

**MANAGING RELATIONSHIPS:**

**MANUFACTURERS, INSTITUTIONAL PROVIDERS AND THEIR AFFILIATED PRACTITIONERS**

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## I INTRODUCTION

Relationships between pharmaceutical and device manufacturers and institutional providers, such as hospitals, medical schools or nursing homes, or their affiliated practitioners raise unique compliance issues.

Relationships extend beyond the prescription or limited purchase of drugs/devices typical of physician/practitioner office settings to include:

- promotional activities, volume purchases, and special discounts
- purchase of services
- sponsorship of clinical trials
- grants
- charitable donations, and
- patient and community programs.

Each such relationship must be justified independently and the interaction among the relationships monitored and managed. Management of relationships by manufacturers, however, may prove difficult because:

- institutional providers have various components (administration, purchasing department, pharmacy, research administration, CME staff, development office, medical staff/physician faculty, clinical staff and/or an affiliated nonprofit foundation) with differing levels of compliance awareness and different objectives;
- institutional providers may have longstanding relationships with manufacturers that create certain expectations or manufacturers and institutional providers have a shared specialization that creates mutual interests;
- institutional providers will often have compliance programs, but their compliance policies will not necessarily correspond to a manufacturer's compliance policies; and
- government enforcement agencies investigating relationships between manufacturers and institutional providers have typically sought settlements from manufacturers, creating a different risk analysis for manufacturers and providers.

This presentation will provide an overview of the unique compliance issues raised by relationships between manufacturers and institutional providers or their affiliated practitioners.

## II OVERVIEW OF APPLICABLE LAWS AND GUIDANCE

Relationships between and among pharmaceutical and device manufacturers, institutional providers, and practitioners can implicate a number of federal and state laws as well as industry codes of conduct. The significant laws and codes repeatedly implicated are discussed below. Other laws are referenced in the discussions of specific activities.

### A. Anti-Kickback Statute

**General Description.** The federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b), imposes criminal penalties on any person that knowingly and willfully solicits, receives, offers, or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, to any person, in return for or to induce such person to do either of the following:

- refer an individual to a person for the furnishing or arranging for the furnishing of an item or service for which payment may be made in whole or in part under a federal health care program, or
- purchase, lease, order, or arrange for or recommend the purchasing, leasing, or ordering of any good, facility, service, or item for which payment may be made in whole or in part under a federal health care program.

The anti-kickback statute is a specific intent statute. The statute is violated if a person: (1) knows that the anti-kickback law prohibits offering or paying remuneration to generate business; and (2) engages in prohibited conduct with the specific intent to disobey the law. The U.S. Department of Health and Human Services Office of the Inspector General (“OIG”) and some courts have taken the position that the intent requirement is met where one purpose of a payment is to induce referrals for, or purchases of, an item or service covered under a federal health program. Under the “one purpose” test, the fact that the parties may have had other good intentions in paying or receiving the payment is irrelevant.

**Application.** Although the statute was traditionally interpreted as applying primarily to relationships between institutional providers or suppliers and practitioners in a position to generate referrals for the providers or suppliers, that interpretation changed with the issuance of a fraud alert that directly addressed pharmaceutical marketing activities and identifies activities potentially suspect under the anti-kickback statute. See 59 Fed. Reg. 65372 (December 19, 1994). The early fraud alert was issued in response to information received about manufacturers that were providing product conversion payments to pharmacists, frequent flier mileage to physicians for completing a questionnaire for new patients placed on a drug or substantial research grants to physicians *de minimis* recordkeeping tasks. The activities identified as suspect included:

- Any prize, gift or cash payment, coupon or bonus (e.g., airline discounts and related travel premiums), offered to physicians and/or suppliers (including pharmacies, mail order prescription drug companies and managed care organizations) in exchange for, or based on, prescribing or providing specific prescription products. These items are particularly suspect if based on value or volume of business generated for the drug company.
- Materials which offer cash or other benefits to pharmacists (or others in a position to recommend prescription drug products) in exchange for performing marketing tasks in the course of pharmacy practice related to Medicare or Medicaid. The marketing tasks may include sales-oriented educational or counseling contacts, or physician and/or patient outreach.
- Grants 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. The grants may nonetheless offer substantial benefits based on, or related to, use of the product.
- Any payment, including cash or other benefit, given to a patient, provider or supplier for changing a prescription, or recommending or requesting such a change, from one product to another, unless the payment is made fully consistent with an anti-kickback safe harbor.

In the aftermath of the fraud alert and subsequent government enforcement actions, there has been widespread acceptance that the scope of the anti-kickback statute is extremely broad and potentially encompasses essentially every proposed financial interaction, whether or not actually implemented, between a pharmaceutical manufacturer and a provider or other individual or entity in a position to influence the drugs prescribed for, or provided to, a beneficiary of a federal health care program. For example, read literally, the statute would prohibit engaging a physician to speak about the benefits of a manufacturer's product ("remuneration...to recommend.")

**Safe Harbors.** Not all interactions encompassed by the broad scope of the statute, however, violate the statute. There are statutory exceptions to the prohibition for certain types of activities (such as discounts). The OIG also has the authority to establish regulatory "safe harbors." The safe harbors describe activities that the government will not prosecute because the government has determined that these activities are unlikely to be abusive. The safe harbors are more likely to apply to price concessions provided in connection with the purchase of drugs or the purchase of expert consulting services than to promotional or other activities that provide "one-sided" value to customers and consumers.

**Facts-and-Circumstances Analysis.** Arrangements that do not fall within an exception or safe harbor are not necessarily illegal, but will be subject to government scrutiny by the OIG. The government scrutiny will seek to determine whether the arrangements involve improper intent or are otherwise abusive (e.g., whether the arrangements adversely affect the quality of patient care).

In the OIG Compliance Program Guidance for Pharmaceutical Manufacturers (“OIG Compliance Guidance”), at 68 Fed. Reg. 23731, 23736 (May 5, 2003), the OIG described the “aggravating considerations” that identify those arrangements that may pose the greatest risk of prosecution. Those considerations include:

- 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 health care 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 overutilization or inappropriate utilization?
- Does the arrangement or practice raise patient safety or quality of care concerns?

**Guidance.** Over the years, the OIG has issued guidance that identifies areas of concern or indicates how the OIG would apply the anti-kickback statute to particular circumstances. The primary sources of administrative guidance on analyzing arrangements under the anti-kickback statute, other than the regulations and commentary on the regulations, include: (1) OIG guidance on developing compliance programs for pharmaceutical manufacturers, (2) administrative bulletins (such as fraud alerts), and (3) advisory opinions.

Government enforcement actions provide additional guidance. The allegations against TAP Pharmaceutical Products, Inc. in the civil qui tam action brought under the FCA with the Department of Justice included allegations that the manufacturer offered and paid illegal remuneration to certain physicians, physicians’ practices, health maintenance organizations and others in various forms as an inducement to those physicians to order, prescribe and administer Lupron to their patients: money, free drugs (samples), nominally priced drugs, discounted prices on one drug to induce placing another drug on formulary, educational grants, debt forgiveness, travel and entertainment (e.g., free trips and conferences), free consulting and audit services, employment as a “consultant”, payment of administrative fees, and VCRs and TVs. (Settlement, October, 2001)

*For guidance on the anti-kickback statute and its interpretation by the OIG, see the OIG regulations at 42 C.F.R. §§ 1001.951 and 1001.952 and visit the OIG web site at <http://oig.hhs.gov>. The website also includes Corporate Integrity Agreements entered into by various manufacturers as the result of settlements.*

## B. False Claim and Fraud Laws

**General Description.** A number of federal criminal and civil laws prohibit individuals and entities from submitting (or causing others to submit) false information or claims for payment to the government or otherwise acting or conspiring to defraud the government. Examples:

- 18 U.S.C. §1001: Criminal sanctions for directly or indirectly submitting a false statement to the government.
- 18 U.S.C. § 1035: an individual or entity may be criminally liable for false or fraudulent statements in connection with the delivery or payment of healthcare services.

The primary statute applicable to false claims or information is the Federal False Claims Act at 31 U.S.C. § 3729-3731 ("FCA"). A person may be subject to penalties under the FCA if the person knowingly submits (or causes another person to submit) false claims. The law is violated if person:

- submitted or caused to be submitted a claim for payment to the federal government;
- the claim was false or fraudulent; and
- the person acted knowingly.

"Knowing" or "knowingly" for the purpose of enforcement means that a person has actual knowledge of the information; acts in deliberate ignorance of the truth or falsity of the information; or acts in reckless disregard of the truth or falsity of the information.

No proof of specific intent to defraud is required. Private persons, acting as "whistleblowers," may bring an action under the FCA.

**Enforcement.** In recent years, government enforcement agencies have alleged that violations of government price reporting obligations, the anti-kickback statute or the FDA prohibition on off-label promotion can constitute violations of the FCA. Examples include:

- In a civil qui tam action under FCA with the Department of Justice, Schering-Plough was alleged to have purchased unneeded utilization data, provided health management services below fair market value, provided interest-free loans and other discounted services in order to provide value to managed care plans. According to the allegations, value was provided to obtain formulary status for Claritin and the value was not included in best price. (Settlement, July 2004)
- In *United States ex rel. Franklin v. Parke-Davis*, 2003 WL 22048255 (D. Mass. 2003), the court denied the manufacturer's request for summary judgment on the FCA claim that the manufacturer falsely and fraudulently promoted the drug

Neurontin to physicians for off-label uses resulting in Medicaid payment for non-covered Neurontin prescriptions. The opinion suggests that the truthful but unlawful promotion of an off-label use of a drug by a manufacturer to physicians could result in the submission of a false claim to state Medicaid programs in violation of the FCA. (The proceeding arose from the civil qui tam action under FCA with the Department of Justice involving Pfizer's Neurontin that was settled in May, 2004.)

- In the Department of Justice investigations of Abbott Laboratories (Ross Products Division) and Novartis, the government alleged that the manufacturers counseled durable medical equipment suppliers to submit to Medicare "unbundled" claims for enteral feeding products, despite receiving a discounted "bundled" rate. The government also alleged that the manufacturers structured the transactions and provided advice to disguise discounts. (Abbott Laboratories Settlement, July, 2003 and Novartis Settlement, February, 2005)

### C. FDA Promotional Restrictions

**General Description.** Federal law prohibits manufacturers from receiving, introducing, or delivering for introduction into interstate commerce any drug or device that is "misbranded." 21 U.S.C. §331(a). A drug or device is misbranded if (among other circumstances):

- its labeling (printed/graphic matter on or accompanying drug) is false or misleading; or
- its advertising (paid message in third-party medium) does not provide a "true statement" including a brief summary of side effects, contraindications, and effectiveness.

21 U.S.C. §352 (a), (n), (q), and (r). (Note that the requirements on advertisements apply only to drugs and "restricted" devices. A device may be restricted (by regulation or by the order for approval of a premarket approval application) to sale, distribution or use only upon the written or oral authorization of an appropriately licensed practitioner or upon other conditions. 21 U.S.C. §360e(d) and (e). Most Class III devices are restricted devices.) Under the prohibition, manufacturers (or their agents) are prohibited from promoting off-label uses of their products (i.e., no suggestion of use for indications or populations not in the approved labeling). Manufacturers also may not disseminate advertisements that are false, lacking in fair balance, or otherwise misleading.

**Exceptions.** The Food and Drug Administration ("FDA") does, however, permit dissemination of off-label information by manufacturers under two exceptions.

- **Bona Fide Scientific Dialogue.** FDA allows manufacturers to discuss information pertaining to off-label uses of drugs through scientific dialogue that is not conducted in a promotional context. For example, with regard to investigational new drugs, the agency does not view the restrictions imposed on

pre-approval promotion “[as] intended to restrict the full exchange of scientific information concerning [a] drug, including dissemination of scientific findings in scientific or lay media.” See 21 C.F.R. § 312.7.

To further clarify this policy, FDA issued a Guidance Document in 1994 stating that manufacturers could not promote investigational drug products through commercial exhibits, but could display information about such drugs at “scientific” exhibits. U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising, and Communications, Guidance: Pre-approval Promotion (Apr. 1994). According to FDA, these scientific exhibits would have to be clearly separated from the commercial exhibit area, be staffed only by scientists, and be devoid of commercial materials for distribution.

- **Unsolicited Requests for Information.** The FDA allows manufacturers to respond to unsolicited requests for information about unapproved uses. FDA recognized this exception as early as 1982, when the agency declared that it “[would] not regulate as labeling any and all unsolicited requests received from outside the company for information about a drug manufactured, distributed, or repackaged by the company.” See U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising, and Communications, Position on the Concept of Solicited and Unsolicited Requests (Apr. 22, 1982). The FDA there indicated that the agency considered requests for drug information from scientists as “personal communication between the requestor and the firm” that represented the “full exchange of valid and legitimate information about the drug.” Id.

The FDA maintained that the policy did not apply to “an exchange precipitated or expressly encouraged by a sales representative . . . specifically for information about the drug that is inconsistent with the approved labeling.” Id. In fact, the agency strongly recommended that manufacturers include in a response to an unsolicited request “some positive statement consistent with the approved labeling about the drug’s use or dosage . . . and also include a reference to ‘accompanying full prescribing information.’” Id.

The FDA affirmed its policy on unsolicited requests in 1994, and elaborated that the agency would not consider as promotional labeling individual, non-promotional responses by drug companies to specific, unsolicited requests for information, provided that: (1) the sponsor maintains documentation concerning the nature of the requests; and (2) there is no pattern of repeated dissemination of materials or no evidence that such requests were solicited by the sponsor (e.g., preparation of material for routine dissemination). See U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising, and Communications, Current Issues and Procedures, (Apr. 1994). Although these statements were issued by the Center for Drug Evaluation and Research, the FDA described its policy later that year in a

Federal Register issuance that speaks to drug and device promotion. The policy is described as:

“Under current FDA policy, companies may also disseminate information on unapproved uses in response to unsolicited requests for scientific information from health care professionals. Scientific departments within regulated companies generally maintain a large body of information on their products. When health care professionals request such information, companies can provide responsive, nonpromotional, balanced, scientific information, which may include information on unapproved uses, without subjecting their products to regulation based on the information. This policy permits companies to inform health care professionals about the general body of information available from the company.”

See 59 Fed. Reg. at 59823 (Nov. 18, 1994). As part of an amendment to the statute explicitly permitting the dissemination of journal articles on off-label use under certain circumstances, the Food Drug and Cosmetic Act (“FDCA”) now includes a specific reference to the policy. 21 U.S.C. § 360aaa-6(a), provides that “Nothing in section 551 [the procedure allowing certain disseminations] shall be construed as prohibiting a manufacturer from disseminating information in response to an unsolicited request from a health care practitioner.”

Manufacturers may communicate information on off-label uses to physicians and other providers under this policy. Manufacturer practices vary, with some manufacturers requiring all responses to unsolicited requests for information to come from a central medical affairs office, while other companies engage field medical personnel for such requests or even permit sales representatives to respond to questions. Manufacturers often train sales representatives on recent literature and other developments concerning off-label uses so that they have the knowledge to recognize questions that involve off-label information and ensure the questions are directed to the appropriate medical affairs department or medical field liaison.

**Application to Physicians.** The prohibition on off-label promotion does not apply to physicians unless physicians operate as agents of a manufacturer (e.g., as a speaker in a manufacturer educational program). Physicians may otherwise discuss off-label uses and prescribe or use products for off-label uses. The practice of medicine is not regulated by the FDA. As a result, a manufacturer’s customers can discuss aspects of the manufacturer’s products that the manufacturers cannot affirmatively address.

**Enforcement.** Government enforcement agencies have pursued actions against manufacturers for off-label promotion although such actions typically alleged violations of other laws (such as the anti-kickback statute or FCA in connection with the off-label promotion). Allegations have included: physicians and other prescribers were given

inducements to prescribe off-label; or physicians and other providers were improperly encouraged to submit claims and receive payment for drugs used off-label (i.e., when the third party payor did not cover those off-label uses). Example:

- In a civil qui tam action under FCA with the Department of Justice, a company acquired by Pfizer (Warner-Lambert) was alleged to have induced doctors to prescribe and seek payment for off-label uses of Neurontin (including uses not covered by third party payors). Alleged bad practices included flying doctors to Hawaii and the Atlanta Olympics, paying “consulting” fees, and providing lavish dinners during discussions of drug. (Settlement, May 2004)

Although enforcement has focused on pharmaceutical manufacturers, government enforcement agencies may apply similar legal theories to device manufacturers. See Ross Kerber, *U.S. Picking Up Pace of Device Inquiries*, Boston Globe (May 19, 2004) (citing recent settlement of Orthofix International of allegations that company billed Medicare and Medicaid for off-label uses of a device).

#### **D. Federal Privacy Law**

**General Description.** The Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and its implementing regulations (45 C.F.R. Part 160 and 45 C.F.R. Part 164) control the use and disclosure of individually identifiable health information by covered entities (specifically, health care providers, health plans, and health care clearinghouses) or their business associates. Such information is protected health information.

- Covered entities (such as providers) may not use or disclose protected health information unless:
- The covered entity is using or disclosing the information to provide treatment, to obtain payment for treatment or to conduct routine health care operations; or
- The subject of the information has specifically authorized the covered entity to use or disclose the information by signing a written authorization; or
- The use or disclosure of the information meets a specific exception to the general prohibition (e.g.) disclosures required by law and certain FDA-related disclosures.

**Applicability.** HIPAA privacy regulations do not directly apply to pharmaceutical or device manufacturers in their capacity as manufacturers. Most manufacturers will not be business associates of providers simply because the sales representatives sell to providers. (Note, however, that some providers may view device manufacturers as business associates if the manufacturer services devices and those devices contain protected health information.) HIPAA privacy regulations will nonetheless affect manufacturer relationships with institutional providers because those providers (and their affiliated practitioners) will be covered entities. Because the HIPAA privacy regulations and clarifying guidance do not focus on manufacturers and their activities,

covered entities, in order to ensure compliance, may adopt a conservative interpretation of the HIPAA privacy requirements. Likewise, concern with adverse publicity and with the implications of state privacy laws may encourage manufacturers to impose limitations on sales representative activities that might implicate patient privacy.

**Access to Providers.** HIPAA does not prohibit covered entities from allowing sales representatives to visit hospitals or physician offices to discuss their products or restock drug samples.

**Interactions with Providers.** The disclosure of patient information in interactions between providers and sales representatives or the use by providers of patient information to identify patients for educational or marketing programs may or may not be permitted depending on the circumstances. Note that ambiguities in interpretations exist.

- Some disclosures may be permissible without a patient authorization:
  - Incidental disclosure of information may be permitted where appropriate safeguards exist (e.g., sales representative in a hospital overhears a conversation).
  - A health care provider may discuss drugs/devices and their experiences using the products with sales representatives so long as protected health information is not disclosed.
  - A health care provider may disclose protected health information to a third party (including manufacturers or their representatives) for treatment purposes.
    - Treatment includes the coordination or management of health care and related services for a particular patient. When a health care provider discloses protected health information to representatives so they can guide the health care provider and patient in the proper use of a drug or device, the disclosure may be permitted at treatment.
    - The disclosure of protected health information to enroll a patient in a patient assistance program can be considered part of the health care provider's management of that patient's care and may be permitted as a disclosure for treatment purposes.
  - Patients may disclose information directly to manufacturers/sales representatives.
  - Providers may market products to patients in face-to-face communications.
- Some disclosures are likely not permissible without an authorization:
  - Reviews of patient charts or records.

- Disclosure of protected health information in morbidity and mortality conferences, grand rounds, tumor boards, and other educational or quality assurance presentations (where sales representative is there for his or her own education).
- Use and disclosure of patient information by providers to identify targets for marketing (other than such marketing conducted through face-to-face communications between provider and patient).

**FDA Filings.** Providers can disclose information directly to the FDA or a manufacturer if required by the FDA requirements even if the subject of the information has not authorized the disclosure. These disclosures are permitted by specific exceptions to the general prohibition on disclosures:

- A provider may disclose protected health information when the disclosure is required by law (such as FDA laws).
- A provider may disclose protected health information to agencies such as the FDA for oversight activities (such as audits or investigations).
- A provider may disclose protected health information to a manufacturer or its agents for activities related to the quality, safety or effectiveness of a manufacturer's product subject to FDA regulation, including:
  - to report adverse events, product defects, problems, or biological product deviations;
  - to track FDA-regulated products;
  - to enable product recalls, repairs, or replacement (including locating and notifying individuals who have received products of product recalls, withdrawals, or other problems); or
  - to conduct postmarketing surveillance to comply with requirements.

**Research.** Protected health information held by a health care provider may only be used or disclosed for research purposes with the authorization of the subject, pursuant to a permissible waiver of the authorization requirement, pursuant to an exception or under a limited data set agreement. (These requirements are discussed in detail in Section III.B (Purchased Services) and Section III.C (Clinical Trial Sponsorship).)

*The Office of Civil Rights within the U.S. Department of Health and Human Services ("HHS") has provided extensive guidance on the HIPAA regulations on its website at <http://www.hhs.gov/ocr/hipaa/>.*

## E. Industry Codes of Conduct

A number of voluntary industry codes apply to manufacturer relationships with institutional providers or their affiliated practitioners. These codes have no independent legal significance and compliance with the codes will not protect a manufacturer from scrutiny and potential prosecution. The codes, however, define general industry practices.

**Interactions with Healthcare Professionals.** Voluntary codes developed by the American Medical Association (“AMA”), Pharmaceutical Manufacturers of America (“PhRMA”), and the Advanced Medical Technology Association (“AdvaMed”) all address interactions between manufacturers and health care professionals. These codes attempt to preserve opportunities for interactions between manufacturer representatives and health care professionals, while limiting those practices which could have a corrupting influence on the professional. The codes therefore focus on limiting the financial benefit provided to professionals (outside of fair market value payments for services) and on limiting social interactions to those interactions that facilitate genuine informational exchange. The codes, like the anti-kickback statute, thus seek to prevent corruption of clinical decision-making (either in the choice of vendor or product). The OIG has indicated, with respect to the PhRMA Code on Interactions with Healthcare Professionals, that compliance will substantially reduce the risk of fraud and abuse and help demonstrate a good faith effort to comply with the applicable federal health care program requirements. Note, however, the codes generally focus on relationships with individual healthcare professionals.

- **AMA Ethical Opinion E-8.061 Gifts to Physicians From Industry.** The ethical opinion establishes guidelines for gifts given to physicians by companies in the pharmaceutical, device, and medical equipment industries to avoid the acceptance of inappropriate gifts.<sup>1</sup> Key guidelines address: educational and practice-related items, third party educational or professional meetings, consultants, scholarships and educational funds, and independence of decision making.
- **PhRMA Code on Interactions with Healthcare Professionals.** The PhRMA Code is a voluntary code of conduct to establish standards for interactions between manufacturers and healthcare professionals. This information is posted on the PhRMA website at: <http://www.phrma.org/publications/policy//2004-01-19.391.pdf>. The PhRMA Code provides general guidelines as well as questions and answers addressing specific practices. Key guidelines address: basis of

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<sup>1</sup> A copy of the opinion is available at: [http://www.ama-assn.org/apps/pf\\_new/pf\\_online?f\\_n=browse&doc=policyfiles/HnE/E-8.061.HTM&&s\\_t=&st\\_p=&nth=1&prev\\_pol=policyfiles/HnE/E-7.05.HTM&nxt\\_pol=policyfiles/HnE/E-8.01.HTM&](http://www.ama-assn.org/apps/pf_new/pf_online?f_n=browse&doc=policyfiles/HnE/E-8.061.HTM&&s_t=&st_p=&nth=1&prev_pol=policyfiles/HnE/E-7.05.HTM&nxt_pol=policyfiles/HnE/E-8.01.HTM&) Questions and answers clarifying the opinion are available at: [http://www.ama-assn.org/apps/pf\\_new/pf\\_online?f\\_n=browse&doc=policyfiles/HnE/E-11.02.HTM&&s\\_t=&st\\_p=&nth=1&prev\\_pol=policyfiles/HnE/E-10.05.HTM&nxt\\_pol=policyfiles/HnE/E-11.01.HTM&](http://www.ama-assn.org/apps/pf_new/pf_online?f_n=browse&doc=policyfiles/HnE/E-11.02.HTM&&s_t=&st_p=&nth=1&prev_pol=policyfiles/HnE/E-10.05.HTM&nxt_pol=policyfiles/HnE/E-11.01.HTM&)

interactions, pharmaceutical company presentations, third party educational or professional meetings, consultants, speaker training meetings, scholarships and educational funds, and educational and practice-related items.

- **AdvaMed Code of Ethics on Interactions with Healthcare Professionals.** The AdvaMed Code is a voluntary code of conduct applicable to medical device manufacturers and their interactions with healthcare professionals and others in a position to generate business for the manufacturers. This information is posted on the AdvaMed website at: [http://www.advamed.org/publicdocs/code\\_of\\_ethics.pdf](http://www.advamed.org/publicdocs/code_of_ethics.pdf). Key guidelines address: manufacturer-sponsored meetings, third party conferences, sales and promotional meetings, consultants, gifts, reimbursement and technical information, and charitable donations. Manufacturers may make donations to charitable organizations for a charitable purpose, such as independent medical research, indigent care, patient education and public education, and sponsorship of events where proceeds are charitable.

Although the three codes are generally consistent, there are differences. A chart comparing the AMA, PhRMA and AdvaMed codes on interactions with healthcare professionals is attached as Attachment A.

**PhRMA Code Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results.** The PhRMA Principles address various issues related to clinical trial research. The principles are posted on the PhRMA website at: <http://www.phrma.org/publications/publications//2004-06-30.1035.pdf>. The PhRMA Principles provide that:

- Clinical trials are conducted in accordance with all applicable laws and regulations, as well as recognized principles of good clinical practice.
- The independence of clinical investigators and others involved in clinical research is respected so they can exercise their own decision-making authority to protect research participants. Compensation to clinical investigators will be reasonable and based on their work. Compensation will not be paid in the stock of the sponsor or otherwise tied to the outcome of the trial.
- Trials must be reviewed by Institutional Review Boards (“IRBs”) or Ethics Committees that have the right to disapprove, require changes, or approve the study. All participation in a clinical trial is based on informed consent, freely given without coercion.
- There should be timely communication of meaningful study results, regardless of the outcome of the study. The results must be reported in an objective, accurate, balanced, and complete manner, with a discussion of the limitations of the study. Study sponsors should not deny publication.

- Those (and only those) who make substantial contributions to a publication should receive acknowledgement as an author of, or contributor to, the publication.

### **III DISCUSSION OF SPECIFIC ACTIVITIES**

#### **A. Drug and Device Sales Activities**

##### **1. General Relationship**

Sales and promotional activities involving institutional providers raise a number of issues.

Institutional providers are often valuable customers because the providers purchase large volumes of drugs or devices. Purchasing decisions are typically made by a limited number of provider representatives. For example, the pharmacy director or formulary committee will determine drug purchases, while influential physicians in clinical specialties will determine the medical devices used in those specialties. Interactions with these representatives are important to promoting sales of a product but often involve heightened sensitivity to avoid the appearance of impropriety. Institutional providers may participate in group purchasing organizations, which offer these providers access to special discounts, and limit the ability of manufacturers to negotiate discounts independently with the institutions. Concerns may arise if manufacturers seek to overcome this obstacle by providing “added-value” to providers (if the added value is perceived as an additional discount). A manufacturer may have a number of relationships with an institutional provider outside the product sales context and may feel pressure to maintain those relationships in order to preserve good relations with the institutional provider.

Institutional providers may often provide a setting for manufacturer sales representatives to have access to physicians on the medical staff and other practitioners (although hospitals are increasingly restricting access). These practitioners may view sales representatives as the primary point of contact for the manufacturer and seek to obtain answers about the products and their uses (both on-label and off-label) from the sales representatives. Focused on scientific exchange, the practitioners may pressure a sales representative to provide more information than permissible under the manufacturer’s policies. Practitioners may have different views of compliant behavior than institutional providers and therefore different expectations.

##### **2. Compliance Concerns**

The primary concern with sales activities is the appropriate treatment of discounts. Discounts largely raise anti-kickback and false claims concerns. Concerns primarily relate to the fact that other financial relationships between manufacturers and providers could be interpreted as an undisclosed discount, but there are certain types of discounts that may raise specific concerns. In addition, for pharmaceutical manufacturers, certain discount arrangements may raise concerns under federal pricing programs.

More generally, however, promotional activities that provide value to physicians or provider representatives with purchasing authority should comply with the PhRMA or AdvaMed codes of conduct to minimize concerns about improper influence. Manufacturers must also be ready to address differences in compliance expectations and communicate compliance policies to institutional providers and develop compliant solutions. Manufacturers that “bend” the rules to accommodate customers’ demands are in a difficult position in creating an culture of compliance when customer requirements undermine strict conformity to the PhRMA Code or implementing policy. Manufacturers should also implement policies to ensure that sales representatives respond appropriately to off-label inquiries by ensuring physicians have ready access to medical liaisons or to the manufacturer’s medical affairs department.

*a. Anti-Kickback Statute*

Discounts are necessarily an inducement to encourage the purchase of a drug or device. Discounts, however, represent one type of activity that receives protection under certain circumstances and is therefore permitted by the anti-kickback statute. Discounts are protected because the government recognizes that public policy generally favors open and legitimate price competition in the health care industry because that competition can benefit federal health care programs. The discount safe harbor, at 42 CFR § 1001.952(h)(5), protects discounts on items and services reimbursed under a federal health care program. The term “discount” is defined as a reduction in the amount a buyer is charged for an item or service based on an arms-length transaction.

- **Discount includes** rebates and other discounts not given at the time of sale.
- **Discount excludes** cash payments or equivalents, supplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service unless both are reimbursed by federal health care programs pursuant to the same methodology (*i.e.*, the same global payment), a reduction in price applicable to one payer but not to federal health care programs, a routine reduction or waiver of any coinsurance or deductible amount, warranties, services provided in accordance with a personal or management services contract, or other remuneration not explicitly defined as a discount.

The OIG has emphasized that the discount must be in the form of a reduction in price given at the time of sale or set at the time of sale. See OIG Compliance Guidance, supra, at 23735. The provision of benefits cannot later be characterized as a discount on a purchase in order to access the protection of the safe harbor.

The discount may qualify for protection when offered or received by buyers, sellers, or offerors (which are not sellers but promote the purchase of an item or service by a buyer at a reduced price) if certain requirements are met. Obligations that sellers and offerors must meet vary depending upon the type of buyer, but can generally be summarized as follows:

- **Medicare or Medicaid managed care plans (which does not include prescription drug plans):** No obligation to disclose discount.
- **Providers that report costs on a cost report:** Discount must be disclosed on invoice or similar statement (and documentation provided if discount not known at time of sale). Buyer must be put on notice of obligation to report discount; and nothing must be done to impede buyer from fulfilling its obligations.
- **Other providers/providers that submit claims for payment:** Discount must be disclosed on invoice or similar statement and documentation provided. Buyer must be put on notice of obligation to report discount; and nothing must be done to impede buyer from fulfilling its obligations.

A chart describing the obligations of buyers, sellers and offerors in detail is attached as Attachment B.

*b. False Claims Act*

Discounts offered to institutional providers implicate the federal false claims and fraud laws. Many institutional providers report costs on cost reports to Medicare or Medicaid – even if payment is no longer based on reasonable costs incurred by the provider – and have an obligation to report costs accurately. Manufacturers must provide accurate information in order for the providers to do so.

Pharmaceutical manufacturers must also track and report discounts accurately under various government pricing programs, many of which require that the price reported include all applicable discounts. Examples include:

- **Medicaid Drug Rebate Program (42 U.S.C. § 1396r-8).** A manufacturer must quarterly report price data to the Centers for Medicare & Medicaid Services (“CMS”). Data includes the “best price” for each drug. “Best price” is “the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States” with certain limited exceptions and must “be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under [the Medicaid rebate program]).”
- **Medicare Part B “Average Sales Price” (42 U.S.C. § 1395w-3a).** Manufacturers must report quarterly the “average sales price” (“ASP”) for each drug covered under Medicare Part B for all purchasers in the United States (excluding purchases exempt from the Medicaid best price calculation). The calculation of the sales price includes volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, and chargebacks and rebates (other than rebates under the Medicaid drug rebate program).

- **Federal Ceiling Price (38 U.S.C. § 1826).** Manufacturers must make covered outpatient drugs available to certain federal agencies (Department of Veterans Affairs, the Public Health Service, the Department of Defense and the Coast Guard) at discounted prices, known as the “federal ceiling price.” The federal ceiling price reflects a minimum discount of 24% off the “non-federal average manufacturer price” or “non-FAMP”. “Non-FAMP” is specifically defined as “the weighted average price of a single form and dosage unit of the drug that is paid by wholesalers in the United States to the manufacturer, taking into account any cash discounts or similar price reductions during that period, but not taking into account--(A) any prices paid by the Federal Government; or (B) any prices found by the Secretary to be merely nominal in amount.”

### 3. **Compliance Issues**

**Discounts.** Concerns primarily relate to the fact that other financial relationships between manufacturers and providers could be interpreted as an undisclosed discount on products purchased. There are also certain types of discount that raise particular issues. In the OIG Compliance Guidance, the OIG emphasized that “any remuneration from a manufacturer provided to a purchaser that is expressly or impliedly related to a sale potentially implicates the anti-kickback statute and should be carefully reviewed. Examples of remuneration in connection with a sale include, but are not limited to, ‘prebates’ and ‘upfront payments,’ other free or reduced-price goods or services, and payments to cover the costs of ‘converting’ from a competitor’s product.” OIG Compliance Guidance, supra, at 23736.

- **Upfront Payments/Signing Bonuses.** Upfront payments and signing bonuses are difficult to conform to the discount safe harbor unless the payments are applied to specific purchases (e.g., payments apply to first year purchases with net price for each purchase dependent upon the number of purchases). The OIG generally views such payments as suspect. See OIG Letter on Upfront Rebates, Prebates and Signing Bonuses (July 7, 2000).
- **Credit Memos.** Credit memos provided in lieu of cash discounts raise cost reporting issues because the credits may be earned based on the purchase of certain products, but are applied to reduce the purchase price of other products. Any agreement should clearly identify the credit as a discount and should be clear on the allocation of the discount.
- **Payments/Discounts on Next Generation Products.** Payment or discount arrangements on next generation products (such as advances in device technology or new drugs replacing drugs about to lose patent protection) may provoke scrutiny, particularly if the new product is more expensive and its superior efficacy unclear. Payments based on shifting market share from the old to new product are more likely to provoke challenge than volume discounts on the new product.

- **Bundled Discounts.** Bundled discounts are eligible for protection under the discount safe harbor only if the bundled products are reimbursed under the same federal health care methodology (which the OIG interprets as the same global payment). For example, under the OIG interpretation, discounts to physicians on different drugs reimbursed under the ASP methodology would not be eligible for protection. For pharmaceutical manufacturers, discounts in bundled products must be appropriately allocated under government price reporting programs.
- **Free Supplies or Equipment.** Manufacturers may offer free supplies or equipment to purchasers if the supplies and equipment are an incidental and integral part of the product purchased, the supplies and equipment have no independent value, and the costs of the supplies and equipment are incorporated into the purchased product. The purchaser is purchasing the total package. See, e.g., OIG Letter on Free Computers, Facsimile Machines, and Other Goods (July 3, 1997). Expensive equipment (such as durable equipment used repeatedly with disposable supplies) is more difficult to justify as having no independent value. Providers are increasingly requesting information on how to allocate the value of such free equipment to other purchases. From a price reporting perspective, pharmaceutical manufacturers must include free goods contingent on a purchase requirement in the calculation of Medicaid best price or Medicare ASP.
- **Product Support/Reimbursement Support.** Manufacturers may offer free product support or reimbursement assistance to physicians or other providers by providing information regarding insurance coverage criteria and reimbursement levels for their products. These services have no independent value to providers apart from the products and may be considered part of the products purchased and their cost may be considered bundles into the products' prices. Other types of reimbursement support programs may represent an independent financial benefit to physicians or other providers. These reimbursement services might include requiring payment for products by purchasers only if the product is reimbursed by third party payors. According to the OIG, these services eliminate the normal financial risks for providers and create overutilization and increased costs. See Advisory Opinion 00-10 and OIG Compliance Guidance, supra, at 23735.

**Promotional Activities.** Institutional providers, based on historical practices, may expect hospitality from manufacturer sales representatives in connection with the promotion of products that is not clearly permissible under the PhRMA Code (or manufacturer policy implementing the PhRMA Code). For example, the PhRMA Code permits an occasional modest meal to facilitate an informational presentation (assuming the presence of the representative and the promotional activity in conjunction with the meal). Institutions, in routinizing their operations, may schedule manufacturer lunch sessions at frequent regular intervals. Institutions may also impose requirements on sales representatives, such as the obligation to purchase food from the institution itself, rather than a manufacturer-approved caterer, which may be inconsistent with a manufacturer's policy prohibiting direct payment to a customer. Similar issues arise if an

institution requests that a sales representative provide lunch outside a meeting room to physicians who are en route to a meeting even though the representative is excluded from the meeting. To resolve conflict, manufacturers could encourage institutional providers to adopt policies for hospitality consistent with the PhRMA Code.

Devices, unlike drugs, may require a demonstration to evaluate the device or training to ensure appropriate use. Manufacturer representatives may provide such demonstration or training. These activities may not always occur at the institutional provider. Manufacturers hosting the activities may (consistent with the AdvaMed Code) reimburse physicians or other provider representatives for reasonable costs of travel and lodging related to attendance at training sessions. Note that the need for the demonstration or training off-site should be clear to avoid challenge. Training activities that occur at the institutional provider may involve exposure to protected health information and should be justified as treatment (under the broad HIPAA definition) or pursuant to patient consent or authorization. Manufacturer representatives should take care, from the risk management or unlicensed practice of medicine perspectives, to limit any advice regarding use of the device. Discussions or demonstrations by manufacturer representatives would be subject to FDA promotional restrictions and should occur only in response to an unsolicited request.

## **B. Purchased Services**

### **1. General Relationship**

Manufacturers may purchase a wide range of services from institutional providers, their personnel or affiliated practitioners:

- advisory board members
- speakers
- preceptorships;
- show site; and
- access to clinical or reimbursement data.

The purchase of research services from institutions and investigators is discussed separately at Section III.C (Clinical Trial Sponsorship).

### **2. Compliance Concerns**

#### **a. Anti-Kickback Statute**

A service arrangement between a manufacturer and an individual or organization in a position to generate business may raise government concerns if the arrangement is not commercially reasonable. An arrangement will not be commercially reasonable if the manufacturer has no reason (other than the generation of business) to enter into the

arrangement or if the arrangement results in excess benefit to the individual or organization. An arrangement may involve an excess benefit if a manufacturer pays above fair market value for services received or charges below fair market value for services provided.

The safe harbor for personal services and management contracts protects certain arrangements. To qualify for safe harbor protection, an arrangement must meet the following conditions:

- the agreement must be set out in writing and signed by both parties;
- the agreement must cover all of the services to be provided for the term of the agreement;
- the agreement must be for at least one year;
- if the agreement provides for the services on a periodic, sporadic or part-time basis, the agreement must specify exactly the schedule of such intervals, their precise length, and the exact charge for such intervals;
- the aggregate compensation paid to the agent over the term of the agreement must set in advance, is consistent with fair market value in arms-length transactions, and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare or a state health program;
- the services performed under the agreement must not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law; and
- the aggregate services contracted for must not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

Compliance with certain requirements often proves difficult, specifically the requirement that aggregate compensation be set in advance and the requirement that periodic services be provided according to a set schedule. Compensation arrangements that do not qualify for safe harbor protection because these requirements are not met may nonetheless be permissible. Payment per unit of service (such as a payment for each hour of advisory board service or an honorarium for each speaking engagement) may survive scrutiny if the unit payment is fixed in advance.

In the OIG Compliance Guidance, the OIG addressed the purchase of services from physicians and its concerns with those arrangements: “In general, fair market value payments to small numbers of physicians for bona fide consulting or advisory services are unlikely to raise any significant concern. Compensating physicians as ‘consultants’ when they are expected to attend meetings or conferences primarily in a passive

capacity is suspect. Also of concern are compensation relationships with physicians for services connected directly or indirectly to a manufacturer's marketing and sales activities, such as speaking, certain research, or preceptor or 'shadowing' services. While these arrangements are potentially beneficial, they also pose a risk of fraud and abuse. In particular, the use of health care professionals for marketing purposes--including, for example, ghost-written papers or speeches--implicates the anti-kickback statute. While full disclosure by physicians of any potential conflicts of interest and of industry sponsorship or affiliation may reduce the risk of abuse, disclosure does not eliminate the risk. . . . Recently, some entities have been compensating physicians for time spent listening to sales representatives market pharmaceutical products. In some cases, these payments are characterized as 'consulting' fees and may require physicians to complete minimal paperwork. Other companies pay physicians for time spent accessing web sites to view or listen to marketing information or perform 'research.' All of these activities are highly suspect under the anti-kickback statute, are highly susceptible to fraud and abuse, and should be strongly discouraged." OIG Compliance Guidance, supra, at 23736.

Note: Codes of conduct also establish principles for the purchase of consultant services that seek to ensure commercially reasonable, fair market value arrangements.

*b. FDA Promotional Restrictions*

Consultants engaged to assist a manufacturer in its scientific or business activities may be privy to information about a manufacturer's products that is not contained in approved product labeling. Just as FDA promotional restrictions obviously do not apply to discussions within a manufacturer's operation, the restrictions do not apply to discussions involving those engaged as consultants. For this reason, consultant meetings have historically been viewed with suspicion as opportunities for the industry to communicate off-label information to select thought leaders, and industry consultant practices have been the subject of government investigations. In response to the new regulatory environment, manufacturers have modified consultant practices to demonstrate more clearly the legitimacy of the consultants and consultant meetings (i.e., meetings with consultants provide opportunities for industry to obtain useful information and direction as the consultants and manufacturer representatives strategize).

When consultants speak promotionally, the consultants are subject to the FDA restrictions on product promotion to the same extent as other agents of the manufacturer. Manufacturers are responsible for all promotional activities, including speaker programs. Speakers, who are chosen for their experience in using a medication or their experience generally, are often concerned with their "academic freedom" to express their own views and may seek to discuss experiences using the manufacturer's product "off-label." Particularly when engaging an academic practitioners as a speaker, manufacturers must be aware of the uniqueness of the manufacturer's compliance concerns in the face of the practitioner's interest in scientific exchange.

c. HIPAA

HIPAA concerns depend on the nature of the arrangement. Some relationships may involve no disclosure of protected health information or only permissible, incidental disclosures. Relationships that may raise issues include the following:

- **Preceptorships.** A typical preceptorship is an arrangement where a sales representative accompanies a health care provider through his or her clinical activities. The sales representative observes while the preceptor provides patient care (whether diagnosis, treatment, or counseling). The main purposes of such preceptorships are to help the sales representative learn more about his or her products, but preceptorships have historically been used to help the representative develop stronger customer relationships. The preceptorship is not usually designed to aid the treatment of a particular patient or to assist health care providers in carrying out their health care operations. Sales representatives will generally have access to protected health information. A health care provider may wish to obtain an authorization from each patient observed during the preceptorship. Problems arise because health care providers may have difficulty obtaining each patient's authorization. A best practice for manufacturers may be to limit preceptorships to formal group learning situations at institutions equipped to obtain appropriate authorizations and to situations, such as the launch of a new product indication, that create a genuine need for observation of care. Note: AMA policy on preceptorships requires patient consent to any monitoring of a patient encounter by a sales representative.
- **Access to Clinical Data.** Manufacturers may seek to obtain existing clinical or reimbursement data from institutional providers or seek access to data registries. Use of such information will generally be considered research and may be disclosed under the requirements applicable to research. See Section III.C (Clinical Trial Sponsorship). Manufacturers may, however, seek to implement a data use agreement. HIPAA permits the use and disclosure for research purposes of a "limited data set" if the covered entity enters into a "data use agreement" with the recipient. A limited data set need only exclude certain "direct identifiers," including names, addresses (other than city, state, and zip code), telephone numbers, and electronic mail addresses. In general, the data use agreement must:
  - limit the recipient's uses and disclosures to research, public health, or health care operations purposes;
  - establish who may use or receive the data set;
  - require the recipient to use appropriate safeguards to prevent use or disclosure of the information other than as permitted by the data use agreement;

- report to the covered entity any unauthorized uses or disclosures of the information of which it becomes aware;
- not “identify the information” or contact the individuals; and
- ensure that the recipient’s agents agree to the same restrictions.

### 3. **Compliance Issues**

**General.** A manufacturer may establish advisory boards, engage speakers for its presentations, or pay physicians to participate in preceptorships. Concerns arise that manufacturers are paying physicians to learn about their products. These concerns are supported if there is no documented need for the purchased services. A need may be difficult to document if the services provided have no value or if the manufacturer purchases more services than necessary. Fair market value may be difficult to document if no services are provided or the services provided have little value. Examples of potentially problematic arrangements might include:

- Manufacturer contracts with numerous physicians across the country to provide feedback on their clinical experiences with the manufacturer’s product over a six-month period.
  - Value. The community physicians are all heavy prescribers of the drug. The drug has been on the market for some time and is about to go off patent.
  - Necessity. The manufacturer does not use the data generated.
- Manufacturer pays physicians to undergo extensive training in order to speak at presentations or seminars sponsored by the manufacturer.
  - Necessity. The manufacturer trains 300 physicians, but only uses 10 physicians as speakers.
  - Value. The physicians receive training in a resort hotel over a long weekend. The training involves only a half day each day.
- Sales representative pays a physician to participate in a preceptorship so that sales representative can learn how physicians use a particular category of drug products.
  - Necessity. The preceptorship is the fourth preceptorship for sales representative in a month and the second with that physician.
  - Value. The physician receives full payment for the preceptorship even though the physician never shows up for the preceptorship.

**Institutional Show Sites.** Device manufacturers with newly-approved technology may seek to market that technology by contracting with a well-known institution to act as a “show site” to provide potential purchasers of the technology with an opportunity to see the technology in action. The institution receives the technology at free or reduced cost for the duration of the agreement, allows manufacturer representatives to bring purchasers into its facility to view the equipment (and sometimes procedures), and often agrees to discuss its experiences with potential purchasers. Key issues are: (1) ensuring that the overall arrangement involves a fair market value exchange; and (2) ensuring that any appropriate authorization is obtained from the patient. The fair market

value exchange can involve an in-kind trade of equipment for services (assuming the value of each is commensurate).

**Institutional Policies and Resources.** Many institutional providers, particularly academic institutions, have conflict of interest policies that limit the financial relationships that physicians or other professionals may have with third parties, such as manufacturers. More generally, institutional providers may limit outside activities of their full-time employees to the extent that those activities interfere with their employment obligations or may require prior consent for other commitments. Manufacturers should limit exposure to any breach of contract claim by requiring professionals to represent and warrant that the professional have the authority to enter into the agreement and the performance of services under the agreement will not constitute a breach of any other obligations. Manufacturers should also ensure, through contract language, that professionals will not make unauthorized use of institution resources (facilities or support staff) in performing services.

**Speaker Programs.** In order to comply with FDA promotional requirements, manufacturers should make clear in their speaker contracts that speakers are viewed by the FDA as promoting products on behalf of the manufacturer, and that the speakers are required as representatives of the manufacturer to give a balanced, on-label presentation. Some manufacturers require speakers certify compliance with a detailed set of guidelines and/or require speakers to adhere to their internally-approved promotional slide decks. Like the manufacturer's medical affairs representatives, speakers are allowed to address unsolicited inquiries about off-label product usage from attendees at speaker meetings. They are not, however, allowed to "seed" or solicit such questions. Manufacturers should have procedures in place that address the re-training of speakers who do not comply with FDA requirements and manufacturer policy, and should also be able to terminate speaker contracts in the face of non-compliance.

**Publication Authorship.** Manufacturers may contract with institutions, directly or through vendors, to have prominent physicians or other professionals prepare publications. Involvement of the author and use of assistance from vendors and manufacturers may vary. Such arrangements may also raise FDA promotional issues if the manufacturers engage the authors to prepare an publications on off-label uses, particularly if the publication is not peer-reviewed and does not involve any new clinical data. Concerns about "ghost-written" articles and requirements regarding disclosure of authorship may limit the willingness of institutions and their professionals to undertake such engagements. PhRMA Principles and criteria adopted by the International Committee of Medical Journal Editors require the recognition as author of any person or entity that: (1) provides a substantial contribution to the concept or design of a study or data acquisition, analysis or interpretation; (2) writes or revises the publication; or (3) has final approval.

## C. Clinical Trial Sponsorship

### 1. General Relationship

Manufacturers contract with physicians and other health care providers to undertake clinical research on their products. The research may be designed:

- to generate the clinical data required in order to obtain FDA approval for a new product or new indication for an existing product; or
- to generate clinical data about an FDA approved product in order to develop marketing programs.

### 2. Compliance Concerns

#### a. Anti-Kickback Statute

Clinical trial sponsorship will raise concerns under the anti-kickback statute to the extent that:

- the clinical trial has no value to the manufacturer (e.g., the trial is not scientifically valid); or
- the compensation paid to the principal investigator/health care provider for conducting the trial exceeds the fair market value of the services provided.

Fair market value concerns also arise if a performance payment is provided and the payment does not correspond to additional effort. Particular concern arises with respect to incentive or performance payments. For example, recruitment bonuses should only be provided to researchers (not physicians identifying subjects) and should be linked to additional effort expended to identify and recruit subjects.

In the OIG Compliance Guidance, the OIG addressed clinical trial sponsorship: “Manufacturers often contract with purchasers of their products to conduct research activities on behalf of the manufacturer on a fee-for-service basis. These contracts should be structured to fit in the personal services safe harbor whenever possible. Payments for research services should be fair market value for legitimate, reasonable, and necessary services. Post-marketing research activities should be especially scrutinized to ensure that they are legitimate and not simply a pretext to generate prescriptions of a drug. Prudent manufacturers will develop contracting procedures that clearly separate the awarding of research contracts from marketing. Research contracts that originate through the sales or marketing functions--or that are offered to purchasers in connection with sales contacts--are particularly suspect.” OIG Compliance Guidance, supra, at 23735-23736.

*b. False Claims Act*

Clinical trial sponsorship by manufacturers may implicate the FCA. The submission of claims to government payors may implicate the FCA if: (1) the services are not Medicare covered services; or (2) the services are Medicare covered services, but the sponsor has paid for the services.

The risk that claims will implicate the statute is potentially enhanced because more health care providers may be billing Medicare for services provided in the context of a clinical trial following the clarification by the Centers for Medicare & Medicaid Services (“CMS”) that Medicare reimbursement is available to providers. The risk is also enhanced where payment by commercial or governmental sponsors under the clinical trial agreement is not linked to specific costs (e.g., fixed payment per subject or percentage of cost payment). See National Coverage Decision on Medicare Coverage of Clinical Trials at <http://www.cms.hhs.gov/coverage/8d2.asp>. With such a payment methodology, it is difficult to be certain what specific services are covered by the sponsor’s payment. The OIG Supplemental Compliance Program Guidance for Hospitals identifies improper claims for clinical trials as a risk area for hospitals. See 70 Fed. Reg. 4858 (January 31, 2005). In addition, manufacturers must submit information to the FDA under FDA regulations governing drugs and devices. Manufacturers need to ensure accurate information is obtained from providers.

*c. HIPAA*

Protected health information held by a health care provider may only be used or disclosed for research purposes if certain requirements are met.

- The health care provider has obtained the individual’s authorization.
  - A research authorization form must include certain information or address certain issues. Manufacturers may want to ensure that the research authorization form protects their interests.
  - The authorization must describe the health information to be used or disclosed. The description of the health information covered by the authorization should be as broad as possible to ensure manufacturer has access to all necessary information. Example of broad description is:
    - “The entire research record and any medical records held by the hospital or other health care providers providing services to you in connection with this study may be used and disclosed except for any information specifically described here: \_\_\_\_\_.”
  - The authorization must identify the persons or class of persons or organizations (by name, position or type) authorized to use or disclose information. Every possible person, class or organization that may need to use or disclose the information should be identified.

- The authorization must identify the persons or class of persons or organizations (by name, position or type) authorized that may receive the health information from the provider. Any person that may use or disclose information should also be able to receive the information. In addition, the research subject, the subject's personal representative or any other person required by law should be able to receive the information.
- The authorization must describe the purpose of the use or disclosure. The manufacturer should have a broad statement of the research purpose. The provider may also want to indicate that the information may be used for the treatment, payment and health care operations of the hospital. Example of such a description is:
  - "The purpose for the uses and disclosures you are authorizing is to conduct the research project explained to you during the informed consent process and to ensure that the information relating to that research is available to all parties who may need it for research purposes. Your information may also be used as necessary for your research-related treatment, to collect payment for your research-related treatment (when applicable), and to run the normal business operations of the provider."
- The authorization must contain a statement on expiration date. The authorization form must state the expiration date or expiration event or state that there is no expiration date/event. No expiration date is most favorable to manufacturers.
- The authorization must discuss the subject's right to revoke authorization. The authorization form must inform the subject of their right to revoke the authorization in writing at any time and how the revocation will affect the continued use and disclosure of their health information.
- The authorization may and should state that treatment is conditioned upon execution of form. From the manufacturer perspective, participation in the clinical study and receipt of research-related treatment should be conditioned on the execution of the research authorization. The authorization must inform the subjects of this condition and the fact that their access to other treatment will not be affected.
- The authorization must notify subjects of the potential for re-disclosure. The authorization form should have a clear statement that information disclosed under the authorization may be re-disclosed.
- The authorization must describe the subject's access to health information during the study.
- The authorization must be written in plain language that is easy to understand.

- The authorization form should inform the subject of the hospital's obligation to provide the individual with a signed copy.
- The authorization should be signed and dated by the subject or the subject's personal representative.
- From the manufacturer perspective, the authorization should not contain other provisions that restrict receipt, use or re-disclosure.
- *An IRB or a privacy board (a special board created to consider privacy issues) approves the alteration or waiver of the requirement for individual authorization.*
  - An IRB or privacy board may allow a clinical site to use or disclose clinical information generated during research if the IRB/privacy board determines the following criteria are met:
  - The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals because:
    - An adequate plan exists to protect the identifiers from improper use and disclosure;
    - An adequate plan exists to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
    - Adequate written assurances exist that the protected health information will not be reused or disclosed to any other person or entity except as otherwise permitted by HIPAA.
  - The research could not practicably be conducted without the waiver or alteration (almost never the case with prospective data collection); and
  - The research could not practicably be conducted without access to and use of the protected health information.
  - The decision of the IRB/privacy board must be appropriately documented.
- *The health information is disclosed to a researcher for protocol development purposes or other reviews preparatory to research.*
  - A researcher may review protected health information maintained by a provider without authorization or IRB/Privacy Board HIPAA waiver if all of the following conditions are met:
    - Access to the protected health information is sought solely for preparatory purposes;

- Protected health information is not removed from provider's premises; and
  - Researcher states in writing that access to the protected health information is necessary for research purposes.
- The health care provider must obtain a representation from researcher that the above requirements are met.
- *The health information is disclosed to a researcher for research on the protected health information of deceased persons (and certain specific requirements are met).*
  - A researcher may use the protected health information of a deceased person maintained by a health care provider without authorization or IRB/Privacy Board HIPAA waiver if all of the following conditions are met:
    - Researcher accesses only protected health information of deceased individual(s);
    - Researcher states protected health information sought solely for research;
    - Researcher documents individuals' death upon request; and
    - Researcher states in writing that access to the protected health information is necessary for research purposes.
  - The health care provider must obtain a representation from researcher that the above requirements are met.

*d. Other Laws*

Numerous laws other regulate commercially-sponsored research. Examples include:

- **FDA**
  - **FDA Regulations on New Drugs (21 C.F.R. 312).** The regulation governs the requirements for conducting clinical investigations of new drugs. Drugs are exempt from the requirements if the drugs are lawfully marketed and meet certain other requirements (e.g., drug is not under investigation for a new indication for use or for a significant change in the labeling). Clinical research is still subject to the IRB requirements and informed consent requirements under 21 C.F.R. Parts 56 and 50.
  - **FDA Regulations on New Devices (21 C.F.R. Part 812).** The regulation governs the requirements for conducting clinical investigations of new devices. Devices are exempt from the requirements under certain circumstances (e.g., device is legally marketed and used in accordance with

- its labeling). Clinical research may still be subject to the IRB requirements and informed consent requirements under 21 C.F.R. Parts 56 and 50.
- **FDA Regulations on Protection of Human Subjects (21 C.F.R. Part 50).** The regulation sets out requirements and general elements for informed consent (see particularly 21 C.F.R. 50.25).
  - **FDA Regulations on Disclosure of Financial Interests by Clinical Investigators (21 C.F.R. Part 54).** The regulation applies to manufacturer or other entity that has submitted a marketing application to the FDA and submits results of “covered clinical studies” (typically studies of effectiveness) as basis for FDA approval. Disclosure obligations apply to FDA applicant, but clinical investigator must provide sufficient information to applicant to allow compliance with disclosure obligations.
  - **FDA Regulations on IRB Requirements and Criteria for Approval of Research (21 C.F.R. Part 56).** IRB can require additional information to that required by FDA regulations for informed consent.
  - **Other FDA Guidance.** Additional FDA guidance is available on the FDA website.
  - **Common Rule.** Most IRBs operate in compliance with the “Common Rule” governing human subjects research which has been adopted by various federal agencies in their regulations. See, e.g., Department of Health and Human Services Regulations on the Protection of Human Subjects: (45 C.F.R. Part 46, Subpart A). Common Rule requirements may be relevant if research is jointly funded by a manufacturer and a government agency or if an institution engaged in manufacturer-sponsored research has filed with HHS or another funding agency an “assurance” of compliance with the Common Rule. Common Rule governs operation of the IRB including informed consent review. The rule is generally consistent with 21 C.F.R. Parts 50 and 56.

### 3. **Compliance Issues**

**Necessity of Clinical Trial.** The manufacturer should be able to establish the purpose of the clinical trial and should also be able to show that the trial is valid for that purpose based on the application of objective scientific criteria. The applicable criteria may vary depending on the purpose of the trial. For example, the criteria may be different if the trial is a premarketing trial conducted to generate data for submission to the FDA as opposed to a postmarketing trial conducted to obtain data about clinical experience with the drug.

The manufacturer should also be able to demonstrate its need for the clinical data generated – both the need for data and the need for the amount of data. Concerns arise if the number of trial sites exceed the number required for the generation of statistically valid data. Necessity is more difficult to demonstrate in postmarketing clinical trials, particularly clinical experience trials. Such trials, which do not involve the

submission of data to the FDA and are therefore not subject to the same criteria about statistically valid data, may be vulnerable to the challenge that the trials are merely “seeding trials” that have been implemented to create a financial incentive for physicians to start or maintain patients on the company’s drug rather than a competitor’s drug.

**Fair Market Value Payment.** Fair market value payment for services rendered may be difficult to demonstrate where the sponsor reimburses the provider a flat fee for the clinical trial or a flat fee per subject enrolled in the clinical trial without indicating the specific services covered by the fee. Such payment methodologies may be characterized by government enforcement agencies as disguising potentially excessive compensation to principal investigators in a position to generate referrals for the manufacturer’s products.

In addition, the payment for each service should be supportable by some fair market value standard, such as the provider’s usual or customary charges for services provided to the general public, discounted fees the provider has negotiated with other third party payers or a fee schedule established by the sponsor as fair market value (e.g., by reference to Medicare reimbursement rates) and applied to all providers. Investigators or clinical institutions involved in research should only receive payment for services actually provided (*i.e.*, if not all clinical services in the schedule are provided, provider will not receive the full subject enrollment fee).

**Financial Incentives to Institution or Investigator.** Enrollment payments, often referred to as recruitment bonuses, create concerns that the investigator or clinical institution is merely receiving a financial incentive to induce patients to join a trial. Enrollment payments should be avoided unless the payments clearly tie to a defined set of services not otherwise compensated under the sponsored research agreement. Such services could be increased advertising or other services designed to address low recruitment. Payments should be provided to the party to the clinical trial agreement (typically the institution). Side payments to investigators or study staff should be avoided.

**Provision of Equipment.** Clinical trials may require the use of equipment not owned by investigators or clinical institutions. Manufacturers may need to provide the equipment to the clinical sites in order for the sites to undertake the trial. The provision of the equipment may raise concerns if:

- the value of the equipment is significant;
- the clinical site derives an independent benefit from the equipment because the clinical site may use the equipment outside the clinical trial in providing care to its patients; and/or
- the clinical site obtains ownership of the equipment.

To address these concerns, a manufacturer may wish to reduce or eliminate the independent and uncompensated value the clinical site might obtain from the equipment. The sponsored research agreement may include the following terms:

- The manufacturer shall provide the equipment to the clinical site for the duration of the study.
- The study site may use the equipment solely in its performance of any necessary services under the clinical study agreement and may not use the equipment outside the clinical study for the treatment of patients or other purposes.
- The study site has the option to return or purchase the equipment from the manufacturer at the end of the study for the fair market value of equipment at that time (e.g., calculated according to a methodology, such as a depreciation schedule, set forth in the clinical study agreement).

**Billing for Clinical Trial Services.** Payment for clinical trial services may raise third party payer billing concerns if the provider bills some or all of the clinical services to patients or third party payers. Services paid by the manufacturer should be clearly identified. Third party payers, such as Medicare or Medicaid, prohibit billing for clinical services where the provider has already received payment for the services from another source. Global per patient payments are susceptible to challenge if not allocated to specific services. A government enforcement agency could take the position that the sponsor aided the provider in the double billing by disguising payments.

**Payments to Study Subjects.** Payments to clinical trial subjects should not be coercive. FDA guidance provides: “It is not uncommon for subjects to be paid for their participation in research, especially during the early phases.... Financial incentives are often used when health benefits to subjects are remote or non-existent. The amount and schedule of all payments should be presented to the IRB at the time of initial review. The IRB should review both the amount of payment and the [schedule]... to assure that neither are coercive or present undue influence...payment should accrue as the study progresses and not be contingent upon the subject completing the entire study.... Payment of a small proportion as an incentive for completion of the study is acceptable to the FDA, providing that such incentive is not coercive.” FDA Information Sheet, Payment to Research Subjects (September, 1998). See also 21 C.F.R. § 50.20.

The OIG, in its report *Recruiting Human Subjects: Pressures in Industry Sponsored Clinical Research* (June, 2000), addresses the promotion of clinical trials and suggests that advertising that emphasizes possibility of earning dollars through clinical trial participation is coercive.

Payments to potential study subjects who are Medicare and Medicaid beneficiaries could also be perceived as an inducement to the beneficiaries to obtain services from the clinical investigator or institution conducting the clinical trial or to receive a manufacturer’s product over another product. The prohibition on inducements to beneficiaries (42 U.S.C. §1320a-7a(a)(5) and 42 C.F.R. §1003.101 and 102(a)(13))

imposes sanctions against individuals or entities that offer remuneration to a program beneficiary that they know, or should know, is likely to influence the beneficiary's decision to order or receive items or services from a particular provider, practitioner or supplier that are reimbursable by Medicare or state health care programs. Prohibition on inducements is triggered because Medicaid and Medicaid will generally cover routine medical care provided in the context of a clinical trial (if not paid for by the sponsor).

**Access to Study Data.** Manufacturers need to ensure access to study data while ensuring compliance with HIPAA restrictions. Key issues in contracting with providers are:

- **Representations and Warranties.** Manufacturers should include in clinical trial agreements representations and warranties related to HIPAA and all other state and federal laws relating to the privacy, confidentiality, or security of health information. For interventional trials, providers should represent and warrant to manufacturer that appropriate HIPAA authorization will be obtained for each subject and authorization will expressly list the manufacturer and all of its contractors as possible recipients of subject's protected health information. Manufacturer could seek to have provider indemnify the manufacturer for negligent failure to comply with state/federal privacy laws (including HIPAA).
- **Notice of Privacy Practices ("NPP").** Providers must distribute the NPP to patients no later than date of first service delivery. The NPP must describe covered entity's uses and disclosures of protected health information, and uses/disclosures must be consistent with the NPP. Manufacturer should ensure that each site/investigator distributes an NPP describing all research uses/disclosures (e.g., pursuant to authorization, waiver of authorization, review preparatory to research, research on decedents' protected health information, or as limited data set).
- **Research Authorization Form ("RAF").** Manufacturers should provide a model RAF to providers listing all parties that might need identifiable data for the research. If a trial site insists on using a different form, manufacturer should review the form for HIPAA compliance. (See discussion of RAF requirements at Section III.C.2.C.)
- **Protocol.** Manufacturer should have its protocols explain the HIPAA authorization form, so that the investigator understands the importance of the form, can implement it properly, and is able to answer any questions about the form.
- **Site Monitors.** Audit responsibilities should include verifying existence of signed authorizations (or combination consent/authorization forms) that permit all necessary disclosures of protected health information and reviewing content of RAF (if not provided by manufacturer). Site monitors should confirm site's NPP contains provisions related to research uses (and includes exceptions to authorization requirement).

- **Investigator Training.** Manufacturer may wish to provide HIPAA compliance training during investigator meetings. Training should emphasize the importance of securing each subject’s authorization for interventional trials. Training should also cover waiver of authorization for registry/database studies.
- **CRO Agreements.** Manufacturer contracts should require CROs (or other third party contractors) to keep patient information confidential, except as necessary for the research or required for legal/regulatory purposes.

Manufacturers should not sign business associate agreements; nor should manufacturers agree to comply with HIPAA as if manufacturers were business associates.

**Disclosure of Financial Interests.** Commercially-sponsored research implicates requirements or issues regarding disclosure of financial interests and/or management of conflicts of interest.

- **Investigators.** FDA regulations (21 C.F.R. Part 54) require disclosure of financial interests by clinical investigators. The regulations apply to the manufacturer or other entity that has submitted a marketing application to the FDA and submits results of “covered clinical studies” (typically studies of effectiveness) as a basis for FDA approval. The purpose is to permit the FDA to have information regarding potential investigator bias in trials. The focus is data reliability and not human subjects protection. Disclosure obligations apply to the FDA applicant, but investigators must provide sufficient information to the FDA applicant to allow compliance with disclosure obligations. Disclosure required covers: (1) financial arrangements between the sponsor and the investigator whereby the value of the investigator’s compensation could be influenced by the outcome of the trial, (2) any proprietary interest in the product studied held by the investigator; (3) significant payment of other sorts over \$25,000 beyond costs of the study; or (4) any significant equity interest in the sponsor of a covered study. (21 CFR 54.4)

Note: Additional disclosure and reporting requirements apply to research funded by the Public Health Service (“PHS”) and to research funded by the National Science Foundation (“NSF”). PHS requirements are at 42 CFR part 50, subpart F, and 45 CFR part 94, while the NSF conflict of interest policy appears at <http://www.nsf.gov/bfa/cpo/gpm95/ch5.htm#ch5>.

In addition, private organizations have issued guidance on identifying and managing conflicts of interest. The PhRMA principles provide that financial compensation to investigators and institutions: (1) should not be tied to the outcome of clinical trials; and (2) should not include company stock or stock options for work on individual clinical trials. In addition, investigators or their immediate families should not have any direct ownership interest (including patent rights or royalty rights) in the specific pharmaceutical product being studied. As another example, the Association of American Medical Colleges

("AAMC") issued *Protecting Subjects, Preserving Trust, Promoting Progress – Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research*. This report provides guidance related to individual financial interests in human subjects research. The report is posted on the AAMC website at: <http://www.aamc.org/members/coitf/firstreport.pdf>.

- **Institution.** The Department of Health and Human Services ("HHS") has issued a Final Guidance Document on *Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subjects Protection*. A copy of the guidance is available at: <http://www.hhs.gov/ohrp/humansubjects/finreltn/fguid.pdf>. The guidance applies to research regulated by the FDA (as well as research funded by HHS). Institutions (as well as IRBs and investigators) are encouraged to (1) consider whether specific financial relationships create financial interests in research studies that may adversely affect the rights and welfare of subjects; and (2) manage conflicts of interest by eliminating the conflicts or mitigating their impact. Actions for institutions to consider are:
  - Establishing the independence of institutional responsibility for research activities from the management of the institution's financial interests.
  - Establishing conflict of interest committees ("COICs") or identifying other bodies or persons and procedures to deal with the individuals' or institutional financial interests in research or verifying the absence of such interests, and address institutional financial interests in research.
  - Establishing criteria to determine what constitutes an institutional conflict of interest, including identifying leadership positions for which the individual's financial interests are such that they may need to be treated as institutional financial interests.
  - Establishing clear channels of communications between COICs and IRBs.
  - Establishing policies on providing information, recommendations, or findings from COIC deliberations to IRBs.
  - Establishing measures to foster the independence of IRBs and COICs.
  - Determining whether particular individuals should report financial interests to the COIC. These individuals could include IRB members and staff and appropriate officials of the institution, along with investigators, among those who report financial interests to COICs.
  - Establishing procedures for disclosure of institutional financial relationships to COIC.
  - Providing training to appropriate individuals regarding financial interest requirements.

- Using independent organizations to hold or administer the institution's financial interest.
- Including individuals from outside the institution in the review and oversight of financial interests in research.
- Establishing policies regarding the types of financial relationships that may be held by parties involved in the research and the circumstances under which those financial relationships and interests may or may not be held.

Note: Numerous private organizations have issued guidance on identifying and managing conflicts of interest. For example, the AAMC issued *Protecting Subjects, Preserving Trust, Promoting Progress II – Principles and Recommendations for Oversight of an Institution's Financial Interests in Human Subjects Research*. This report offers a conceptual framework for assessing institutional conflicts of interest and a set of specific recommendations for the oversight of certain financial interest in human subjects research. The report is posted on the AAMC website at: <http://www.aamc.org/members/coitf/2002coireport.pdf>.

- **Subjects.** There is no requirement in the FDA informed consent regulations or financial disclosure regulations that a study subject be informed of an investigator's financial compensation or financial interest in conducting the clinical investigation. Industry guidelines recommend disclosure. For example, the PhRMA Principles state: "Clinical investigators are encouraged to disclose to potential research participants during the informed consent process that the investigator and/or the institution is receiving payment for the conduct of the clinical trial." OIG recommended consideration of disclosure in *Recruiting Human Subjects: Pressures in Industry Sponsored Clinical Research*, suggesting that industry groups fill in the gaps in FDA guidance and determine whether there is a patient interest in information about the compensation structure of the study.
- **Disclosure of Clinical Trial Results.** Disclosure of clinical trial results has emerged as a new research issue (although the issue does not necessarily relate to relationships with institutional providers).
  - There have been recent settlements. An example is the GlaxoSmithKline ("GSK") settlement with the New York Attorney General in August of 2004. The New York Attorney General alleged that GSK committed fraud by systematically withholding negative clinical data about the use of Paxil (paroxetine) in children and adolescents while, at the same time, publicly disseminating positive off-label information about Paxil in that patient population. The settlement requires GSK to post summaries of all clinical trials for its products on the internet. Clinical studies are defined broadly to include any research investigation on human subjects to answer specific questions about a GSK drug. The obligation lasts for ten years and applies to

clinical trials completed after December 27, 2000 and any other clinical trials material to a physician's judgment for prescription drugs actively marketed by GSK.

- PhRMA Principles address the issue. Section 4(a) states: "We commit to timely communication of meaningful results of controlled clinical trials of marketed products or investigational products that are approved for marketing, regardless of outcome." A Question and Answer states that PhRMA member companies commit to publish the results of "all hypothesis-testing clinical trials [they] conduct, regardless of outcome, for marketed products or investigational products that are approved for marketing." The PhRMA Principles encourage sponsors to communicate clinical trial results by means of publication in a peer-reviewed medical journal, such as the New England Journal of Medicine, but recognize that manufacturers do not control which studies get published and that not all studies will merit publication in a peer-reviewed journal. Principles provide for alternate methods of communication, such as through presentation at a public scientific meeting or posting the results on a website.
- PhRMA has also established a clinical study results database to contain results from all "hypothesis-testing" clinical trials (mainly Phase III and Phase IV trials) since October 1, 2004. The database is at: [www.clinicalstudyresults.org](http://www.clinicalstudyresults.org).

## **D. Grants**

### ***1. General Relationship***

A pharmaceutical manufacturer provides a grant to an individual or organization fund a specific activity. The activity will generally have scientific, educational, or community service value. While a manufacturer may fund a specific activity, the manufacturer does not expect to receive a benefit in return for the grant other than incidental benefits such as the general promotion of goodwill for its name or public awareness about health issues. For example, grants may fund physician-initiated research, educational programs about particular disease states, or screening tests for the community. A grant recipient may or may not be a charitable organization. If the recipient is a charitable organization, the grant may qualify as a charitable donation.

Grants represent a regulatory paradox because government enforcement agencies have acknowledged that a for-profit company may provide funding to third parties (including parties other than charitable organizations) even though there is no direct, measurable benefit to the manufacturer other than the promotion of goodwill. Government enforcement agencies, however, expect that the manufacturer can demonstrate that the grant is a legitimate grant and not a disguised discount or other inducement.

## 2. **General Compliance Concerns**

### a. *Anti-Kickback Statute*

Grants can raise concerns under the anti-kickback statute where the grant is made to an individual or entity in a position to influence the prescription or purchase of products or the influential individual or entity receives the benefit of the grant. Such grants could be construed as a disguised inducement to the individual or entity to encourage the use of a manufacturer's products. For example, such an interpretation could be appropriate where a "grant" is provided to cover a routine expense the customer would otherwise incur or substitute for a product discount because such "grants" are not really grants.

In the OIG Compliance Guidance, the OIG provided guidance on reducing risks in the provision of grants: "To reduce the risks that a grant program is used improperly to induce or reward product purchases or to market product inappropriately, manufacturers should separate their grant making functions from their sales and marketing functions. Effective separation of these functions will help insure that grant funding is not inappropriately influenced by sales or marketing motivations and that the educational purposes of the grant are legitimate. Manufacturers should establish objective criteria for making grants that do not take into account the volume or value of purchases made by, or anticipated from, the grant recipient and that serve to ensure that the funded activities are bona fide. The manufacturer should have no control over the speaker or content of the educational presentation. Compliance with such procedures should be documented and regularly monitored." OIG Compliance Guidance, supra, at 23735.

### b. *False Claims Act*

Grants may implicate the FCA to the extent that grants are perceived as disguised discounts.

### c. *FDA Promotional Restrictions*

Grants to institutional providers or practitioners may raise off-label promotion concerns if the grants fund activities involving off-label discussion or off-label use. Manufacturers are not prohibited from providing funding for such activities. The risk from funding such activities is reduced if the manufacturer has not solicited the grant request and if the program or activity content has genuine scientific value. If the grantees develop proposals for grants and implement funded activities independently, manufacturers are facilitating independent scientific exchange. In the wake of the Pfizer Neurontin settlement, business strategies that focus on funding off-label publications, educational activities and research so as to drive particular off-label use could be challenged (particularly if the manufacturer were perceived as encouraging requests for such grants).

### 3. **General Compliance Concerns**

To reduce risk under the anti-kickback statute and FCA, grant activities should be insulated from sales and marketing activities. The following safeguards may assist in the insulation:

- **Grants should not be used to obtain new customers or reward existing customers.** Funding should not be conditioned upon the purchase of a product. Manufacturers may wish to reduce the appearance that access to grants is related to a business relationships by making information about grants generally accessible (e.g., by posting information on its website). Readily accessible information avoids a situation in which the only way an individual or institution could find out about available grant funds was through contact with a sales representative who seeking to initiate, maintain or reward a customer relationship.
- **The activity funded should meet established criteria uniformly applied to assess similar activities.** For example, research funded should meet objective scientific criteria. Policies or other documentation regarding the availability of grants, eligibility requirements for grants and the application/approval process should be maintained.
- **The funding should not be offered in lieu of a discount or to otherwise provide value to a customer.** Sales representatives should not promise grants or otherwise indicate that grants will be provided to fund a particular activity even if the activity meets all criteria for an award. Decisions about awarding grants should be made prior to the activity and not after the activity to fill funding gaps. Grants should not subsidize routine business operations of the customer.
- **Manufacturers should have no control over the conduct of the activity.** Manufacturers should not influence the protocol or other aspects of research nor determine the content of the educational program.
- **Grants should be reasonable and used for the purposes awarded.** Grant recipients should submit budgets and account for grant funds used. Excess funds should be returned to the manufacturer or, with the approval of the manufacturer, applied to similar activities.

Manufacturers should have policies and procedures in place to ensure and monitor compliance with the safeguards implemented. Institutions also need to have policies in place that recognize that the solicitation of grants may implicate the anti-kickback statute. An institution should not link grant funding to sales representatives' access to providers or for a health care professional affiliated with an institution to imply that past access or past product use entitles the institution to grant support from the manufacturer. Many manufacturers have in place policies that prohibit the support of grant requests where an implication has been made that the grant is important to the institutional/manufacturer business relationship.

#### 4. **Specific Compliance Concerns**

##### a. *Educational Activities*

Academic medical centers are often educational providers (including continuing medical education (“CME”) providers) and their affiliated physicians often serve as faculty for independent educational programs.

In the OIG Compliance Guidance, the OIG identified its concerns with educational grants: “While educational funding can provide valuable information to the medical and health care industry, manufacturer grants to purchasers, GPOs, PBMs and similar entities raise concerns under the anti-kickback statute. Funding that is conditioned, in whole or in part, on the purchase of product implicates the statute, even if the educational or research purpose is legitimate. Furthermore, to the extent the manufacturer has any influence over the substance of an educational program or the presenter, there is a risk that the educational program may be used for inappropriate marketing purposes.” OIG Compliance Guidance, supra, at 23735.

Educational activities must comply with FDA promotional requirements. The FDA distinguishes between (1) educational activities (programs and materials) performed by, or on behalf of, manufacturers; and (2) activities, supported by manufacturers, that are otherwise independent from the promotional influence of the supporting manufacturer. Programs offered by manufacturers are subject to the FDA prohibition on off-label promotion. For example, speakers in speaker programs held by manufacturer must have presentations that affirmatively address only approved uses. Speakers may only respond directly to unsolicited questions about off-label uses. Truly independent and non-promotional industry-supported activities are not subject to FDA regulation. See Food and Drug Administration (FDA) Guidance for Industry: Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64073 (December 3, 1997).

Commercial support of continuing medical education activities offered by educational providers accredited by the Accreditation Council for Continuing Medical Education (“ACCME”) must comply with the *ACCME Standards for Commercial Support (Revised September, 2004)*. ACCME standards seek to ensure that continuing medical education (“CME”) activities of accredited providers are independent, free of commercial bias and beyond the control of commercial sponsors. Revised standards were recently adopted and accredited providers must comply with the revised standards by May of 2005. Interpretations of certain standards (such as the standard on resolving conflicts of interest) are still undergoing significant evolution so requirements for compliance are currently uncertain. Key changes for industry are:

- Financial disclosure requirement has been expanded to encompass individuals other than faculty and require greater information on the nature of the support. The disclosure requirement applies to anyone involved in content development as well as spouses or partners. Also, the nature of in-kind support must now be disclosed.

- Disclosure of financial relationship is no longer adequate to preclude commercial bias. Conflicts of interest must be “resolved”. ACCME has provided guidance on potential mechanisms for resolving conflicts: elimination of conflict; removal from substantive input; and/or implementation of peer review safeguards.
- Manufacturers cannot jointly sponsor an activity with a CME provider.
- CME providers now have enhanced accountability requirements with respect to funds use. Manufacturer may request accurate documentation of funds use rather than just report. Standards do not impose requirement for CME provider to return any unused funds.
- Standards require a written agreement with the CME sponsor addressing specific issues.
- Standards provide detailed and media-specific instructions on the separation of CME and promotional activity.
- Manufacturer personnel can no longer distribute CME materials on behalf of CME provider. Personnel can only distribute brochures.

Depending upon how the conflict of interest provisions are ultimately applied, institutional providers and affiliated physicians may have their CME involvement limited.

The risk associated with funding of educational programs that involve off-label discussions, including CME programs, can be further reduced if: (1) a manufacturer provides funding to programs that receive support from a number of manufacturers; and (2) a manufacturer provides funding to a number of educational providers (to avoid any suggestion that an educational provider is dependent upon the manufacturer and will cater to the manufacturer in developing content).

#### *b. Publication Grants*

Manufacturer funding of a publication discussing off-label uses through a grant to third party (such as university) could raise off-label promotion issues if: (1) the publication was not unsolicited; (2) the content of the publication was known at the time of funding; (3) the publication has little scientific value; and/or (4) the publication is part of an overall strategy to fund off-label publications.

#### *c. Research Grants*

In the OIG Compliance Guidance, the OIG also identified its concerns with research grants: “Pharmaceutical manufacturers sometimes provide funding to their purchasers for use in the purchasers' own research. In many cases, the research provides valuable scientific and clinical information, improves clinical care, leads to promising new treatments, promotes better delivery of health care, or otherwise benefits patients. However, as with educational grants, if linked directly or indirectly to the purchase of product, research grants can be misused to induce the purchase of business without

triggering Medicaid Best Price obligations. To reduce risk, manufacturers should insulate research grant making from sales and marketing influences.” OIG Compliance Guidance, supra, at 23735.

Manufacturer funding (or the provision of free drug) for investigator-initiated clinical trials involving off-label uses could also raise off-label promotion issues if the manufacturer focused on off-label research and/or funded off-label research with no scientific value (e.g., research unlikely to produce new clinical insight). The current trend is for manufacturers to provide free drug in all legitimate investigation-initiated research.

## **E. Charitable Donations**

### **1. General Relationship**

Manufacturers have historically sought to promote research, education and community service activities through charitable contributions. A charitable contribution is a donation of funds to a charitable organization (an organization determined by the Internal Revenue Service to be tax-exempt under 26 U.S.C. § 501(c)(3) entity) that supports the charitable purposes of the organization. Many health care providers, such as hospitals or physician groups associated with academic medical centers, are also charitable organizations. Manufacturers may be solicited for donations because providers will often look to members of the community or business partners in seeking donations because such individuals or organizations are familiar to the provider. Manufacturers, having provided a donation once, may be placed on a donor list and receive requests for donations whenever the hospital engages in fundraising. Manufacturers may feel pressure to meet or exceed prior donations to maintain good relations.

### **2. Compliance Concerns**

#### **a. Anti-kickback Statute**

A charitable donation generally raises concerns under the anti-kickback statute when provided to organizations in a position to generate business for the manufacturers. Like grants, donations represent a benefit to the recipient and the government may be concerned that such donations are not bona fide donations, but are instead disguised payments for referrals, hidden discounts on purchased drugs or are otherwise provided with the expectation that the donation will result in enhanced business. No safe harbor applies to donations and each donation will therefore be subject to scrutiny to determine the potential for abuse.

For example, Advisory Opinion No. 01-2 considered whether participation by vendors of a hospital in an annual charity golf tournament would be prohibited under the anti-kickback statute. The OIG concluded that participation presented a minimal risk of abuse based on the following facts:

- golf tournament appeared to be a bona fide charitable event intended to benefit the community;

- the participation of the vendors was incidental to broad community solicitation and participation; and
- hospital certified that tournament solicitation or participation was not taken into account when entering into contracts or purchasing services.

*b. False Claims Act*

Charitable donations may implicate the FCA if the donations are not bona fide donations, but are instead disguised discounts. In particular, Medicare cost report principles do not require offset of gifts, grants, and donations against allowable costs. Provider Reimbursement Manual §§ 600, et seq. Medicare cost report principles do, however, provide that payments to a provider by a vendor will be considered as discounts, refunds, or rebates in determining Medicare allowable costs even though these payments may be treated as “contributions” or “unrestricted grants” by the hospital and the vendor. See Provider Reimbursement Manual § 806. The principles acknowledge, however, that payments may represent an actual donation or grant where circumstances suggest a bona fide donative intent. Examples provided include:

- contributions are made by a vendor in response to building or other fundraising campaigns in which community-wide contributions are solicited;
- contributions are in addition to discounts, refunds, or rebates, which have been customarily allowed under arrangements between the hospital and the vendor;
- the volume or value of purchases is so nominal that no relationship to the contribution can be inferred; or
- the contributor is not engaged in business with the hospital or a facility related to the hospital.

Medicare cost report principles also provide that, where an owner or other official of a provider directly receives from a vendor monetary payments or goods or services for his own personal use as a result of the provider’s purchases from the vendor, the value of such payments, goods, or services constitutes a type of refund or rebate and should be applied as a reduction of the provider’s costs for goods or services purchased from the vendor. See Provider Reimbursement Manual § 807.

**3. Minimizing Compliance Concerns**

Manufacturers may reduce the potential anti-kickback and cost report concerns by implementing certain safeguards:

- **Charitable contributions by a manufacturer should evidence a *bona fide* charitable purpose.** Charitable donations should not be solicited or offered in the context of negotiating purchasing or other business arrangements. Charitable contributions should be made in connection with charitable events or

fundraising initiatives, such as charity benefits, capital campaigns or community walk-a-thons.

- **Any charitable contribution should be handled by the appropriate personnel within the manufacturer and the charitable organization.** The manufacturer should allocate responsibility for charitable donations. At a minimum, the manufacturer should allocate responsibility for review and approval of charitable contributions to individuals not directly responsible for business interactions with the institution requesting the contribution. Any interaction with the charitable organization should be with its development office or fundraising personnel (not the purchasing department).
- **Benefits from charitable donations should be incidental.** Manufacturers should generally not expect to receive any benefit from charitable donations other than acknowledgment of the donation or corporate sponsorship. Donations, such as the purchase of tickets to a charity benefit or slots in a golf tournament, may entitle the donor to the receipt of certain benefits. These benefits, if used, should be used by representatives of the manufacturer and not provided to individuals or entities in a position to generate referrals for the manufacturer.
- **Charitable donations should be properly recognized.** Manufacturers should obtain from charitable organizations an acknowledgment of a charitable donation and should appropriately report the donation on their tax returns.

## **F. Patient/Community Programs**

### **1. General Relationship**

Manufacturers may undertake activities to promote patient health or otherwise provide benefits to the community (such as sponsoring health fairs or providing free goods to providers for delivery to patients).

### **2. Compliance Concerns**

#### *a. Prohibition on Inducements to Beneficiaries*

The prohibition on inducements to beneficiaries (42 U.S.C. §1320a-7a(a)(5) and 42 C.F.R. §1003.101 and 102(a)(13)) imposes sanctions against individuals or entities that offer remuneration to a program beneficiary that they know, or should know, is likely to influence the beneficiary's decision to order or receive items or services from a particular provider, practitioner or supplier that are reimbursable by Medicare or state health care programs. Remuneration includes the transfer of items and services for free or for other than fair market value. Exceptions exist for certain types of remuneration, including incentives given to individuals to promote the delivery of preventive care. The OIG has also interpreted the statute not to apply to incentives of nominal value (\$10 or less per gift and no more than \$50 per year). See 65 Fed. Reg. 24410 – 24411 (April 26, 2000).

Providers (with the assistance of manufacturers) could be interpreted as providing a benefit to patients to induce them to use the hospital or to seek pharmaceutical product where the hospital passes on gifts provided by pharmaceutical manufacturers. For example, in Advisory Opinion No. 02-14, the OIG considered whether an infusion therapy company could offer free safety equipment to patients with hemophilia (e.g., helmets or knee pads) and free electronic pagers to their parents. No value limits were placed on the safety equipment and the value of the pagers was more than nominal. The OIG concluded that the program could constitute remuneration prohibited as an inducement to beneficiaries.

Note: The prohibition on inducements to beneficiaries does not apply directly to manufacturers offering benefits to encourage use of their products because manufacturers are not Medicare “providers” “suppliers” or “practitioners”.

*b. Anti-Kickback Statute*

Although the prohibition on inducements to beneficiaries does not apply to manufacturers offering benefits to patients, these activities will raise concerns under the anti-kickback statute. The manufacturer could be perceived as encouraging patients to use its products.

**3. Compliance Issues**

**Patient Care Assistance Programs.** Manufacturers may generally provide free drug to financially needy patients (or to institutions that serve financially needy patients for use by such patients). See Advisory Opinion 03-3. Patient care assistance programs operated by manufacturers that subsidize the cost-sharing amounts (such as copayments and deductibles) incurred by financially needy patients covered under federal health care programs would implicate the anti-kickback statute and would likely be impermissible if the drugs were billed to the federal health care programs. Such subsidization:

- shifts all or part of the cost of the drug to the Medicare program; and
- creates incentives for physicians (who will receive full payment) and patients (who do not have to pay the cost-sharing amounts) to choose one drug over a competing drug.

See Advisory Opinion 03-3. Patient care assistance programs that subsidize cost-sharing amounts of drugs for financially needy patient covered under federal health care programs may involve reduced concern if the cost subsidization is undertaken by an organization sufficiently independent of a manufacturer. The risk will depend on the facts-and-circumstances.

The OIG has approved the ability of non-profit foundations to undertake funding of cost-sharing amounts for specific diseases where manufacturers pooled funding and the non-profit provided funding to qualified needy patients after the patient had already chosen its physician and drugs. See Advisory Opinion Nos. 02-01, 02-13 and 04-15.

The OIG found impermissible similar activities by a non-profit foundation funded by one manufacturer to subsidize cost-sharing for its own product and the funding was advertised to physicians.

**Other Programs.** To minimize compliance concerns, manufacturers should generally limit the value of goods or services provided to \$10 per gift/\$50 in the annual aggregate (which amounts the OIG has indicated are not sufficient to influence patients). Manufacturers should also limit programs/participation to open community events. Manufacturers should avoid providing goods and services to patients that institutional providers would otherwise have to provide (so that manufacturers are not perceived as subsidizing the routine operational expenses of the institution).

February 28, 2005

## ATTACHMENT A

### Comparison of Voluntary Codes of Ethics: Interactions Between Healthcare Professionals and Health-Related Industries

*This chart summarizes and compares the major components of three codes of ethics: the American Medical Association (AMA) Code on Gifts to Physicians From Industry, the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals and the Advanced Medical Technology Association (AdvaMed) Code of Ethics on Interactions with Health Care Professionals. The summary comparison includes relevant information not in the three codes, but addressed in clarifying question and answer documents produced by the AMA, PhRMA and AdvaMed. Significant differences among the codes are highlighted in bold.*

	<b>AMA Gifts to Physicians From Industry</b>	<b>PhRMA Code on Interactions with Healthcare Professionals</b>	<b>AdvaMed Code of Ethics on Interactions with Health Care Professionals</b>
<b>Scope</b>	Addresses gifts offered to physicians by the “industry” (all proprietary health-related entities that might create a conflict of interest, including pharmaceutical, device and medical equipment manufacturers).	Addresses interactions between research-based pharmaceutical and biotechnology companies and healthcare professionals with respect to marketed products and related pre-launch activities.	Addresses interactions between medical technology companies and health care professionals (including all individuals, both clinical and non-clinical, who make decisions regarding the purchase, lease or use of medical technology).
<b>General Independence of Decision Making</b>	It is the responsibility of individual physicians to minimize conflicts of interest that may be at odds with the best interest of patients and to access the necessary information to inform medical recommendations.	Members should not provide or offer grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items to a healthcare professional in exchange for prescribing products or for a commitment to continue prescribing products.	Members shall encourage ethical business practices and socially responsible industry conduct and shall not use any unlawful inducement in order to sell, lease, recommend, or arrange for the sale, lease, or prescription of, their products.

	<b>AMA Gifts to Physicians From Industry</b>	<b>PhRMA Code on Interactions with Healthcare Professionals</b>	<b>AdvaMed Code of Ethics on Interactions with Health Care Professionals</b>
<b>Product Training and Education</b>	<ol style="list-style-type: none"> <li>1. If a medical device company insists on training on site as a means of protecting itself from liability for improper usage, physicians and their specialties should make their own judgments regarding the propriety of accepting reimbursement for necessary travel expenses.</li> <li>2. Physicians should not accept honoraria for attending product training.</li> </ol>	Not addressed.	<ol style="list-style-type: none"> <li>1. Setting should be conducive to effective transmission of knowledge.</li> <li>2. Hands-on training should be at training facilities, medical institutions, laboratories, or other appropriate facilities. Training staff should have proper qualifications and expertise.</li> <li>3. Members may provide modest meals and receptions in connection with program if they are subordinate in time and focus to the program.</li> <li>4. Members may reimburse health care professionals for reasonable travel and modest lodging costs.</li> <li>5. Members should not reimburse for health care professionals' guests or any person who does not have a bona fide professional interest in the meeting.</li> </ol>
<b>Informational Presentations by or on behalf of a Pharmaceutical Company</b>	<ol style="list-style-type: none"> <li>1. A legitimate "conference" or "meeting" is any activity (a) held at an appropriate location, (b) dedicated to promoting objective scientific and educational activities and discourse, and (c) driven by the incentive to further attendees' knowledge on the topic presented. An appropriate disclosure of financial support or conflict of interest should be made.</li> <li>2. Physicians should not accept direct subsidies from industry. Physicians</li> </ol>	<ol style="list-style-type: none"> <li>1. Members may provide occasional, modest meals if they provide scientific or educational value and occur at a venue conducive to informational communication.</li> <li>2. Members should not include a healthcare professional's spouse or guest.</li> <li>3. Members should not provide take out meals or meals to be eaten without a company representative present.</li> </ol>	Not addressed.

	<b>AMA Gifts to Physicians From Industry</b>	<b>PhRMA Code on Interactions with Healthcare Professionals</b>	<b>AdvaMed Code of Ethics on Interactions with Health Care Professionals</b>
	<p>should not accept direct or indirect subsidies to cover (a) costs of travel, lodging or other personal expenses or (b) value of time.</p> <p>3. Physicians should not accept subsidies for hospitality other than modest meals or social events held as part of conference or meeting.</p>	<p>4. Members should not provide entertainment or recreational events.</p>	
<b>Third Party Educational Conferences</b>	<p>1. A legitimate “conference” or “meeting” is any activity (a) held at an appropriate location, (b) dedicated to promoting objective scientific and educational activities and discourse, and (c) driven by the incentive to further attendees’ knowledge on the topic presented. An appropriate disclosure of financial support or conflict of interest should be made.</p> <p>2. Physicians should not accept any direct subsidies from industry. Physicians should not accept direct or indirect subsidies to cover (a) costs of travel, lodging or other personal expenses or (b) value of time.</p> <p>3. Physicians should not accept subsidies for hospitality other than modest meals or social events held as part of conference or meeting.</p> <p>4. Industry should not have responsibility for and/or control over the selection of content, faculty, educational methods, materials and venues. These should belong to the organizers of the conference or</p>	<p>1. A “conference” or “meeting” is any activity (a) held at an appropriate location, (b) dedicated to promoting objective scientific and educational activities and discourse, and (c) driven by the incentive to further attendees’ knowledge on the topic presented.</p> <p>2. Members may provide financial support for continuing medical education, other third-party scientific and educational conferences or professional meetings. Support should be given directly to conference sponsor.</p> <p>3. Members should not provide financial support, directly or indirectly, for cost of travel, lodging, or other personal expenses of non-faculty healthcare professionals. Should not provide funding to compensate healthcare professionals for their time.</p> <p>4. Members may provide funding to sponsor for meals or receptions. Members may provide modest meals or receptions directly if</p>	<p>1. Members may provide educational grants to conference sponsors if conference is primarily dedicated to promoting objective scientific and educational activities and discourse and is sponsored by an organization with a genuine educational purpose or function.</p> <p>2. Members may provide funding to support meals and hospitality. Members may provide modest meals or receptions directly if subordinate in time to educational activities. Meals and receptions should be provided in a manner consistent with sponsor’s guidelines.</p> <p>3. Members may provide funding to sponsors for reasonable honoraria, travel, lodging, and meals for conference faculty.</p> <p>4. Members may make educational grants to training institutions or conference sponsors to allow attendance at conference by medical students, residents, fellows</p>

	<b>AMA Gifts to Physicians From Industry</b>	<b>PhRMA Code on Interactions with Healthcare Professionals</b>	<b>AdvaMed Code of Ethics on Interactions with Health Care Professionals</b>
	<p>meeting in accordance with their guidelines.</p> <p>5. Medical students, residents, and fellows may accept scholarships or other special funds to attend carefully selected conferences if the individuals receiving the funds are selected by the academic or training institution.</p> <p>6. Physicians serving as conference faculty may accept honoraria and reimbursement for reasonable travel, lodging and meal expenses.</p> <p><b>7. If a company schedules a conference and appropriate meals are provided, a physician's spouse may partake in the meals.</b></p>	<p>conducive to discussion and subordinate in time to educational activities.</p> <p>5. Members may provide financial assistance for scholarships or other funds to permit medical students, residents, fellows, and other healthcare professionals in training to attend carefully selected educational conferences if the individuals receiving the funds are selected by the academic or training institution.</p> <p>6. Members should not have responsibility for and/or control over the selection of content, faculty, educational methods, materials and venues. These should belong to organizers of the conferences or meetings in accordance with their guidelines.</p>	<p>and others who are health care professionals in training if the individuals receiving funds are selected by the training institution or the conference sponsor.</p> <p>5. Members should not have responsibility for and/or control over the selection of program content, faculty, educational methods, and materials. These should belong to organizers of the conferences or meetings.</p> <p>6. Members may purchase advertisements and lease booth space for company displays at conferences.</p>
<b>Sales and Promotional Meetings</b>	<p>1. Physicians should not accept direct subsidies from industry.</p> <p><b>2. Physicians should not accept direct or indirect subsidies to cover (a) costs of travel, lodging or other personal expenses or (b) value of time.</b></p> <p>3. Physicians should not accept subsidies for hospitality other than modest meals or social events held as part of conference or meeting.</p>	<p>Not addressed. (Principles on International Presentations by a company should be applied.)</p>	<p>1. Members may meet with health care professionals to discuss product features, contract negotiations and sales terms.</p> <p>2. Members may provide occasional modest meals and receptions for meeting attendees if conducive to the exchange of information.</p> <p><b>3. Members may reimburse health care professionals for reasonable, necessary travel costs.</b></p> <p>4. Members should not reimburse</p>

	<b>AMA Gifts to Physicians From Industry</b>	<b>PhRMA Code on Interactions with Healthcare Professionals</b>	<b>AdvaMed Code of Ethics on Interactions with Health Care Professionals</b>
			health care professionals' guests or any person who does not have a bona fide professional interest in the meeting.

	AMA Gifts to Physicians From Industry	PhRMA Code on Interactions with Healthcare Professionals	AdvaMed Code of Ethics on Interactions with Health Care Professionals
<p style="text-align: center;"><b>Consultants</b></p> <p>brunts lewis.DOC</p>	<ol style="list-style-type: none"> <li>1. Physicians providing genuine services as consultants may accept reasonable compensation and reimbursement for reasonable travel, lodging, and meal expenses.</li> <li>2. Token consulting arrangements do not justify compensation.</li> <li>3. Physicians serving as consultants may attend company-sponsored meetings that serve a genuine research purpose. Only modest hospitality should be provided at the meetings; recreation or entertainment should not be provided.</li> <li><b>4. Physician's spouse may accept meals and lodging at meeting of consultants if cost to company is nominal.</b></li> <li>5. Factors that support a genuine research purpose: <ol style="list-style-type: none"> <li>a. Existence of a valid study protocol;</li> <li>b. Recruitment of physicians with appropriate qualifications and expertise; and</li> <li>c. Recruitment of appropriate number of physicians.</li> </ol> </li> </ol>	<ol style="list-style-type: none"> <li>1. Members may offer reasonable compensation to consultants providing genuine services and may reimburse consultants for reasonable travel, lodging, and meal expenses.</li> <li>2. Token consulting arrangements do not justify compensation.</li> <li>3. Factors that support the existence of a legitimate consulting arrangement: <ol style="list-style-type: none"> <li>a. Written, signed, specific agreement.</li> <li>b. Legitimate need for and purpose of services identified prospectively.</li> <li>c. Selection criteria for consultant directly related to purpose of service.</li> <li>d. Reasonable number of consultants retained.</li> <li>e. Records maintained concerning consultant's services.</li> <li>f. Services of consultant used appropriately.</li> <li>g. Meetings with consultants at appropriate venue.</li> <li>h. Hospitality provided at meetings is subordinate in time and focus to the primary purpose of the meeting.</li> </ol> </li> <li>4. Members should not pay honoraria, travel or lodging expenses to non-faculty and non-consultant attendees at company sponsored meetings including attendees who participate in interactive sessions.</li> </ol>	<ol style="list-style-type: none"> <li>1. Members may offer reasonable compensation to consultants providing bona fide consulting services.</li> <li>2. Factors that support the existence of a bona fide consulting arrangement: <ol style="list-style-type: none"> <li>a. Written, signed, specific agreement.</li> <li>b. Compensation at fair market value. Payment only for reasonable and actual expenses incurred by consultants (travel, modest meal and lodging costs).</li> <li>c. Legitimate need for and purpose of services identified prospectively.</li> <li>d. Consultant selected based on qualifications and expertise.</li> <li>e. Meetings with consultants at appropriate venue.</li> <li>f. Hospitality provided at meetings is modest in value and subordinate in time and focus to the primary purpose of the meeting.</li> <li>g. Reasonable number of consultants retained.</li> <li>h. If consultant is performing research services, a written research protocol should be created.</li> </ol> </li> </ol>

	<b>AMA Gifts to Physicians From Industry</b>	<b>PhRMA Code on Interactions with Healthcare Professionals</b>	<b>AdvaMed Code of Ethics on Interactions with Health Care Professionals</b>
<b>Gifts</b>	<ol style="list-style-type: none"> <li>1. Physicians may accept gifts that offer a benefit to patients. <b>Gifts should not be of substantial value (\$100 or less).</b> Value of gift is based on cost to physician on open market.</li> <li>2. Physicians may accept individual gifts of minimal value if related to their work.</li> <li>3. Physicians should not accept gifts if there are strings attached.</li> <li>4. Physicians should not accept gifts of cash or cash equivalents.</li> <li>5. Physicians may use drug samples for personal or family use if such use does not interfere with patient access to drug samples and is not for long-term treatment of a chronic condition. Non-retired physicians should not request free pharmaceuticals for family or personal use.</li> </ol>	<ol style="list-style-type: none"> <li>1. Members may offer occasional gifts to healthcare professionals if gifts are primarily for the benefit of patients. Members may not offer gifts intended for the personal benefit of healthcare professionals. <b>Gifts should not be of substantial value (\$100 or less).</b></li> <li>2. Members may offer promotional items of minimal value if they are primarily associated with the healthcare professional's practice.</li> <li>3. Members should not offer gifts in the form of cash or cash equivalents.</li> <li>4. Members may offer product samples for patient use in accordance with the Prescription Drug Marketing Act.</li> </ol>	<ol style="list-style-type: none"> <li>1. Members may offer occasional gifts to health care professionals if they benefit patients or serve a genuine educational function. <b>Gifts should have a fair market value of less than \$100, unless they are medical textbooks or anatomical models used for educational purposes.</b></li> <li>2. Members may provide branded promotional items of minimal value occasionally if they are related to the health care professional's work or are for the benefit of patients.</li> <li>3. Members should not offer gifts in the form of cash or cash equivalents.</li> </ol>
<b>Provision of Reimbursement and Other Economic Information</b>	Not addressed.	Not addressed.	<ol style="list-style-type: none"> <li>1. Members may provide health care professionals with reimbursement information regarding product to support accurate and responsible Medicare billing.</li> <li>2. Members may provide technical support or other information regarding products to health care professionals to aid in appropriate and efficient use or installation.</li> <li>3. Members should not provide technical or other support as</li> </ol>

	<b>AMA Gifts to Physicians From Industry</b>	<b>PhRMA Code on Interactions with Healthcare Professionals</b>	<b>AdvaMed Code of Ethics on Interactions with Health Care Professionals</b>
			inducement for health care professional to purchase, lease, recommend, use or arrange for the purchase, lease, or prescription of the product.
<b>Grants and Other Charitable Donations</b>	Not addressed. (Principles on Third Party Educational Conferences may apply to certain grants.)	Not addressed. (Principles on Third Party Educational Conferences may apply to certain grants.)	<ol style="list-style-type: none"> <li>1. Members may make donations for a charitable purpose to charitable organizations or, in rare instances, to individuals engaged in genuine charitable missions.</li> <li>2. Members should not make donations to induce a health care professional to purchase, lease, recommend, use or arrange for the purchase, lease, or prescription of the product.</li> <li>3. Members should appropriately document charitable donations.</li> </ol>
<b>Speaker Training Meetings</b>	<ol style="list-style-type: none"> <li>1. Physicians being trained as speakers or faculty for educational conferences and meetings should not accept reimbursement for travel.</li> </ol>	<ol style="list-style-type: none"> <li>1. Members may offer reasonable compensation for time and reimbursement for reasonable travel, lodging, and meal expenses to healthcare professionals participating in speaker training programs when: <ol style="list-style-type: none"> <li>a. Participants receive extensive training on company's drug products and on compliance with FDA regulatory requirements for communications about such products;</li> <li>b. Training will result in</li> </ol> </li> </ol>	Not addressed.

	<b>AMA Gifts to Physicians From Industry</b>	<b>PhRMA Code on Interactions with Healthcare Professionals</b>	<b>AdvaMed Code of Ethics on Interactions with Health Care Professionals</b>
		<p>participants providing valuable service to company; and</p> <p>c. Participants meet criteria for consultants.</p>	

## ATTACHMENT B

Discount Safe Harbor			
Type of Buyer	Buyer Obligations	Seller Obligations	Offeror Obligations
<p><b>Buyer Reports Costs on a Cost Report</b></p>	<p>The discount must be earned based on purchases of that same good or service bought within a single fiscal year of the buyer.</p> <p>The buyer must claim the benefit of the discount in the fiscal year in which the discount is earned or the following year.</p> <p>The buyer must fully and accurately report the discount in the applicable cost report.</p> <p>The buyer must provide information provided by the seller regarding discount when requested by government payor.</p>	<p><b>If the value of the discount is known at time of sale, the seller must:</b></p> <p>(1) fully and accurately report discount on the invoice, coupon or statement submitted to the buyer;</p> <p>(2) inform the buyer in a manner that is reasonably calculated to give notice to the buyer of its of its obligations to report the discount and provide information concerning the discount; and</p> <p>(3) refrain from doing anything that would impede the buyer from meeting its obligations.</p> <p><b>If the value of the discount is not known at time of sale, the seller must:</b></p> <p>(1) fully and accurately report the existence of a discount program on the invoice, coupon or statement submitted to the buyer;</p> <p>(2) inform the buyer in a manner that is reasonably calculated to give notice to the buyer of its of its obligations to report the discount and provide information concerning the discount;</p> <p>(3) when the value of the discount becomes known, provide the buyer with</p>	<p>The offeror must inform the buyer in a manner that is reasonably calculated to give notice to the buyer of its of its obligations to report the discount and provide information concerning the discount.</p> <p>The offeror must refrain from doing anything that would impede the buyer from meeting its obligations</p>

		<p>documentation of the calculation of the discount identifying the specific goods or services purchased to which the discount will be applied; and</p> <p>(4) refrain from doing anything that would impede the buyer from meeting its obligations.</p>	
<b>Buyer Is Managed Care Plan with Medicare or Medicaid Risk Contract</b>	No requirement to report discount to government payor.	No requirement to report discount to buyer.	No requirement to report discount to buyer.
<b>Buyer Is Entity in whose Name Claim for Payment is Submitted for Discounted Item or Service</b>	<p>The discount must be made at the time of the original sale of the good or service or the terms of the rebate must be fixed and disclosed in writing to the buyer at the time of the initial sale of the good or service.</p> <p>The buyer must provide information provided by the seller regarding discount when requested by government payor.</p>	<p><b>If the seller submits a claim or request for payment on behalf of the buyer and the item or service is separately claimed,</b> the seller must provide information provided by the offeror regarding discount when requested by government payor.</p> <p><b>If the buyer submits a claim,</b> the seller must:</p> <p>(1) fully and accurately report discount on the invoice, coupon or statement submitted to the buyer;</p> <p>(2) inform the buyer in a manner reasonably calculated to give notice to the buyer of its obligations to report discount and to provide information concerning the discount; and</p> <p>(3) refrain from doing anything that would</p>	<p>The offeror must inform the entity submitting the claim in a manner that is reasonably calculated to give notice to the buyer of its of its obligations to report the discount and provide information concerning the discount.</p> <p>The offeror must also refrain from doing anything that would impede the buyer or seller from meeting its obligations.</p>

		impede the buyer from meeting its obligations.	
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