer's product are qualified to consult. This means that the selection decision will often utilize criteria that correlate with the volume of purchases made by the customer (i.e., the more purchases, the more experience with the product). Fair market value is difficult to establish, particularly when the consultant will be engaging in specialized activities, such as product development. This means that outsiders may be suspicious that the arrangement involves an overpayment for an illicit purpose.

Even so, like other transfers of value, consulting relationships are permissible under the AKS if they are entered into for some purpose other than inducing specific types of prohibited behavior. In fact, the AKS even has a safe harbor for personal service arrangements, which, while almost impossible to comply with (because of the requirement that, in the case of part-time services, the schedule for performance services be laid out with particularity and the requirement that aggregate compensation be set in advance), at least signifies acknowledgement that these relationships can be appropriate.¹¹⁸

¹¹⁸ See 42 C.F.R. § 1001.952(d).

The AdvaMed Code sets out a practical, process-oriented approach to compliance in this area:

Many Health Care Professionals serve as consultants to Members, providing valuable *bona fide* consulting services, including research, participation on advisory boards, presentations at Member-sponsored training, and product collaboration. It is appropriate to pay Health Care Professionals reasonable compensation for performing these services.

The following factors support the existence of a *bona fide* consulting arrangement between Members and Health Care Professionals:

- Member consulting arrangements should be written, signed by the parties and specify all services to be provided.
- Compensation paid to consultants should be consistent with fair market value for the services provided.
- Consulting agreements should be entered into only where a legitimate need and purpose for the services is identified in advance.
- Selection of consultants should be on the basis of the consultant's qualifications and expertise to address the identified purpose, and should not be on the basis of volume or value of business generated by the consultant.
- The venue and circumstances for Member meetings with consultants should be appropriate to the subject matter of the consultation. These meetings should be conducted in clinical, educational, conference, or other setting,

including hotel or other commercially available meeting facilities, conducive to the effective exchange of information.

- Member-sponsored hospitality that occurs in conjunction with a consultant meeting should be modest in value and should be subordinate in time and focus to the primary purpose of the meeting.
- Members may pay for reasonable and actual expenses incurred by consultants in carrying out the subject of the consulting arrangement, including reasonable and actual travel, modest meals and lodging costs incurred by consultants attending meetings with, or on behalf of, Members.
- When a Member contracts with a consultant for research services, there should be a written research protocol.

6. Charitable Contributions

Manufacturers also may make charitable contributions to healthcare professionals. These may be in the form of product or cash, and may occur in a number of contexts, including: responding to general fundraising drives (e.g., buying tickets to charitable golf tournaments); funding specific projects (e.g., underwriting a medical research project); and donating of product for use by indigent patients. The authorities suggest that charitable contributions can be acceptable under certain circumstances.¹¹⁹

¹¹⁹ OIG Advisory Opinion 06-14 (Sept. 21, 2006), *available at* www.oig.hhs.gov/fraud/docs/advisoryopinions/2006/Adv-Opn06-14.pdf; OIG Advisory Opinion 01-7 (July 2, 2001), *available at* www.oig.hhs.gov/fraud/docs/advisoryopinions/2001/ao01-07.pdf.

However, charitable contributions also may be viewed as a vehicle for delivering an illegal kickback.

With respect to charitable contributions, the AdvaMed Code focuses on assuring a proper recipient and purpose for the contribution:

Members may make donations for a charitable purpose, such as supporting genuine independent medical research for the advancement of medical science or education, indigent care, patient education, public education, or the sponsorship of events where proceeds are intended for charitable purposes. Donations should be made only to charitable organizations or, in rare instances, to individuals engaged in genuine charitable missions for the support of that mission. It is not appropriate for Members to make such donations for the purpose of unlawfully inducing Health Care Professionals to purchase, lease, recommend, use, or arrange for the purchase, lease or prescription of Members' products. All donations should be appropriately documented. Examples of appropriate charitable grants and related considerations cited by the AdvaMed Code are:

- *Advancement of Medical Education.* Members may make grants to support the genuine medical education of medical students, residents, and fellows participating in fellowship programs, which are charitable or have an academic affiliation or, where consistent with the preamble to this section,

other medical personnel. (For additional considerations regarding educational grants, see Supporting Third Party Educational Conferences, *infra*.)

- *Support of Research with Scientific Merit.* Members may make research grants to support genuine medical research. The purpose of the grant must be clearly documented.
- *Public Education.* Members may make grants for the purpose of supporting education of patients or the public about important health care topics.

7. Gifts

Under the AdvaMed Code's guidance, manufacturers may give customers gifts in a number of contexts. For example, small reminder items (e.g., pens) may be given as part of a promotional campaign, or a welcome gift may be given to conference participants. While many gifts can be seen as being simply an advertising mechanism, or as business courtesies, it is also possible to see them as kickbacks. The AdvaMed Code tries to constrain the value and type of gifts that may be given, so as to negate even an implication of impropriety. The AdvaMed Code directs:

Members occasionally may provide modest gifts to Health Care Professionals, but only if the gifts benefit patients or serve a genuine educational function. Other than the gift of medical textbooks or anatomical models used for educational purposes, any gift from a Member should have a fair market value of less than \$100.

In addition, Members may occasionally give Health Care Professionals branded promotional items of minimal value related to the Health Care Professional's work or for the benefit of patients. Gifts may not be given in the form of cash or cash equivalents.

This section is not intended to address the legitimate practice of providing appropriate sample products and opportunities for product evaluation.

This section of the AdvaMed Code leaves open many of the same questions discussed above with respect to business courtesies. In addition, it specifically refrains from addressing the provision of free product as samples or for evaluation. In doing so, the AdvaMed Code signals that these practices can be legitimate, and deserve a distinct analysis.

8. Supporting Third-Party Educational Conferences

Manufacturers often sponsor or underwrite conferences that are arranged by third parties, such as professional societies. Since the attendees at these conferences are often the manufacturer's customers, the sponsorship, to the extent it defrays costs that would otherwise be passed on to attendees, could be seen as valuable to the customers. Moreover, if the party putting on the conference is a customer (e.g., an academic medical center), it might be possible to see the manufacturer's contribution as being an improper inducement to that party.

The AdvaMed Code focuses on assuring that the conference is a bona fide conference and not a junket. It also seeks to ensure that any benefits provided to

attendees or faculty are provided through the conference sponsor, thereby breaking a direct tie with the manufacturer and, presumably, reducing the opportunities for improper influence. Finally, it attempts to distinguish and protect the practice of purchasing advertising at such venues.

In particular, the AdvaMed Code provides:

- *Bona fide* independent, educational, scientific, or policymaking conferences promote scientific knowledge, medical advancement and the delivery of effective healthcare. These typically include conferences sponsored by national, regional, or specialty medical associations, conferences sponsored by accredited continuing medical education providers, and grand rounds. Members may support these conferences in various ways.
- *Educational Grants*. Members may provide a grant either directly to the conference sponsor to reduce conference costs, or to a training institution or the conference sponsor to allow attendance by medical students, residents, fellows, and others who are Health Care Professionals in training. Members may provide educational grants when: (1) the gathering is primarily dedicated to promoting objective scientific and educational activities and discourse; and (2) the training institution or the conference sponsor selects the attending Health Care Professionals who are in training. Such grants should be paid only to organizations with a genuine educational purpose or function, and may be used only to reimburse the legitimate expenses for bona fide educational activities. Such grants also should be consistent with relevant

guidelines established by professional societies or organizations. The conference sponsor should be responsible for and control the selection of program content, faculty, educational methods, and materials.

- *Faculty Expenses.* Members may make grants to conference sponsors for reasonable honoraria, travel, lodging, and meals for Health Care Professionals who are bona fide conference faculty members.
- *Advertisements and Demonstration.* Members may purchase advertisements and lease booth space for company displays at conferences.

The AdvaMed Code provides a useful tool for compliance with the AKS. It can assist a company in identifying some, but not all, of the critical risk areas that arise in connection with its interactions with customers. Parsed carefully, it also provides a roadmap to defusing the risks attendant to these areas. However, significant additional work is required to actually implement and assure adherence to the principles expressed in the AdvaMed Code.

V. Enforcement Trends

Government enforcement of federal and state laws against healthcare providers and individuals and entities with whom they do business has generated high dollar penalties. In fiscal year 2006, the OIG reported savings and expected recoveries of nearly \$38.2 billion: \$35.8 billion in implemented recommendations and other actions to put funds to better use, \$789.4 million in audit receivables, and \$1.6 billion in investigative

receivables.¹²⁰ In this same year, OIG reported exclusions of 3,425 individuals and entities for fraud or abuse involving federal healthcare programs and/or their beneficiaries; 472 criminal actions against individuals or entities that engaged in crimes against departmental programs; and 272 civil actions, which include FCA and unjust enrichment suits filed in federal district court, civil monetary penalty law¹²¹ settlements, and administrative recoveries related to provider self-disclosure matters.¹²² Over the past few years, many such cases and settlements have involved vendors for allegations based in part, on their relationships with physicians. A number of cases have involved allegations that grants given to physicians by pharmaceutical manufacturers were, in fact, kickbacks. Most notable examples of the recent trend in enforcement activities include the recent actions against TAP Pharmaceuticals, AstraZeneca Pharmaceuticals, Pfizer, Serono, Schering-Plough, Medtronic, and Advanced Neuromodulation Systems, as well as individual physicians.

A. TAP Pharmaceuticals

One of the landmark investigations and settlements involving a physician-pharmaceutical manufacturer relationships occurred in 2001 when TAP Pharmaceutical Products Inc. (TAP), a joint venture between Abbott Laboratories and Takeda Chemicals of Japan, agreed to pay \$875 million to resolve criminal charges and civil liabilities in connection with its fraudulent drug pricing and marketing conduct with

¹²⁰ OIG, Semiannual Report to Congress (Apr. 1, 2006 - Sep. 30, 2006) ("Semiannual Report"), *available at* www.oig.hhs.gov/publications/docs/semiannual/2006/Semiannual%20Final%20FY%202006.pdf; *see also* Department of Health and Human Services (DHHS) & Department of Justice (DOJ), Health Care Fraud and Abuse Control Program Annual Report for FY 2005 (Aug. 2006), *available at* www.usdoj.gov/dag/pubdoc/hcfareport2005.pdf.

¹²¹ 42 U.S.C. § 1320a-7a.

¹²² *Id.*

regard to Lupron®, a drug sold by TAP primarily for treatment of advanced prostate cancer in men.¹²³ The government alleged that TAP provided kickbacks in the form of free samples of Lupron® to physicians, who then billed Medicare the full price for the drug. The government further alleged that TAP sought to influence physician decisions by paying physicians sham consulting fees for speaking and other advisory arrangements; sponsoring speaking engagements and meetings; and giving money disguised as educational and research grants, which was used to cover cocktail party bar tabs, office Christmas parties, medical equipment, travel expenses, and discounts on Lupron®.¹²⁴ In addition to TAP as an entity, six TAP executives and one physician were named in the indictment. Prior to the indictment, four other physicians were charged and pled guilty.¹²⁵ The actual civil and criminal charges in the case were conspiracy to defraud Medicaid programs in a number of states, conspiracy to violate the PDMA (which forbids billing for free samples), and violations of the AKS and FCA. TAP signed a seven-year Corporate Integrity Agreement (CIA) with the OIG that included provisions requiring TAP to develop policies and procedures related to marketing and sales; to provide four hours of compliance training for its “Covered Persons” that must include proper methods of promoting, marketing, and selling

¹²³ See DOJ, Press Release, TAP Pharmaceutical Products Inc. & Seven Others Charged with Health Care Crimes; Company Agrees to Pay \$875 Million to Settle Charges (Oct. 3, 2001), *available at* www.usdoj.gov/opa/pr/2001/October/513civ.htm (“TAP Press Release”).

¹²⁴ *Id.* The investigation into TAP practices was launched after a physician/medical director of Tufts Health Plan in Boston alleged that he was approached and offered a large sum in grant money to be used for any purpose if he would include Lupron® in the Tuft’s formulary instead of the lower priced substitute, Zoladex ®. Reportedly, the medical director first was offered \$20,000 in grant money, but, on the second visit from TAP marketing personnel, he was offered \$65,000 in unrestricted funds accompanied by \$100,000 in discounts on other TAP products.

¹²⁵ See TAP Press Release, *supra* note 123. Dr. Rodney Mannion, an urologist practicing in LaPorte and Michigan City, Indiana, was charged on February 28, 2000 with healthcare fraud. Dr. Mannion pleaded guilty to that charge on April 25, 2000. Dr. Jacob Zamstein, a urologist practicing in Bloomfield, Connecticut, was charged on November 3, 2000 with healthcare fraud and pleaded guilty on December 27, 2000. Dr. Joseph Spinella, an urologist practicing in Bristol, Connecticut, was charged on December 8, 2000 with healthcare fraud and pleaded guilty on March 29, 2001. Dr. Joel Olstein, a urologist practicing in Lewiston, Maine, was charged on April 11, 2001 with healthcare fraud and pleaded guilty on July 18, 2001.

products in accordance with the PDMA and AKS; and to dedicate one of three independent review organization (IRO) reviews to sales and marketing. One physician, a urologist agreed to pay \$213,198 to resolve allegations of improper billing of Medicaid and Medicare for free drug samples received from TAP.¹²⁶ At the time, the TAP settlement was the largest criminal and civil recovery in any healthcare fraud case in the country and set the standard for future settlements involving pharmaceutical manufacturer marketing activities with physicians.

B. AstraZeneca Pharmaceuticals

On June 20, 2003, AstraZeneca Pharmaceuticals pleaded guilty and agreed to pay a total of \$355 million in a criminal and civil settlement relating to the pricing and marketing of Zoladex®, a drug used for treating prostate cancer. AstraZeneca allegedly provided thousands of "free samples" of Zoladex® to physicians "knowing and expecting" that some of these physicians would prescribe the drug samples to their patients and bill Medicare, Medicaid, TriCare, and other federal governmental healthcare programs for the samples. The government also alleged that AstraZeneca offered and paid illegal remuneration in various forms, including providing free Zoladex®, making unrestricted educational grants, funding business assistance grants and services, and paying for travel and entertainment, consulting services, and honoraria to induce physicians to prescribe the drug. Other allegations included that AstraZeneca: (1) marketed the spread between the Medicare average wholesale price and the discounted price to physicians as additional profit to be returned to the

¹²⁶ *Oregon Urologist Settles with Government on Allegations of Free Drug Sample Billing*, BNA HEALTH CARE FRAUD REP. (Nov. 17, 2004).

physician's practice from Medicare reimbursements for Zoladex® under a "Return-to-Practice" program; and (2) failed to provide its "best price" for Zoladex® to state Medicaid programs by not accounting for off-invoice price concessions provided in the form of services and free goods and grants that were contingent on purchase requirements.

AstraZeneca pled guilty to conspiring to violate the PDMA and paid a \$63,872,156 criminal fine. To settle its FCA liabilities, AstraZeneca paid the federal government a total of \$266,127,844. AstraZeneca also agreed to pay an additional \$24,900,000 to the federal government and the states, and executed a five-year CIA with the OIG that has similar provisions as the TAP CIA. In addition, three physicians had been charged, and two have pled guilty, for their role in conspiring to bill for Zoladex® samples.

C. Pfizer

On May 13, 2004, Pfizer, Inc. agreed to pay \$430 million to settle charges, including \$240 million in criminal fines, in connection with its Warner Lambert/Parke-Davis division's illegal and fraudulent promotion of unapproved uses of the drug Neurontin®.¹²⁷ The illegal promotional activity occurred between 1996 and 2000, prior to Pfizer's acquisition of Warner Lambert.¹²⁸ The government alleged that Warner Lambert employed a number of marketing tactics including improper payments to physicians (1) through "consultants' meetings" in which physicians received a fee for attending

¹²⁷ See DOJ, Press Release, *Warner-Lambert to Pay \$430 Million to Resolve Criminal & Civil Health Care Liability Relating to Off-Label Promotion* (May 13, 2004) available at www.usdoj.gov/opa/pr/2004/May/04_civ_322.htm ("Pfizer Press Release").

¹²⁸ *Id.* The investigation was commenced in the District of Massachusetts when a former medical liaison for Warner-Lambert, Dr. David Franklin, filed a suit on behalf of the U.S. government.

expensive dinners or conferences, including trips to Florida, the 1996 Atlanta Olympics, and Hawaii, during which presentations about off-label uses of Neurontin® were made but little or no significant consulting was provided by the physicians; (2) in the form of grants to physicians who advocated the drug's off-label uses; (3) in the form of honoraria for the use of their names on scientific articles intended for publication that were actually ghost written by company agents; and (4) for speaker fees in large amounts for making presentations wherein they advocated the off-label use of Neurontin®.¹²⁹ According to the DOJ, “[a]s a consequence of the unlawful promotion scheme, patients who received the drug for unapproved and unproven uses had no assurance that their doctors were exercising their independent and fully-informed medical judgment, or whether the doctor was instead influenced by misleading statements made by, or inducements provided by, Warner-Lambert.”¹³⁰ Pfizer executed a five-year CIA¹³¹ with the OIG that was similar to the TAP CIA, but also included a requirement for policies and procedures to ensure that (i) speaker meetings, advisory board meetings, and all other consultant arrangements or related events are used for legitimate and lawful purposes in accordance with applicable federal healthcare program and FDA requirements related to the dissemination of information about off-label use of products and (ii) sponsorship or funding of CME, grants, and research or related activities meets federal healthcare program and FDA requirements.

¹²⁹ *Id.*

¹³⁰ See Pfizer Press Release, *supra* note 127.

¹³¹ Pfizer had executed a CIA in 2002, but pursuant to its terms, the May 2004 CIA superceded the 2002 CIA.

D. Serono

In October 2005, Swiss corporation, Serono, S.A., and its U.S. subsidiaries and related entities agreed to pay \$704 million to settle criminal charges and civil allegations.¹³² The settlement resolves allegations that, among other things, as part of Serono's marketing and sale of its drug Serostim®, Serono knowingly and willfully offered and paid illegal remuneration, including, but not limited to, providing free bioelectrical impedance analysis devices and software, free trips to Cannes, France, and SeronAIDS and SALSA survey payments to physicians in violation of the AKS.¹³³

As part of its settlement, Serono Holding, Inc. is subject to a five-year CIA¹³⁴ that requires, e.g., specific policies on interactions with healthcare professionals to ensure that such arrangements and events are used for "legitimate and lawful purposes in accordance with applicable Federal health care program requirements and FDA Advertising and Promotional Requirements"; additional training for sales and marketing personnel; policies and procedures relating to grants to third-party medical educational and patient education programs that require, among other things, disclosure of Serono's financial support of the educational activity; and IRO review of the third-party medical educational and patient education program grants.

¹³² DOJ, Press Release, *Serono to Pay \$704 Million for the Illegal Marketing of AIDS Drug* (Oct. 17, 2005), available at www.usdoj.gov/opa/pr/2005/October/05_civ_545.html.

¹³³ Serono Settlement Agreement, at 5 (Oct. 14, 2005).

¹³⁴ Corporate Integrity Agreement Between the OIG of the Department of Health and Human Services and Serono Holding, Inc. at 9 (Oct. 14, 2005).

E. Schering-Plough

On August 29, 2006, Schering-Plough Corporation, together with its subsidiary, Schering Sales Corporation (Schering-Plough) reached a \$435 million dollar settlement with the U.S. Attorney's Office to resolve criminal charges and civil liabilities in connection with allegedly illegal sales and marketing programs for its drugs Temodar® and Intron A®.¹³⁵ The civil settlement resolves allegations that Schering-Plough knowingly caused the submission of false and/or fraudulent claims for drugs that were not eligible for reimbursement. The allegations also included the government's claims that Schering: (1) induced physicians to start patients on Intron A® for Hepatitis C by paying them remuneration through three marketing programs, and (2) induced physicians to use Temodar® for certain patients with brain tumors and brain metastases and to use Intron A® for certain patients with superficial bladder cancer through improper preceptorships, sham advisory boards, lavish entertainment, and improper placement of clinical trials.¹³⁶ Schering-Plough was subject to an amendment to its existing five-year CIA, which requires the company to continue its work in monitoring its drug sales, marketing, and pricing activities.¹³⁷

¹³⁵ See U.S. Attorney's Office District of Massachusetts, Press Release, *Schering to Pay \$435 Million for the Improper Marketing of Drugs and Medical Fraud* (Aug. 29, 2006), available at <http://149.101.1.32/usao/ma/Press%20Office%20-%20Press%20Release%20Files/Aug2006/ScheringPlough-GlobalSettlement.html>.

¹³⁶ *Id.*

¹³⁷ *Id.* In 2004, Schering Plough entered into a CIA with the OIG to correct its government pricing and Medical rebate reporting failures. See DOJ, Press Release, *Schering-Plough to Pay \$345 Million to Resolve Criminal and Civil Liabilities for Illegal Marketing of Claritin* (July 30, 2004), available at www.usdoj.gov/opa/pr/2004/July/04_civ_523.htm.

F. Medtronic

In addition to allegations of improper physician-pharmaceutical relationships, the Department of Justice recently began focusing on cases involving allegations of inappropriate physician gift-giving on the part of vendors and device manufacturers. In July 2006, Medtronic Sofamor Danek (MSD), a division of one of the country's largest medical device makers, Medtronic, Inc., entered into a five-year CIA to strengthen its employee training and compliance systems surrounding sales and marketing practices¹³⁸ and agreed to pay the United States \$40 million to settle civil allegations that it paid kickbacks to spine surgeons to induce them to use MSD's spinal implant devices.¹³⁹ Similar to the allegations in many of the prior pharmaceutical manufacturer prosecutions, the government alleged that MSD paid kickbacks in a number of forms, including sham consulting agreements, sham royalty agreements, and trips to desirable locations, in addition to hosting medical conferences where the company's main objective was to persuade the physicians "through any financial means necessary" to use its devices.¹⁴⁰ According to one report, Company notes disclosed in the investigation also suggested the existence of arrangements in which physicians helped design new spinal devices in exchange for giving their business solely to MSD.¹⁴¹ Investigations of these types of practices have not ended with MSD. U.S. Attorneys in Boston and Newark recently issued subpoenas to eight major manufacturers, as part of

¹³⁸ See Medtronic, Inc., Press Release, *Medtronic Resolves Qui Tam Suits* (July 18, 2006), available at www.medtronic.com/Newsroom/NewsReleaseDetails.do?itemId=1153234741878&lang=en_US ("Medtronic Press Release").

¹³⁹ See DOJ, Press Release, *Medtronic to Pay United States \$40 Million to Settle Kickback Allegations* (July 18, 2006), available at <http://memphis.fbi.gov/dojpressrel/pressrel06/me071806.htm> ("DOJ Medtronic Press Release").

¹⁴⁰ R. Abelson, *Whistle-Blower Suit Says Device Maker Generously Awards Doctors*, N.Y. TIMES (Jan. 24, 2006).

¹⁴¹ *Id.*

a wide-ranging investigation into the relationships between doctors and makers of devices,¹⁴² highlighting that the physician-medical device manufacturer relationship is one of current focus and interest.

G. Advanced Neuromodulation Systems, Inc.

On July 2, 2007, Advanced Neuromodulation Systems, Inc. (ANS), a medical device company, agreed to pay \$2.95 million to the federal government and entered into a three-year CIA to resolve allegation that it paid and gave gifts to physicians in exchange for using the company's products. The OIG alleged that ANS engaged in a marketing program in which a number of physicians were paid \$5,000 for every five new patients tested with an ANS product. The OIG alleged that this program did not have any significant clinical value but rather served as a marketing tool to increase ANS sales. In addition, the OIG alleged that ANS sales and marketing personnel provided physicians with sports tickets, free trips, free dinners, grants, and other gifts during the relevant time period. ANS, which is based in Plano, Texas, cooperated with OIG's investigation that resulted in the settlement. During the OIG's investigation, ANS was purchased by St. Jude Medical, Inc., a publicly traded company headquartered in St. Paul, Minnesota.

H. Individual Physicians

The pharmaceutical companies and medical device manufacturers are not the only parties in recent enforcement activities. The physician portion of this relationship also

¹⁴² *Id.*

has been under scrutiny, as reflected in some of the settlements discussed above and the following examples of enforcement activity involving physicians:

- On February 16, 2006, two south Florida pulmonologists agreed to pay \$65,066 and \$57,030, respectively, and enter into a three-year CIA to resolve their liability under the AKS provision of the CMPL and the Stark Law. **The OIG alleged that the doctors violated those laws by accepting gifts, including Miami Dolphins tickets and meals, from a durable medical equipment supplier in exchange for patient referrals.**
- On April 5, 2006, a Maryland psychiatrist was indicted for participating in an alleged nationwide scheme to unlawfully promote Xyrem® for non-approved purposes and receiving “tens of thousands of dollars by Xyrem® manufacturer in furtherance of this scheme” to give lectures around the country promoting off-label use of Xyrem®.¹⁴³
- A Tennessee physician agreed in August 2003 to pay \$71,400 in restitution for selling samples and to enter into a CIA to settle allegations under the CMPL provision applicable to false claims and kickbacks.

As these actions indicate, continued enforcement activity, including close scrutiny of relationships with physicians, is likely to continue. Indeed, in considering physician relationships with pharmaceutical and device manufacturers and the inclusion of guidance related to these relationships in physician compliance materials, it is important

¹⁴³ See U.S. Attorney's Office, Press Release, Psychiatrist Charged with Conspiracy to Illegally Market the Prescription Medication Xyrem, also known as 'Ghb,' for Unapproved Medical Uses on Behalf of Its Manufacturer (Apr. 5, 2006), *available at* www.usdoj.gov/usao/nye/pr/2006/2006apr05.htm.

to remember that the **AKS criminalizes and punishes conduct on both sides of a knowing transaction; that is, both the party who pays remuneration and the party who receives remuneration.** Further, these relationships may implicate federal conspiracy and aiding and abetting laws. For these reasons, the importance of proactive policies and procedures, incorporated in a compliance plan cannot be overstated.

VI. Legislative Activities

A. Legislative Inquiry

Federal lawmakers have questioned the pharmaceutical industry's practices of providing gifts and payment to physicians. On April 25, 2007, Senate Finance Committee Chairman Max Baucus (D-MT) and Ranking Member Chuck Grassley (R-IA) released results of a Committee inquiry into pharmaceutical company grants to fund continuing education for medical providers.¹⁴⁴ The report addressed the pharmaceutical industry's use of educational grants for improper purposes, such as rewarding physicians for prescribing their drugs, influencing clinical practice guidelines and Medicaid formularies, or promoting drugs for uses that have not been approved by the FDA—an illegal practice called “off-label promotion.” The report revealed that pharmaceutical companies have spent more than a billion dollars a year to fund CME programs that are accredited by ACCME.

¹⁴⁴ Twenty-three pharmaceutical manufacturers cooperated fully in the Committee's investigation. The companies reported that they continue to fund educational grants as part of a broad business strategy to sell their products, but that they have set policies to distance educational grant funding from marketing. Committee staff concluded that the pharmaceutical industry has focused more on compliance with guidance for educational grants, but risks still exist for kickbacks, veiled advertising of drugs, efforts to bias clinical protocols, and off-label promotion.

On June 27, 2007, the Senate Special Committee on Aging held a hearing to discuss the current state of the physician/drug industry relationship, recent attempts at the state level to increase disclosure of payments, and attempts to reduce the influence of the drug industry on physician prescribing behaviors. In the hearings, Committee Chairman Herb Kohl (D-WI) promised to continue oversight of the relationship between physicians and the pharmaceutical industry and proposed a national registry to require disclosure of payments and gifts to physicians.

On September 18, 2007, Attorney General Milgram of New Jersey announced the formation of a task force to explore pharmaceutical and medical device makers' gifts and other compensation to physicians and their impact, if any, on patient care.

B. Proposed Federal Legislation

Similar to the state statutes and legislation on this issue, House Democrats introduced HB 3023, entitled "Drug and Medical Device Company Gift Disclosure Act," on July 12, 2007, that would require drug and device manufacturers to disclose to the FDA the value, nature and purpose of (1) any marketing and promotional gift over \$50 given to a healthcare professional, including physicians, nurses, therapists, hospitals, nursing homes, pharmacists, health benefit plan administrators, or any other person authorized to prescribe or dispense drugs and (2) any cash rebate, discount, or any other financial

consideration given to any pharmaceutical benefit manager.¹⁴⁵ These disclosures would be made available to the public on the FDA's website. As of July 18, 2007, HB 3023 was referred to the House Committee on Energy and Commerce. One question this legislation raises is whether this bill would preempt state legislation on this issue.

In a July 13, 2007 statement, reported in *BNA Health Care Daily*, PhRMA Senior Vice President Ken Johnson responded to HB 3023, stating that while the industry group still had to review the legislation, "it is important to stress that adequate safeguards are already in place to make sure the information provided by pharmaceutical company representatives to physicians is accurate and well-substantiated."¹⁴⁶ PhRMA Senior Vice President Johnson further stated that drug companies "must comply with Food and Drug Administration regulations," and PhRMA "provides comprehensive voluntary marketing guidelines that help ensure that the companies and health providers have meaningful discussions about medicines." Johnson reminded that the PhRMA marketing code "says all forms of entertainment, including competitive sporting events or games of golf are inappropriate. The guidelines also say that only modest meals should be allowed and gifts should not exceed \$100 in value and should be only those items that support a medical practice, such as a stethoscope or a medical dictionary."

AdvaMed's President Stephen Ubl also responded to the bill, as reported in *BNA Health Care Daily*, stating that while AdvaMed is still reviewing the legislation, "we are concerned that any proposed gift registry may include education, training and other

¹⁴⁵ HB 3023, 110th Congress (2007).

¹⁴⁶ *House Democrats' Proposal Takes Aim at Drug, Device Company Gifts to Doctors*, 12 BNA HEALTH CARE DAILY (July 17, 2007), available at <http://pubs.bna.com>.

efforts essential to the appropriate use of medical devices.”¹⁴⁷ Further, the AdvaMed President said that, unlike pharmaceutical development, “which happens in large laboratories, medical device advancements frequently result from timely feedback from doctors using a product. Moreover, device manufacturers may have a legal and ethical obligation to ensure appropriate training of health care professionals using sophisticated medical technology.” Ubl said AdvaMed’s concern was that the proposals “might chill the timely exchange of information between device firms and physicians.”

C. Proposed State Legislation

Given the scrutiny of vendor marketing practices under federal law and the recent study results and concern regarding the undue influence these practices may have on physicians’ professional judgment, it is not surprising that there is a growing movement by state legislators, seeking to prohibit or substantially limit gifts, free samples, and other promotional incentives given by vendors to healthcare professionals.

In addition to the states that have already passed legislation, to date in 2007, twenty-seven states proposed legislation requiring marketing disclosures by drug manufacturers, regulating direct-to-consumer advertising of prescription drugs by pharmaceutical companies or prohibiting prescription information from being sold for commercial purposes.¹⁴⁸

¹⁴⁷ *Id.*

¹⁴⁸ See National Conference of State Legislatures (NCSL), 2007 Prescription Drug State Legislation, *available at* www.ncsl.org/programs/health/drugbill07.htm (last visited Aug. 19, 2007).

State legislators in California, Hawaii, Illinois, Massachusetts, New Hampshire, New York, Ohio, and Pennsylvania are taking a strict approach and are considering statutes that regulate pharmaceutical companies' marketing campaigns. Most of these bills would require public disclosure of any gift valued at \$25 or more, while others go further and require disclosure of drug manufacturers' marketing budgets. A proposal in Massachusetts would ban gifts to healthcare providers altogether.

VII. Compliance Planning Considerations

The industry codes described above identify the potential pitfalls of commonly occurring transactions, and suggest an approach to resolving those conflicts. However, the codes are only one piece in the compliance puzzle.

While the industry codes certainly reflect their drafters' take on the current state of the relevant law, and while some of the codes are recognized by government authorities, the codes are not, and do not purport to be, a comprehensive dissertation on what the law requires of vendors or healthcare professionals. The guidance embodied in the codes is not so much compelled by law, but, rather, represents only various approaches to avoiding legal or ethical imbroglios. While each code provides some basic guidance on how to approach common situations, a fully informed approach requires reference to other industry codes, the codes and policies of customers, and the relevant laws. First among these authorities are the various laws dealing with healthcare professional-vendor relationships; in particular, federal and state anti-kickback statutes and related authorities, as well as statutes dealing with advertising, promotion and

competition.¹⁴⁹ OIG industry guidance and the ethical codes of customers and other industry segments can also be useful tools.¹⁵⁰

Common healthcare professional-vendor relationships are simply not addressed by the industry codes. For example, some significant relationships with current relevance not specifically addressed by the codes include: the extension of investment opportunities in manufacturers or distributors to healthcare professionals; the purchase of intellectual property by vendors from healthcare professionals; and the provision of free or discounted products by manufacturers to providers. The codes provide guidance relevant to these situations, but do not specifically address them.

Most significantly, the codes do not, for the most part, grapple with the issue of intent. Under the AKS, no interaction with a customer is illegal without the requisite intent to induce recommendations or referrals. The codes, however, presume that illicit intent is likely to be inferred from certain arrangements and advises structuring those arrangements to negate that implication. The codes regulate appearance, not intent, and consequently, a “violation” of the codes will not necessarily be a violation of the AKS, nor will compliance with the codes ensure absolution under the AKS.

These limitations, and others, mean that the codes must be read in conjunction with other applicable authorities, when formulating a compliance program or seeking to avoid legal or ethical problems. As such, healthcare professionals and vendors would

¹⁴⁹ See, e.g., 42 U.S.C. §§ 1320a-7b(b), 1395nn; CAL. BUS. & PROF. CODE § 650 *et seq.*; *Id* § 650.02.

¹⁵⁰ See OIG website at www.oig.hhs.gov.

be well-advised to incorporate the AKS and conflict of interest concepts discussed above into their compliance planning considerations.

First and foremost, any policy should be structured with the OIG's concerns in mind and should include sufficient safeguards to reduce the likelihood of implicating the AKS.

Inducements offered by vendors to healthcare professionals to purchase drugs or other medical supplies over those of a competitor's products fall squarely within the ambit of the AKS. Suggested questions found in the OIG Pharmaceutical CPG are relevant to both healthcare professionals and vendors incorporating these concerns into their compliance plans:¹⁵¹

- Does the arrangement or practice have a potential to interfere with, or skew, clinical decision-making? Does it have a potential to undermine the clinical integrity of a formulary process? If the arrangement or practice involves providing information to decision-makers, prescribers, or patients, is the information complete, accurate, and not misleading?
- Does the arrangement or practice have a potential to increase costs to the federal healthcare programs, beneficiaries, or enrollees? Does the arrangement or practice have the potential to be a disguised discount to circumvent the Medicaid Rebate Program Best Price calculation?
- Does the arrangement or practice have a potential to increase the risk of over- utilization or inappropriate utilization?

¹⁵¹ Pharmaceutical CPG, *supra* note 62, at 23734.

- Does the arrangement or practice raise patient safety or quality of care concerns?
- What degree of influence does the healthcare professional have, directly or indirectly, on the generation of business for the vendor? Does the vendor have other direct or indirect relationships with the healthcare professional or members of the healthcare professional's group?
- Is there remuneration and, if so, does the remuneration take into account, directly or indirectly, the volume or value of business generated (e.g., is the remuneration only given to persons who have prescribed or agreed to prescribe the manufacturer's product)? Is the remuneration conditioned in whole or in part on referrals or other business generated? Is there any service provided other than referrals?
- Is the remuneration more than trivial in value, including all gifts to any individual, entity, or group of individuals? Do the fees for services exceed the fair market value of any legitimate, reasonable, and necessary services rendered by the healthcare professional to the vendor?

Addressing these issues can protect goodwill between healthcare professionals and vendors as well as ensure that both sectors of the industry meet their legal obligations.

When dealing with gifts, companies must take fairly significant steps if they are committed to implementing the principles set forth in the industry codes and OIG guidance. For example, reasonable spending limits must be identified, set, and adhered

to. Setting an objective amount and frequency limits for different categories of expenditures, tracking expenditures, and assuring adherence to established limits all present significant practical problems. To set objective spending limits, companies must decide, among other things: How much is too much? Should the limits vary by geography, or depend on the context of the meeting? Should certain expenditures be aggregated (e.g., should any expenditure made in one day, or by the same company representative, or in connection with the same medical practice count towards a particular limit)? If the company desires to establish frequency limits, it must not only establish the appropriate limit on aggregate expenditures, but also establish a measuring period (e.g., a calendar year, or a rolling twelve-month period, or a quarter). Tracking expenditures may require the development of complex and expensive systems, where customers are assigned a unique identifier and all expenditures made on their behalf are tied to them. Compelling adherence requires thoughtful exploration of various approaches including creating a culture of compliance, engaging in auditing and monitoring activities, and imposing appropriate discipline for violations. Vendors have come a long way in establishing these types of programs, and industry associations can provide a helpful networking opportunity for discussion of these policies and procedures.

Consulting arrangements are another area of focus by the government. The focus of industry codes is on assuring and demonstrating the absence of an improper purpose. Implementing the AdvaMed and PhRMA Codes' approach will require, among other things, the development of several important processes. First, the vendor will have to establish a process by which need for particular consulting services is established.

This process may be part of an annual business planning activity, or may be considered as opportunities present themselves. Second, the vendor will have to develop a process by which fair market value is established. This endeavor might involve the development of tools for determining appropriate levels of compensation by specialty, with reference to comparable salary data derived from reputable surveys. Third, and perhaps most critical for demonstrating the bona fide nature of a consulting relationship, is the development and application of appropriate selection criteria to assure that selection will be based on qualifications rather than buying power.

Similar issues to those raised by consulting agreements arise when vendors either purchase intellectual property, or seek investments from healthcare professionals. The industry codes do not address either of these situations. The AKS and related authorities do attend to the latter, for example, through the various guidance and opinions that the OIG has given on joint ventures¹⁵² and the investment interest safe harbor,¹⁵³ but not to the former. Suffice it to say that analysis of these arrangements, like analysis of consulting arrangements, should take into account, at a minimum:

- Why the opportunity is being accorded to the healthcare professional. This question requires attention to the facts surrounding the choice of the healthcare professional as a party to the joint venture or the investor of the capital.

¹⁵² See, e.g., OIG Special Advisory Bulletin on Contractual Joint Ventures (Apr. 2003), *available at* www.oig.hhs.gov/fraud/fraudalerts.html; OIG Special Fraud Alert on Joint Venture Arrangements (Aug. 1989), *available at* www.oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html.

¹⁵³ 42 C.F.R. § 1001.952(a).

- Whether the joint venture or investment is key to business goals of the vendor. This inquiry will require scrutiny of the vendor's business objectives.
- Whether fair market value is being paid or given in exchange for the item or payment. This analysis will require the development of touchstones for assessing fair market value and will require an analysis of whether the healthcare professional is contributing an adequate share to the joint venture or investment.
- Assurance of proper documentation of acceptable answers to the foregoing questions.

A charitable contribution from a vendor to a healthcare professional raises a red flag under the industry guidance and the AKS. As such, vendors must focus on developing a process to assure a proper charitable purpose behind the donation. This process might be expected to have the following components: an established charitable giving plan; criteria for decision making (e.g., assessing the proposal's consistency with the objectives of the charitable giving plan) and a mechanism for separating charitable decision making from sales-related concerns (e.g., by establishing an automated application process, and excluding sales personnel from the intake, decision and administrative process).

VIII. Conclusion

This past year has seen a relative explosion of change in the area of healthcare professional-vendor relationships from an enforcement perspective, from an industry policies and procedures standpoint, and from proposed legislation. Given the pendulum shift, 2007-2008 promises to be interesting to see whether these trends persist or if healthcare professionals and vendors pursue more of a compromise approach.

Regardless, the flurry of activity on this front certainly suggests that providers need to be prepared and, as part of that preparedness, adopt policies and procedures that will enable them to address legal concerns, in addition to the ethical issues that arise from these relationships.

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