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COMMITTEE STAFF REPORT TO THE CHAIRMAN AND RANKING MEMBER

USE OF EDUCATIONAL GRANTS BY PHARMACEUTICAL MANUFACTURERS

PREPARED BY THE STAFF OF THE

COMMITTEE ON FINANCE
UNITED STATES SENATE

MAX BAUCUS, *Chairman*
CHARLES E. GRASSLEY, *Ranking Member*

APRIL 2007

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I. Executive Summary

The United States Senate Committee on Finance (Committee) has exclusive jurisdiction over the Medicare and Medicaid programs. Accordingly, the Committee has a responsibility to protect the safety and well-being of the more than 80 million Americans who receive health care coverage under Medicare and Medicaid, as well as a responsibility to all Americans to ensure that program funds are spent properly. In recent years, Medicaid payments for prescription drugs have grown faster than any other area of the Medicaid program. With the addition of the outpatient prescription drug benefit to the Medicare program in 2006, Federal spending on prescription drugs became even more substantial. Therefore, drug marketing and utilization patterns are of great concern to the Committee.

Pharmaceutical manufacturers fund educational programs that physicians and other health care workers attend, including some used to fulfill their licensure requirements. In 2005, the Committee staff became aware through reports that pharmaceutical companies were routinely using educational grants to help build market share for their newer and more lucrative products. This raises two primary concerns. First, new products tend to be more expensive than older products, thereby increasing total program spending. Second, new products have less clinical history, and may expose patients to greater risks than older products with better established safety and efficacy.

Beginning in June 2005, the Committee wrote to the 23 largest pharmaceutical manufacturers to inquire about their use of educational grants and subsequently sent questions to the Accreditation Council for Continuing Medical Education (ACCME), the primary accrediting body for continuing medical education (CME) for physicians. The Committee staff reviewed answers from the pharmaceutical manufacturers and the ACCME, as well as reports published in journals and the popular press and other publicly available data.

In reviewing enforcement actions by Federal agencies, and reports in the popular press and medical journals, the Committee staff found that drug companies have used educational grants as a way to increase the market for their products in recent years. This practice is of particular concern when the companies use educational grants to encourage physicians to prescribe products for uses beyond their Food and Drug Administration (FDA) approval. Based on the Committee staff's review of responses from the pharmaceutical manufacturers, it appears the manufacturers have implemented policies meant to rein in these activities. The companies have taken steps to separate the grant-making process for educational programs from their marketing efforts. In addition, various industry groups and government agencies have created guidelines

for educational grants to reduce the potential for abuse. Drug companies, however, are not mandated to follow the guidelines and a significant gray area continues to exist regarding the use of educational grants to serve marketing purposes.

Indeed, ACCME's records reveal numerous cases over the past 3 years in which companies had too much influence over the content of supposedly independent educational programs. In one case, a CME provider was cited for allowing a company to help select presenters; in another, the company allegedly influenced the setting and frequency of educational events. One CME provider was cited for promoting the "proprietary business interests of a commercial interest" during an educational program. During 2005 and 2006, 18 of the 76 CME providers reviewed by ACCME—or 24 percent—did not comply with at least one of the standards meant to ensure independence.

Another continuing concern for the Committee staff is the lack of proactive or real time oversight for educational grant programs. CME providers are not required to run prepared text by the FDA, ACCME, or any regulatory authority in advance of CME programs, and the FDA and ACCME do not routinely place monitors in CME audiences to assess what information is presented. Both the FDA and ACCME have intervened after the fact when presented with evidence that abuse occurred in educational grant programs. They do not, however, pre-approve or directly monitor educational grant programs and oversight actions may occur long after the problematic educational activity occurred. Even when ACCME determines that the CME providers repeatedly failed to distance themselves from the drug companies that sponsor them, ACCME can take years to impose penalties. Based on ACCME policies, it can take as long as 9 years from the date of a non-compliant educational activity for an educational provider to lose accreditation.

II. Introduction

The United States Senate Committee on Finance (Committee) has exclusive jurisdiction over the Medicare and Medicaid programs. Accordingly, the Committee has a responsibility to protect the safety and well-being of the more than 80 million Americans who receive health care coverage under Medicare and Medicaid, as well as a responsibility to all Americans to ensure that program funds are spent properly. In recent years, Medicaid payments for prescription drugs have grown faster than any other area of the Medicaid program. With the addition of the outpatient prescription drug benefit to the Medicare program in 2006, Federal spending on prescription drugs became even more substantial.

Pharmaceutical manufacturers fund educational programs that physicians and other health care workers attend, including programs used to fulfill their licensure requirements. These educational grants have become a well-established tool that all of the major pharmaceutical manufacturers use to disseminate information to the medical community. Drug companies routinely fund educational grants to support programs that favorably discuss the companies' newer and more lucrative products, thereby encouraging physicians to prescribe those products and, ultimately, driving sales. The Committee staff has reviewed numerous recent cases

and reports that highlight the potential for abuse with educational grants:

- Warner-Lambert was accused by the Department of Justice (DOJ) and the Health and Human Services Office of Inspector General (HHS OIG) of using educational grants to fund purportedly independent educational programs that actually served to promote the anti-epilepsy drug Neurontin for off-label uses. In 2004, Warner-Lambert paid $430 million to settle claims involving off-label promotion of Neurontin.
- In 2005, Serono Laboratories paid $704 million to settle claims involving off-label promotion of the AIDS drug Serostim. The government's allegations against Serono included the use of educational grants to fund purportedly independent educational programs that actually served to promote Serostim for off-label uses.
- Steven J. Fiorello, a pharmacy official for the State of Pennsylvania, was charged in 2006 with conflict of interest and other ethics violations for accepting educational grant money from drug companies and failing to disclose those payments. As Director of Pharmacy for the Office of Mental Health for the Pennsylvania Department of Public Welfare, Mr. Fiorello helped decide what psychiatric drugs would be used in all state hospitals, thereby influencing more than $9 million in annual Medicaid drug spending.

Beyond the potential civil and criminal issues that arise from the abuse of educational grants, cases like these raise various concerns. First, new products tend to be more expensive than older products, thereby increasing total spending by Medicare, Medicaid, and other health care programs funded by taxpayers. Second, new products have less clinical history, and may expose patients to greater risks than older products with better-established safety and efficacy. Evidence of safety and effectiveness for off-label uses of new products may be even more sparse.

Senators Max Baucus (D-MT) and Charles E. Grassley (R-IA), Chairman and Ranking Member of the Committee, began an inquiry into the use of educational grants in 2005, after reports that drug companies were using the grants to promote prescription drugs for conditions not approved by the FDA. In June 2005, the Committee wrote to the 23 largest drug manufacturers based on U.S. sales to inquire about their use of educational grants. Based on each company's initial response, the Committee sent follow-up letters. All manufacturers voluntarily complied with the Committee's requests for documents and information.

The Committee staff reviewed the manufacturers' responses, including information regarding written policies and procedures for educational grants, data on the magnitude and distribution of past grant spending, and information on budgeting for grant spending. Senators Baucus and Grassley also sent questions to the ACCME, the primary accrediting body for CME for physicians.

This Committee staff report presents the information received from the pharmaceutical manufacturers and the ACCME, as well as other publicly available data. The appendices to this report include:

(1) Appendix A—Accreditation Council for Continuing Medical Education (ACCME) 2004 "Standards for Commercial Support: Standards to Ensure the Independence of CME Activities";
(2) Appendix B—Health and Human Services Office of Inspector General (HHS OIG) 2003 "Compliance Program Guidance for Pharmaceutical Manufacturers";
(3) Appendix C—Pharmaceutical Research and Manufacturers of America (PhRMA) 2002 "Code on Interactions With Healthcare Professionals"; and
(4) Appendix D—Food and Drug Administration (FDA) 1997 "Guidance for Industry: Industry-Supported Scientific and Educational Activities."

III. Scope and Methodology

In June 2005, the Committee wrote to the 23 largest pharmaceutical manufacturers (based on U.S. sales) to inquire about their use of educational grants. Based on each company's initial response, the Committee sent follow-up letters tailored to the particular information provided. All manufacturers voluntarily complied with the requests for documents and information. The Committee greatly appreciates the manufacturers' high level of cooperation with its inquiry.

ACCME is the primary accrediting body for CME for physicians. Many of the manufacturers' responses indicated that the manufacturers rely on grant recipients' accreditation by ACCME and the recipients' promise to comply with ACCME's Standards for Commercial Support as safeguards that the educational grants will be used for legitimate purposes. A primary principle of ACCME's standards is that CME programs must be independent and the commercial sponsor must not control program content. The pharmaceutical manufacturers described most of their grants as funding independent education programs, but none of them elaborated on what independence means or the extent to which they can select what educational topics they wish to fund, while still designating the programs as independent.

In December 2006, the Committee wrote to ACCME to inquire about how much influence ACCME would allow sponsoring pharmaceutical manufacturers to exert over topic selection, without deeming a CME program to lack independence, and the extent of ACCME's ability and actions to ensure that accredited CME is truly independent from sponsors' influence and compliant with ACCME's standards. The Committee greatly appreciates ACCME's full cooperation with its inquiry.

In addition to information gathered directly from the pharmaceutical manufacturers and ACCME, Committee staff considered other relevant sources of information, including: publicly available data on industry funding of medical education; reports in the popular press and medical literature; codes of conduct promulgated by the industry; compliance guidelines issued by the HHS OIG and the FDA; and publicly reported enforcement actions undertaken by DOJ and the HHS OIG.

IV. Background

Off-Label Use

When the FDA deems a drug to be safe and effective for a specific use, the FDA approves the drug to be marketed for that indication. However, once a drug is approved and legally marketed for an indication, it is legal for physicians to prescribe the drug for other uses, even though the FDA has not deemed the product safe and effective for those other uses. These unapproved uses are known as off-label uses. Drug companies can earn profits from off-label sales of their products, but they are not permitted to advertise or otherwise promote the products for off-label uses because the Food, Drug, and Cosmetic Act (FDC Act) prohibits drug companies from promoting their products for any uses other than those approved for marketing by the FDA. In addition to the FDC Act, off-label promotion may also implicate the False Claims Act because the underlying FDC Act violation potentially renders any claim for Federal health care dollars a false claim.

Despite the prohibition on promotion, off-label uses account for a substantial volume of drug prescriptions and, accordingly, drug profits. A recent study funded by the Agency for Health Research and Quality attempted to estimate the percent of prescriptions for outpatient drugs that reflect an off-label use, and concluded that off-label uses account for upwards of 20 percent of drug prescriptions in the United States.[1] The study further concluded that 73 percent of off-label drug uses, and 94 percent of off-label uses for psychiatric medications, lack evidence of efficacy. For some drugs the magnitude of off-label use is even more striking.

Neither the ACCME nor the pharmaceutical manufacturers compile information regarding the number or percent of manufacturer-sponsored educational programs that discuss an off-label use of the sponsor's drugs. ACCME, in fact, changed its rules in 2004 to allow speakers at its educational programs to make presentations about prescription drugs without saying whether the recommended use is off-label or on-label, according to a New York Times article published in July 2006.[2]

Partners in Compliance and Oversight

Several parties play a role in enforcing drug companies' compliance with the Anti-Kickback Statute, the False Claims Act, and the prohibition on off-label promotion.

Food and Drug Administration

The FDA has primary responsibility for enforcing the FDC Act. The FDC Act imposes limits on how manufacturers may advertise their products and forbids them from marketing or promoting their drugs for uses that have not been approved by the FDA. However, these marketing restrictions and the prohibition on off-label promotion apply only to entities involved in the manufacture or sale of the drugs. The FDA lacks jurisdiction over favorable discussions

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[1] "Off-Label Prescribing Among Office-Based Physicians," DC Radley et al., *Archives of Internal Medicine,* 2006; 166:1021–1026.

[2] "Indictment of Doctor Tests Drug Marketing Rules," *The New York Times,* July 22, 2006.

of a product, including a product's off-label uses, by individuals or in settings independent from the manufacturer. Thus, the FDA does not claim jurisdiction over academic discussions or exchanges of scientific thought regarding off-label uses, except where attributable to the manufacturer.

Evidence suggests that educational programs are commonly used as a forum for favorable discussions of off-label drug uses. Whether or not the FDA has authority to regulate these activities hinges on whether the product messages can be attributed back to the drug's manufacturer. In 1997, the FDA released guidelines for companies involved in industry-supported educational activities. The guidelines expressed the FDA's intention not to regulate CME as long as it is independent from the companies whose products are discussed. The FDA advised that educational providers should maintain control over the content of their programs, disclose company funding of programs and connections to speakers, and discuss all relevant treatments for a condition, rather than focusing entirely on the newest medication or on one particular company's product(s). Beyond this guidance, the FDA does little to ensure that educational grants are used for *bona fide* educational purposes. Nor does the FDA have a system in place to monitor educational programs.

The FDA enforces the prohibition on off-label promotion through two departments: the Division of Drug Marketing, Advertising, and Communications (DDMAC) and the Office of Criminal Investigation (OCI). Based on information the FDA provided to the Committee, DDMAC currently employs 41 people, including 22 investigators who conduct primary reviews of promotional materials released by drug companies. DDMAC reviews more than 60,000 promotional materials every year, including brochures, promotional posters, and print, Internet and television advertisements. Most of these materials are submitted voluntarily to the FDA by drug manufacturers, but agency investigators also independently review television, print and Internet advertisements.

DDMAC fields about 150 complaints about promotional materials from people outside the agency. Of those complaints, 5 to 10 per year are lodged against educational materials or programs. In determining which promotional materials to review first, the division considers the overall impact on public health, whether the drug in question is new or has a high-risk profile, and whether the drug has a history of problems.

When DDMAC finds questionable material or receives well-founded complaints, it asks the company to stop using those promotional materials, make corrections if possible, and to respond in writing within 15 days. Most companies comply with requests from DDMAC, though some ask to discuss the reasoning behind these requests. If investigators find that the company used a misleading statement in numerous promotional pieces, they will ask that all such materials be withdrawn. In serious cases, DDMAC will ask the drug company to release a corrective notice or advertisement in the same manner as the offending promotion explaining any inaccuracies or misstatements in its promotions.

The FDA's OCI has primary jurisdiction for all FDA criminal investigations. It can seek fines and restitution in cases of off-label

promotion in violation of the FDC Act. DDMAC often refers cases to OCI for enforcement. Again, based on information the FDA provided to the Committee, OCI can have up to 226 full-time employees and is currently near that limit. OCI handles all criminal inquiries at the FDA, but most of its work relates to prescription drugs. For fiscal year 2006, 73 percent of OCI cases dealt with prescription drugs, as compared to 8 percent for devices and 19 percent for other inquiries.

The FDA's oversight of CME generally occurs after the educational event. DDMAC receives few complaints about CME and has referred some of those to OCI. None of those criminal inquiries had been completed as of March 1, 2007. Dealing with complaints about CME is complicated because the events are convened and conducted by third-party providers. Investigators must first determine whether a drug company exerted undue influence on the medical education company that was supposed to be independent before continuing on with their inquiry. To do so, the FDA sends inquiry letters to the drug companies and asks them about their involvement in the CME, subsequent to the educational event.

Departments of Justice and Health and Human Services

The Departments of Justice and Health and Human Services, through its Office of Inspector General (HHS OIG), are responsible for pursuing violations of the Anti-Kickback Statute and the False Claims Act. Several recent actions against pharmaceutical manufacturers included allegations of illegal off-label promotion.

In 2004, Warner-Lambert paid $430 million to settle claims involving off-label promotion of Neurontin. The government alleged that Warner-Lambert used educational grants to fund purportedly independent educational programs that actually served to promote Neurontin for off-label uses. Warner-Lambert had extensive input into the speakers and content covered at those educational seminars, according to DOJ and the HHS OIG. The action was initiated by company employees acting as whistleblowers. Pfizer, the corporate successor to Warner-Lambert, remains subject to a corporate integrity agreement (CIA) the company executed with the HHS OIG. The CIA obligates Pfizer to take certain corrective actions, and includes terms to ensure the company does not engage in off-label promotional activities.

In 2005, Serono paid $704 million to settle claims involving off-label promotion of Serostim. The government's allegations against Serono included the use of educational grants to fund purportedly independent educational programs that actually served to promote Serostim for off-label uses. The action was initiated by company employees acting as whistleblowers. Serono remains subject to a CIA the company executed with HHS OIG. The CIA obligates Serono to take certain corrective actions, and includes terms to ensure the company does not engage in off-label promotional activities.

Besides pursuing enforcement actions, the HHS OIG has taken a proactive role in offering pharmaceutical manufacturers guidance on how to comply with the fraud and abuse laws. In May 2003, the HHS OIG released the "Compliance Program Guidance for Pharmaceutical Manufacturers." That guidance document discussed

educational grants as a key area of potential risk for fraud and abuse and recommended the following measures to reduce that risk:

(1) manufacturers should separate grant making functions from sales and marketing functions;
(2) manufacturers should establish objective criteria for awarding grants that do not take into account the volume or value of the recipient's purchases;
(3) manufacturers should establish objective criteria for awarding grants that ensure that the funded activities are *bona fide;* and
(4) manufacturers should not have control over the speaker or the content of educational activities funded by grants.

HHS OIG's compliance program guidance is not mandatory. Rather, it represents HHS OIG's suggestions for strategies to ensure compliance with the fraud and abuse laws. Many of the drug companies surveyed stated that they had voluntarily adopted the principles of the HHS OIG compliance program guidance.

Pharmaceutical Research and Manufacturers of America

The Pharmaceutical Research and Manufacturers of America (PhRMA) is the primary trade association representing the drug companies we surveyed. In 2002, PhRMA promulgated a new "Code on Interactions with Healthcare Professionals" (PhRMA Code). The PhRMA Code allows drug companies to sponsor educational events operated by third-party CME providers, but requires that the CME provider retain control over the selection of content, faculty, educational methods, materials, and venue for the activity.

The PhRMA Code also restricts what remuneration drug companies may provide to physicians. In the context of educational programs, the PhRMA Code allows companies to underwrite general program costs, but prohibits direct funding of specific attendee's participation, and limits the types of hospitality that may be provided in conjunction with the educational event.

Many of the drug companies we surveyed specifically included compliance with the PhRMA Code in their educational grant policies. The Committee staff did not inquire about actions taken by PhRMA to actively enforce its code or identify violations of its Code by member companies.

Consumers

Several types of consumer litigation against pharmaceutical manufacturers have involved allegations of misuse of educational grants and off-label promotion. Civil actions include:

(1) product liability claims by patients who used the drugs;
(2) fraud actions on behalf of shareholders who purchased stock in reliance on false information disseminated by the company; and
(3) actions by pension plans and private insurers to recover payments for illegally promoted drugs.

One example of consumer litigation currently receiving significant attention in the press involves the drug Zyprexa, and its manufacturer, Eli Lilly & Co. The FDA approved Zyprexa for the treat-

ment of schizophrenia and acute mania in bipolar disorder. In the course of a consumer-driven products liability action, documents came to light suggesting Eli Lilly & Co. promoted Zyprexa for elderly patients with dementia and other off-label uses and concealed the risks of the drugs. The States of Alaska, Louisiana, Mississippi, Pennsylvania, and West Virginia are suing Eli Lilly & Co. on behalf of their Medicaid programs for money spent on Zyprexa as well as costs to treat injuries caused by the drug.[3]

V. Discussion

General Funding Statistics

All of the 23 pharmaceutical companies surveyed funded educational grants. Most of the companies spent tens of millions of dollars annually to fund thousands of educational grants and educational programs. Educational grant budgets reported by individual companies for 2004 ranged from less than $2 million to $117 million. In 2004, total expenditures by commercial sponsors to support CME exceeded $1 billion.

In addition to providing information on total grant spending, 18 of the companies provided data that included grant funding by therapeutic area, allowing Committee staff to analyze spending by therapeutic areas. In 2003, 2004, and 2005, oncology was the therapeutic area that received the most grant funding, followed by cardiovascular disease and then neurology/psychology. The companies reported that for 2005 they had budgeted approximately $218 million in total grant funding for oncology, $112 million for cardiovascular disease, and $104 million for neurology/psychology. Total grant spending on these three therapeutic areas was even higher in 2004, with approximately $230 million spent on oncology, $186 million on cardiovascular disease, and $182 million on neurology/psychology. Actual spending in these areas for all 23 surveyed companies was higher, as these calculations do not include spending by the five companies that did not break down grant funding by therapeutic area.

Accreditation

The bulk of pharmaceutical manufacturers' educational grant money is used to fund accredited educational programs for physicians. ACCME is the main accrediting body for programs targeting physicians, but some educational programs may be accredited by medical societies or local accrediting organizations. Generally, physicians may only count accredited CME towards licensure requirements. Continuing education for nurses, pharmacists, and other health care workers as well as patients, lay care givers, and the general public also receive industry funding, although not to the same extent as physician education. Educational programs targeting members of other health professions are generally not accredited by ACCME, but may be accredited by other organizations specific to those professions (*e.g.,* the Accreditation Council for

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[3] "Pa. Sues Eli Lilly, AstraZeneca Over Antipsychotic Medications: State Says Three Drug Makers Fraudulently Marketed Medicines" Margaret Cronin Fisk, *Bloomberg News,* March 5, 2007.

Pharmacy Education or the American Nurses Credentialing Center). No comparable accreditation system exists for educational programs targeted at patients, lay care givers, or the general public. Over a billion dollars of pharmaceutical industry money is used each year to fund ACCME-accredited CME for physicians.

The Committee asked the drug companies to provide information regarding how much of their grant spending supported ACCME-accredited educational programs versus programs not accredited by ACCME. A few companies responded that they did not track whether programs were accredited, or by which accrediting body. However, most of the companies submitted detailed information about the magnitude of grant funding they provided to sponsor accredited versus non-accredited educational programs. All of the companies that reported accreditation data indicated that the majority of their grant funding went towards accredited educational programs. On the high end, three companies reported that 90 percent of their grant funding went to accredited programs and five other companies reported 80 percent. On the low end, one company reported that 57 percent of its grant funding went to ACCME-accredited programs and another reported 62 percent. Committee staff's compilation of the companies' responses yielded an estimate of 75 percent of the total educational grant funding is used to support accredited educational programs.

Most of the pharmaceutical companies' educational grant funding goes to accredited CME providers to sponsor programs for physicians. Only one pharmaceutical manufacturer reported providing educational grants to individual physicians and physician group practices. Most of the educational grants are awarded to third-party CME providers, such as medical education and communication companies, that are accredited by ACCME to run CME programs. More than 700 entities are accredited by ACCME as CME providers. ACCME tabulated data indicate that in 2005, $2.25 billion was spent on ACCME-accredited CME, of which $1.12 billion represented commercial support.[4]

Policies and Procedures for Awarding Grants

Based on the responses provided by the pharmaceutical manufacturers, it appears that most of the major companies established written policies and procedures regarding educational grants. Review of the policies submitted indicates that most of the companies established, or are in the process of establishing, a centralized grant process, which involves submitting grant requests through a central portal and using designated personnel to review the requests. Most of the major drug companies explicitly prohibit sales representatives from soliciting or accepting grant requests, or from promising grant funding to customers. Only one pharmaceutical manufacturer reported allowing field representatives to collect grant requests from customers.

Most of the major drug companies budget grant funding by product or by disease state or category. Grant funding is generally

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[4] Data from ACCME 2005 annual report (available at *http://www.accme.org/dir_docs/doc_upload/9c795f02-c470-4ba3-a491-d288be965eff_uploaddocument.pdf*).

budgeted at the headquarters level and is no longer broken down by geographic region or particular sales representative or team.

The participation of sales and marketing personnel in the grant process has generally been limited, but not entirely eliminated, and it has been transferred from field operations to company headquarters. Examples of statements in corporate policies include:

- "The marketing department has a limited role in grant-making to support independent medical education (IME). The marketing department is permitted to make an initial determination regarding whether the general IME topic is one of interest to [the drug company]. If the marketing department determines that a proposal is of interest, the proposal is forwarded on to the medical education department for review and analysis."
- "[The drug company] permits its marketing teams to provide [the drug company's grant office] staff with information regarding their business strategy for a given year. This helps [the drug company's grant office] review committees, which are comprised of employees from [the drug company's] medical organization, ensure that the Company's grant making is consistent with its business strategy. However, our policy expressly precludes any contact between [the drug company's grant office] and [the drug company's] marketing personnel with regard to any individual grant request or requestor."

Most of the companies surveyed promulgated policies professing a commitment to comply with all relevant fraud and abuse laws. Many drug companies included broad statements denying an untoward purpose for educational grants. The following is one such example from one company's submission to the Committee: "[The drug company] adheres to a policy that grant support not be conditioned on any implicit or explicit agreement by the recipient organization to purchase, prescribe, recommend, influence, or provide favorable formulary status for [drug company] products."

Many of the companies also expressed an intent to comply with the PhRMA Code on Interactions with Health Care Professionals, the ACCME Standards for Commercial Support, and the HHS OIG Compliance Program Guidance for Pharmaceutical Manufacturers. The companies expressed a commitment to ensuring the independence of CME, as required by PhRMA, ACCME, and the HHS OIG, but several companies have policies that include provisions that may give their companies more input into the design of the educational programs they sponsor. For example, several companies' grant policies prohibit them from offering unsolicited suggestions for speakers or topics to be covered in CME programs, but allow the companies to make these suggestions if requested by the CME providers they fund. Similarly, some company policies prohibit the unsolicited presentation of study data, including data regarding off-label uses of the company's products, but allow the companies to provide this data if requested by the CME provider.

Clinical Practice Guidelines

Physicians and third-party payers increasingly rely on evidence-based medicine and treatment algorithms to guide clinical decision-

making. Thus, it is important to know the genesis of these recommended treatment protocols and ensure that they are free from commercial bias. The Committee staff also examined pharmaceutical companies' use of educational grants to fund development of clinical protocols, such as treatment algorithms and clinical practice guidelines. The drug companies' responses revealed a few examples of industry funding for protocol development.

Several companies helped fund the Texas Medical Algorithm Program (TMAP) run by the Texas Department of State Health Services to develop psychiatric treatment algorithms. The State of Florida also ran a similar program, the Behavioral Pharmacy Management Program, to define optimal psychiatric treatment regimens. The pharmaceutical companies' corporate policies allowed the companies to fund protocol development, but stated that funding should not entail influence over content or favorable treatment for the sponsor's drugs.

Whether industry-funded protocols remain free from bias is difficult to determine. The Committee staff is aware of several press reports criticizing the commercially-sponsored protocols for recommending the use of newer more expensive drugs, even where less expensive drugs may be equally effective.

The involvement of drug companies in clinical protocol development entails more than direct sponsorship from the drug companies. The experts tasked with developing the guidelines often have preexisting relationships with companies that market drugs the protocols will evaluate. "As many as 59 percent of the authors of clinical guidelines endorsed by many professional associations have had financial relationships with companies whose drugs might be affected by those guidelines."[5]

Policies for Accrediting Educational Providers

ACCME is responsible for accrediting CME providers. ACCME accreditation largely determines whether a physician's participation in a particular activity will qualify as CME to satisfy professional licensure requirements. The ACCME imprimatur identifies an activity as educational, as opposed to promotional, and thus, lends credibility. Therefore, physicians may have greater motivation to attend accredited CME versus non-accredited CME, and may be more likely to believe information learned in the former context rather than the latter.

In 2004, ACCME promulgated "Standards for Commercial Support: Standards to Ensure the Independence of CME Activities" (ACCME Standards). The ACCME Standards require CME providers to ensure that the following decisions are made free from the control of the commercial interest:

(1) identification of CME needs;
(2) determination of educational objectives;
(3) selection and presentation of content;
(4) selection of all persons and organizations that will be in a position to control the content of the CME;

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[5] "Doctors and Drug Companies," D Blumenthal, *NEJM,* 351;18, Oct. 28, 2004, 1885–1890, 1886.

(5) selection of educational methods; and
(6) evaluation of the activity.

ACCME policies further require that "presentations must give a balanced view of therapeutic options."

In December 2006, the Committee wrote to ACCME seeking information about how ACCME ensures that CME providers actually operate with the required level of independence. ACCME's response revealed that ACCME reviews accredited CME providers at intervals of 2, 4, or 6 years, depending on the CME provider's past history of compliance. ACCME uses three sources of information to conduct these re-accreditation reviews:

(1) self study report—written by the CME provider and submitted to ACCME;
(2) accreditation interview—conducted by two individuals from ACCME involving an interview of representative(s) of the CME provider; and
(3) a sample of CME activities—ACCME selects a sample of the CME provider's CME activities (usually 15 activities per provider) and asks the CME provider to submit a documentary file on each activity—ACCME then reviews the documents submitted to look for policies and procedures indicating that the CME provider complied with ACCME policies. It appears that ACCME review relies on information supplied by ACCME-accredited CME providers, and does not involve an independent investigation and/or review. ACCME reviews the CME provider's submission of the policies and procedures used to develop a CME activity and the signed contracts with the commercial sponsor, but does not appear to conduct an independent assessment of the content of the CME programs.

ACCME reviews the information described above as part of its process for determining whether a CME provider complies with ACCME standards, and ultimately whether the provider should retain ACCME accreditation. ACCME describes the re-accreditation process as follows: "ACCME compliance findings are determined at a provider level, not the activity (or presentation) level. Generally speaking, when ACCME finds that 80 percent of activities are found 'in compliance' from documentation review, then the ACCME will find the provider 'in compliance' with the accreditation element." Thus, a CME provider would be deemed to be in compliance with ACCME standards even if ACCME determines, based on the CME provider's own information, that some of the CME provider's educational activities failed to comply with its standards.

If ACCME determines that a CME provider is not in compliance with ACCME standards, the CME provider enters a multi-year corrective action process that may eventually result in the loss of accreditation. When an accredited CME provider is found not in compliance, the CME provider has an opportunity to provide ACCME with a written submission that describes the provider's compliance. The provider is generally allowed 1 year to submit this progress report to ACCME. If ACCME decides that the progress report adequately demonstrates compliance, no further action is taken. If ACCME decides that the progress report does not adequately dem-

onstrate compliance, then the provider may be allowed 6 months to submit another progress report. If that second progress report also does not demonstrate compliance, ACCME may put the provider on probation. If the CME provider does not resolve the problem after 2 years on probation, ACCME may rescind their accreditation. ACCME's finding of non-compliance is the first step down the road to potentially losing accreditation, which may occur up to 3½ years after the initial finding of non-compliance and as many as nine years after the problematic educational activities occurred.

ACCME reported that it reviewed 76 accredited CME providers for compliance with the ACCME Standards. Eighteen of these CME providers were found to be in non-compliance with at least one element of the ACCME standards. Examples from ACCME's written findings of non-compliance include [emphasis in original]:

- "The provider does not ensure that decisions regarding the planning and implementation of CME activities are made independent of commercial interests. A commercial interest influenced where and how many presentations were scheduled for three years of a CME activity."
- "The provider does not ensure that decisions regarding the planning and implementation of CME activities are made independent of commercial interests. Evidence from one activity reviewed indicates that a commercial interest was involved in the selection of faculty and other activities that interfered with independence."
- "The provider does not ensure that a mechanism(s) has been implemented to identify and resolve all conflicts of interest prior to education activities being delivered to the learner."
- "The provider does not demonstrate appropriate management of commercial support. . . . Written agreements for commercial support were signed after the CME activity. However, the ACCME Standards for Commercial Support require written agreements to include the terms and conditions to which both provider and supporter agree to abide. Therefore, it is the expectation of ACCME that agreements are signed prior to the activity taking place."
- "The provider does not demonstrate appropriate management of commercial promotion associated with educational activities. One commercially supported activity contains recurring use of one company's product trade name at the exclusion of other products."
- "The provider does not demonstrate that the content and format of educational activities is without commercial bias. One activity reviewed promotes the proprietary business interests of a commercial interest."

The inquiry to ACCME also sought delineation of the scope of independence the CME provider must have in selecting the topic for a commercially-sponsored CME program. ACCME's response indicated that a commercial sponsor can designate the topic (*e.g.,* diagnosis or treatment of a particular disease) for the CME activity without being determined to control content or otherwise violating ACCME policies. ACCME does not keep track of how many CME programs favorably discuss a drug sold by the commercial sponsor

either for an approved use or for an off-label use. No information was gathered regarding whether the CME providers' educational activities favorably discuss uses of the commercial sponsor's products in a fashion that is disproportionate to what might be expected from an independent activity that has no relation to the sponsor's commercial interests.

VI. Observations

The pharmaceutical industry is paying increased attention to educational grants and its compliance with fraud and abuse laws. The Committee staff's review suggests that, in recent years, the major drug companies have limited the direct involvement of field sales representatives and sales and marketing departments in the educational grant-making process. Until a few years ago, it was common industry practice for the drug companies' marketing departments to be responsible for awarding educational grants and for grant funding to come directly from the marketing budget, often from the specific product budget for a particular sales team. While many companies still allow marketing personnel to offer input, the grant-making authority has largely been removed from the marketing department and placed with medical affairs departments, medical education departments, or general business units.

In the past, companies generally allowed field representatives to solicit grant requests from customers and collect grant applications. With one exception, the companies have terminated this practice and have generally removed field representatives from the grant process.

The responses to the Committee's inquiry showed that the companies have undertaken some efforts to train employees in complying with corporate policies. However, the responses did not include any information that would allow Committee staff to draw conclusions regarding the quality or effectiveness of this training, or measures of actual employee compliance.

The response from ACCME indicates that some CME activities offered by accredited CME providers are improperly influenced by commercial sponsors. The Committee staff has not gathered information to show the extent to which the educational programs sponsored by pharmaceutical manufacturers actually operate with the level of independence promised by ACCME standards or recommended by the HHS OIG Compliance Program Guidance or the PhRMA Code. The use of third party CME providers makes it difficult to demonstrate that the educational programs' favorable product messages should be attributed to the sponsoring drug company.

The Committee staff's review suggests that much of the industry funding for CME occurs in the following manner: A for-profit medical education and communications company submits a grant proposal seeking funding to run an ACCME-accredited educational program. The drug company agrees to fund a program on a general topic (*e.g.,* treatment of a specific condition—and the condition is one for which at least one of the sponsoring drug company's products is used), but the specifics of the content are determined by the medical education and communications company.

The documents provided by the pharmaceutical companies do not reveal an explicit agreement that the CME program will favorably discuss a company product or an off-label use of a company product. However, it is possible that both parties reasonably expect that to be the result.

VII. Considerations

The Committee staff found some promising trends in pharmaceutical manufacturers' use of educational grants, but risks remain for fraud and abuse in several areas. In recent years, the pharmaceutical manufacturers appear to have moved grant policies to the front-burner and crafted corporate policies that, if fully implemented, would ensure that the companies' actions comply with all applicable laws. This is clearly a step in the right direction, and a dramatic improvement from the past when many companies lacked formal policies or had official corporate policies that did not reflect a commitment to compliance. However, while the fact that corporate headquarters now espouse a commitment to compliance is certainly promising, it does not guarantee that all the company's agents, operating in a highly competitive marketplace and an industry in which employees' compensation is often tied to sales volumes, will put those policies into practice. There is evidence that some companies have taken some steps to train field employees on these issues. However, it is difficult to know whether this training has effectively imparted knowledge to the field staff, whether field staff members perceive it as a true corporate commitment to compliance, and whether field staff actually adhere to the companies' professed principles in their daily activities.

Continuing medical education has developed into a multi-billion dollar a year industry, much of which is funded by pharmaceutical manufacturers. It seems unlikely that this sophisticated industry would spend such large sums on an enterprise but for the expectation that the expenditures will be recouped by increased sales. Press reports and documents exposed in litigation and enforcement actions confirm these suspicions in some instances. There is also evidence from ACCME that some accredited CME providers still allow commercial sponsors to exert improper influence on educational activities that are supposed to be independent from commercial interests.

What can be learned by relying on voluntary cooperation from the pharmaceutical companies under review is limited. The Committee staff's review has led to the conclusion that the major drug companies have adopted corporate policies that, on their face, do not allow educational grants to be awarded for unlawful purposes. However, corporate policies still allow this industry to walk a fine line between violating rules prohibiting off-label promotion and awarding grant money in a manner likely to increase sales of their products, including sales for off-label uses. The opportunity for abuse remains, particularly in the following four areas: (1) kickbacks; (2) veiled advertising; (3) bias in clinical protocols; and (4) off-label promotion.

Kickbacks

The Anti-Kickback Statute prohibits pharmaceutical companies from providing remuneration to induce or reward physicians for prescribing the company's products for beneficiaries of Federal health care programs, including Medicare and Medicaid. In the past, the pharmaceutical industry commonly used CME sponsorship as a conduit for remuneration to physicians. Companies funded physicians' travel to and participation in CME programs, where it appeared that sometimes entertainment overshadowed education. The companies' ostensible purpose was to give physicians something of value (*e.g.,* money, tickets to sporting events, meals, entertainment, plane tickets, and hotel stays) in exchange for prescribing certain drugs.

It appears that the overt use of educational grants to provide kickbacks to physicians who attend educational programs has decreased over time. At the same time, it is difficult to quantify the risk of kickbacks related to industry-sponsored education where companies overpay high-prescribing physicians as "consultants" or "speakers" for minimal work to develop educational material or teach at educational programs.

With one exception, the major pharmaceutical companies are not overtly giving educational grants to individual physicians or physician group practices. Although this was a common practice in the past, the major pharmaceutical companies now conduct their educational grants activities in a way that is less likely to involve the direct transfer of remuneration from the company to physicians.

Veiled Advertising

Educational grants are often used to sponsor programs to teach physicians about treatment options for particular diseases. The information presented often encourages physicians to change their prescribing practices to favor certain drugs. When favorable messages about a drug are delivered in the marketing context, physicians should easily recognize the potential bias favoring the drug being promoted, and should be aware of the need to weigh information from other sources to ensure the promotional message does not exert undue influence. However, when the favorable message is delivered in the context of education—even if corporate sponsorship is disclosed—there is an imprimatur of credibility and independence.

The Committee staff's review suggests that some CME programs that claim to be independent from commercial interests may not actually operate with true independence. There is a risk that physicians will allow favorable drug messages learned in an educational context to change their clinical practices to favor use of those drugs, without critically appraising the evidence or fully assessing information from other sources.

Bias in Clinical Protocols

As with educational grants, commercial funding of clinical protocol development raises concerns about the introduction of commercial bias—favoring products marketed by the companies that helped fund the program. However, nothing in the documents produced by the drug companies suggests that any funding for clinical

protocols was tied to the conclusions of the protocols. While company funding of protocol development, and involvement of experts with financial ties to the industry, certainly raise questions about company influence over the treatment recommendations, more investigation would be required to make such a determination, if it exists.

Off-label Promotion

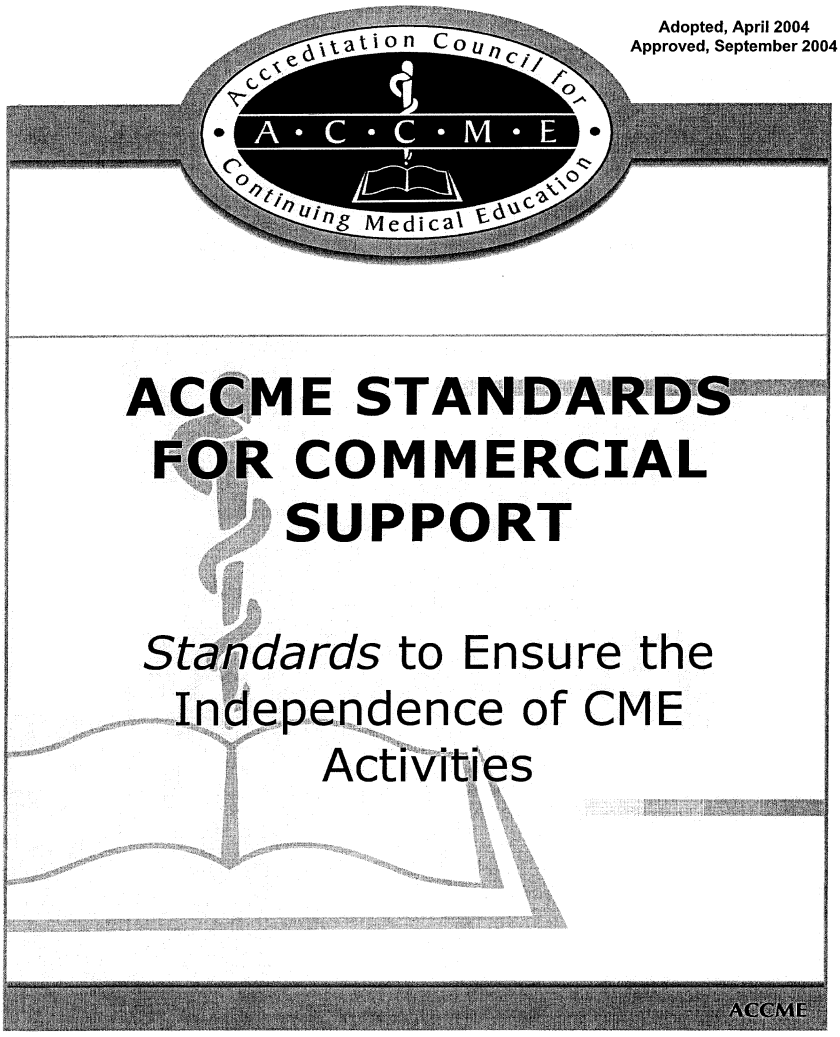
The off-label promotion risk of educational grants appears to pose the greatest threat to the Federal health care programs and beneficiaries, but it is also the most difficult to demonstrate conclusively. There is a risk that the drug industry may be using the medical education industry to deliver favorable messages about off-label uses that the drug companies cannot legally deliver on their own using standard marketing tools.

Encouraging doctors to prescribe drugs for unapproved uses exposes patients to heightened risks. While drug companies are forbidden to promote off-label uses of their products, it is legal for independent third parties to run educational sessions that recommend those products for off-label uses, so long as the educational program is independent and the decision to favorably discuss the off-label use cannot be attributed to the drug company. It is noteworthy that, in recent years, a multi-billion dollar industry of for-profit medical education and communications companies has developed to run medical education programs sponsored by drug companies.

Equally important, it is not possible to know exactly how much of the pharmaceutical market represents off-label use, but it is definitely substantial. The drug companies earn significant profits from off-label drug use. For some drugs, the magnitude of off-label use, and proportional magnitude of company profits, is striking. There is a fine line between illegal pharmaceutical company promotion and legal company-sponsored education that happens to recommend an off-label use. If pharmaceutical manufacturers adhere to the relevant guidelines referenced in this report, educational grants will be less prone to abuse.

APPENDIX A

ACCREDITATION COUNCIL FOR CONTINUING MEDICAL EDUCATION (ACCME) 2004 "STANDARDS FOR COMMERCIAL SUPPORT: STANDARDS TO ENSURE THE INDEPENDENCE OF CME ACTIVITIES"


Accreditation Council for
A · C · C · M · E
Continuing Medical Education
Adopted, April 2004
Approved, September 2004
ACCME STANDARDS FOR COMMERCIAL SUPPORT
Standards to Ensure the Independence of CME Activities
ACCME

The ACCME Standards for Commercial Support

Standards to Ensure Independence in CME Activities

STANDARD 1: Independence

1.1 A CME provider must ensure that the following decisions were made free of the control of a commercial interest. The ACCME defines a "commercial interest" as any proprietary entity producing health care goods or services consumed by, or used on, patients, with the exemption of non-profit or government organizations and non-health care related companies.[1]

(a) Identification of CME needs;
(b) Determination of educational objectives;
(c) Selection and presentation of content;
(d) Selection of all persons and organizations that will be in a position to control the content of the CME;
(e) Selection of educational methods;
(f) Evaluation of the activity.

1.2 A commercial interest cannot take the role of non-accredited partner in a joint sponsorship relationship.⌘

STANDARD 2: Resolution of Personal Conflicts of Interest

2.1 The provider must be able to show that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any commercial interest to the provider. The ACCME defines "'relevant' financial relationships" as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.

2.2 An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.

2.3 The provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners.⌘

STANDARD 3: Appropriate Use of Commercial Support

3.1 The provider must make all decisions regarding the disposition and disbursement of commercial support.

3.2 A provider cannot be required by a commercial interest to accept advice or services concerning teachers, authors, or participants or other education matters, including content, from a commercial interest as conditions of contributing funds or services.

3.3 All commercial support associated with a CME activity must be given with the full knowledge and approval of the provider.

Written agreement documenting terms of support

3.4 The terms, conditions, and purposes of the commercial support must be documented in a written agreement between the commercial supporter that includes the provider and its educational partner(s). The agreement must include the provider, even if the support is given directly to the provider's educational partner or a joint sponsor.

3.5 The written agreement must specify the commercial interest that is the source of commercial support.

3.6 Both the commercial supporter and the provider must sign the written agreement between the commercial supporter and the provider.

Expenditures for an individual providing CME

3.7 The provider must have written policies and procedures governing honoraria and reimbursement of out-of-pocket expenses for planners, teachers and authors.

3.8 The provider, the joint sponsor, or designated educational partner must pay directly any teacher or author honoraria or reimbursement of out-of–pocket expenses in compliance with the provider's written policies and procedures.

3.9 No other payment shall be given to the director of the activity, planning committee members, teachers or authors, joint sponsor, or any others involved with the supported activity.

3.10 If teachers or authors are listed on the agenda as facilitating or conducting a presentation or session, but participate in the remainder of an educational event as a learner, their expenses can be reimbursed and honoraria can be paid for their teacher or author role only.

Expenditures for learners

3.11 Social events or meals at CME activities cannot compete with or take precedence over the educational events.

[1] Modified by ACCME Board of Directors, March 2006

3.12 The provider may not use commercial support to pay for travel, lodging, honoraria, or personal expenses for non-teacher or non-author participants of a CME activity. The provider may use commercial support to pay for travel, lodging, honoraria, or personal expenses for bona fide employees and volunteers of the provider, joint sponsor or educational partner.

Accountability

3.13 The provider must be able to produce accurate documentation detailing the receipt and expenditure of the commercial support. ⌘

STANDARD 4. Appropriate Management of Associated Commercial Promotion

4.1 Arrangements for commercial exhibits or advertisements cannot influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CME activities.

4.2 Product-promotion material or product-specific advertisement of any type is prohibited in or during CME activities. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Live (staffed exhibits, presentations) or enduring (printed or electronic advertisements) promotional activities must be kept separate from CME.

- For ***print***, advertisements and promotional materials will not be interleafed within the pages of the CME content. Advertisements and promotional materials may face the first or last pages of printed CME content as long as these materials are not related to the CME content they face **and** are not paid for by the commercial supporters of the CME activity.
- For ***computer based***, advertisements and promotional materials will not be visible on the screen at the same time as the CME content and not interleafed between computer 'windows' or screens of the CME content
- For ***audio and video recording***, advertisements and promotional materials will not be included within the CME. There will be no 'commercial breaks.'
- For ***live, face-to-face CME***, advertisements and promotional materials cannot be displayed or distributed in the educational space immediately before, during, or after a CME activity. Providers cannot allow representatives of Commercial Interests to engage in sales or promotional activities while in the space or place of the CME activity.

4.3 Educational materials that are part of a CME activity, such as slides, abstracts and handouts, cannot contain any advertising, trade name or a product-group message.

4.4 Print or electronic information distributed about the non-CME elements of a CME activity that are not directly related to the transfer of education to the learner, such as schedules and content descriptions, may include product-promotion material or product-specific advertisement.

4.5 A provider cannot use a commercial interest as the agent providing a CME activity to learners, e.g., distribution of self-study CME activities or arranging for electronic access to CME activities. ⌘

STANDARD 5. Content and Format without Commercial Bias

5.1 The content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest.

5.2 Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CME educational material or content includes trade names, where available trade names from several companies should be used, not just trade names from a single company.⌘

STANDARD 6.Disclosures Relevant to Potential Commercial Bias

Relevant financial relationships of those with control over CME content

6.1 An individual must disclose to learners any relevant financial relationship(s), to include the following information:

- The name of the individual;
- The name of the commercial interest(s);
- The nature of the relationship the person has with each commercial interest.

6.2 For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.

Commercial support for the CME activity.

6.3 The source of all support from commercial interests must be disclosed to learners. When commercial support is 'in-kind' the nature of the support must be disclosed to learners.

6.4 'Disclosure' must never include the use of a trade name or a product-group message.

Timing of disclosure

6.5 A provider must disclose the above information to learners prior to the beginning of the educational activity. ⌘

APPENDIX B

Department of Health and Human Services Office of Inspector General (HHS OIG) 2003 "Compliance Program Guidance for Pharmaceutical Manufacturers"

Dated: April 18, 2003.
Elizabeth M. Duke,
Administrator.
[FR Doc. 03–10934 Filed 5–2–03; 8:45 am]
BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

OIG Compliance Program Guidance for Pharmaceutical Manufacturers

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice

SUMMARY: This **Federal Register** notice sets forth the recently issued Compliance Program Guidance for Pharmaceutical Manufacturers developed by the Office of Inspector General (OIG). Through this notice, the OIG is setting forth its general views on the value and fundamental principles of compliance programs for pharmaceutical manufacturers and the specific elements that pharmaceutical manufacturers should consider when developing and implementing an effective compliance program.

FOR FURTHER INFORMATION CONTACT: Mary E. Riordan or Nicole C. Hall, Office of Counsel to the Inspector General, (202) 619–2078.

SUPPLEMENTARY INFORMATION:

Background

Compliance program guidance is a major initiative of the OIG in its effort to engage the health care community in preventing and reducing fraud and abuse in federal health care programs. The purpose of the compliance program guidance is to encourage the use of internal controls to efficiently monitor adherence to applicable statutes, regulations and program requirements. In the last several years, the OIG has developed and issued compliance program guidance directed at the following segments of the health care industry: the hospital industry; home health agencies; clinical laboratories; third-party medical billing companies; the durable medical equipment, prosthetics, orthotics and supply industry; Medicare+Choice organizations offering coordinated care plans; hospices; nursing facilities; individual and small group physician practices; and ambulance suppliers.

Copies of these compliance program guidances can be found on the OIG Web site at *http://oig.hhs.gov/fraud/complianceguidance.html.*

Developing the Compliance Program Guidance for Pharmaceutical Manufacturers

On June 11, 2001, the OIG published a solicitation notice seeking information and recommendations for developing compliance program guidance for the pharmaceutical industry (66 FR 31246). In response to that solicitation notice, the OIG received eight comments from various outside sources. We carefully considered those comments, as well as previous OIG publications, such as other compliance program guidances and Special Fraud Alerts. In addition, we have taken into account past and ongoing fraud investigations conducted by the OIG's Office of Investigations and the Department of Justice, and have consulted with the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration). In an effort to ensure that all parties had a reasonable opportunity to provide input into a final product, draft compliance program guidance for the pharmaceutical industry was published in the **Federal Register** on October 3, 2002 (67 FR 62057) for further comments and recommendations.

Elements for an Effective Compliance Program

This compliance program guidance for pharmaceutical manufacturers contains seven elements that have been widely recognized as fundamental to an effective compliance program:

- Implementing written policies and procedures;
- Designating a compliance officer and compliance committee;
- Conducting effective training and education;
- Developing effective lines of communication;
- Conducting internal monitoring and auditing;
- Enforcing standards through well-publicized disciplinary guidelines; and
- Responding promptly to detected problems and undertaking corrective action.

These elements are included in previous guidances issued by the OIG. As with previously issued guidances, this compliance program guidance represents the OIG's suggestions on how pharmaceutical manufacturers can establish internal controls to ensure adherence to applicable rules and program requirements. The contents of this guidance should not be viewed as mandatory or as an exclusive discussion of the advisable elements of a compliance program. The document is intended to present voluntary guidance to the industry and not to represent binding standards for pharmaceutical manufacturers.

Office of Inspector General's Compliance Program Guidance for Pharmaceutical Manufacturers

I. Introduction

The Office of Inspector General (OIG) of the Department of Health and Human Services is continuing in its efforts to promote voluntary compliance programs for the health care industry. This compliance guidance is intended to assist companies that develop, manufacture, market, and sell pharmaceutical drugs or biological products (pharmaceutical manufacturers) in developing and implementing internal controls and procedures that promote adherence to applicable statutes, regulations, and requirements of the federal health care programs[1] and in evaluating and, as necessary, refining existing compliance programs.

This guidance provides the OIG's views on the fundamental elements of pharmaceutical manufacturer compliance programs and principles that each pharmaceutical manufacturer should consider when creating and implementing an effective compliance program. This guide is not a compliance program. Rather, it is a set of guidelines that pharmaceutical manufacturers should consider when developing and implementing a compliance program or evaluating an existing one. For those manufacturers with an existing compliance program, this guidance may serve as a benchmark or comparison against which to measure ongoing efforts.

A pharmaceutical manufacturer's implementation of an effective compliance program may require a significant commitment of time and resources by various segments of the organization. In order for a compliance program to be effective, it must have the support and commitment of senior management and the company's governing body. In turn, the corporate leadership should strive to foster a culture that promotes the prevention, detection, and resolution of instances of problems. Although an effective compliance program may require a reallocation of existing resources, the long-term benefits of establishing a compliance program significantly outweigh the initial costs.

In a continuing effort to collaborate closely with the pharmaceutical industry, the OIG published a notice in

[1] (Endnotes appear at end of document)

the **Federal Register** soliciting comments and recommendations on what should be included in this compliance program guidance.[2] Following our review of comments received in response to the solicitation notice, we published draft compliance guidance in the **Federal Register** in order to solicit further comments and recommendations.[3] In addition to considering the comments received in response to that solicitation notice and the draft compliance guidance, in finalizing this guidance we reviewed previous OIG publications, including OIG advisory opinions, safe harbor regulations (including the preambles) relating to the federal anti-kickback statute,[4] Special Fraud Alerts, as well as reports issued by the OIG's Office of Audit Services and Office of Evaluation and Inspections relevant to the pharmaceutical industry. (These materials are available on the OIG Web page at *http://oig.hhs.gov.*) In addition, we relied on the experience gained from investigations of pharmaceutical manufacturers conducted by OIG's Office of Investigations, the Department of Justice, and the state Medicaid Fraud Control Units. We also held meetings with four groups of industry stakeholders—Pharmaceutical Research and Manufacturers of America (PhRMA) and pharmaceutical manufacturer representatives; health plan and health plan association representatives; representatives of pharmacy benefit managers (PBMs) and representatives of the American Medical Association (AMA) and its member organizations.

A. Benefits of a Compliance Program

The OIG believes a comprehensive compliance program provides a mechanism that addresses the public and private sectors' mutual goals of reducing fraud and abuse; enhancing health care provider operational functions; improving the quality of health care services; and reducing the cost of health care. Attaining these goals provides positive results to the pharmaceutical manufacturer, the government, and individual citizens alike. In addition to fulfilling its legal duty to avoid submitting false or inaccurate pricing or rebate information to any federal health care program or engaging in illegal marketing activities, a pharmaceutical manufacturer may gain important additional benefits by voluntarily implementing a compliance program. The benefits may include:

- A concrete demonstration to employees and the community at large of the company's commitment to honest and responsible corporate conduct;
- An increased likelihood of preventing, or at least identifying, and correcting unlawful and unethical behavior at an early stage;
- A mechanism to encourage employees to report potential problems and allow for appropriate internal inquiry and corrective action; and
- Through early detection and reporting, minimizing any financial loss to the government and any corresponding financial loss to the company.

The OIG recognizes that the implementation of a compliance program may not entirely eliminate improper conduct from the operations of a pharmaceutical manufacturer. However, a good faith effort by the company to comply with applicable statutes and regulations as well as federal health care program requirements, demonstrated by an effective compliance program, significantly reduces the risk of unlawful conduct and any penalties that result from such behavior.

B. Application of Compliance Program Guidance

Given the wide diversity within the pharmaceutical industry, there is no single "best" pharmaceutical manufacturer compliance program. The OIG recognizes the complexities of this industry and the differences among industry members. Some pharmaceutical manufacturers are small and may have limited resources to devote to compliance measures. Conversely, other companies are well-established, large multi-national corporations with a widely dispersed work force. Some companies may have well-developed compliance programs already in place; others only now may be initiating such efforts. The OIG also recognizes that pharmaceutical manufacturers are subject to extensive regulatory requirements in addition to fraud and abuse-related issues and that many pharmaceutical manufacturers have addressed these obligations through compliance programs. Accordingly, the OIG strongly encourages pharmaceutical manufactures to develop and implement or refine (as necessary) compliance elements that uniquely address the areas of potential problems, common concern, or high risk that apply to their own companies (or, as applicable, to the U.S. operations of their companies).

For example, although they are not exhaustive of all potential risk areas, the OIG has identified three major potential risk areas for pharmaceutical manufacturers: (1) Integrity of data used by state and federal governments to establish payment; (2) kickbacks and other illegal remuneration; and (3) compliance with laws regulating drug samples. The risk areas are discussed in greater detail in section II.B.2. below. The compliance measures adopted by a pharmaceutical manufacturer should be tailored to fit the unique environment of the company (including its organizational structure, operations and resources, as well as prior enforcement experience). In short, the OIG recommends that each pharmaceutical manufacturer should adapt the objectives and principles underlying the measures outlined in this guidance to its own particular circumstances.[5]

II. Compliance Program Elements

A. The Basic Compliance Elements

The OIG believes that every effective compliance program must begin with a formal commitment by the pharmaceutical manufacturer's board of directors or other governing body. Evidence of that commitment should include the allocation of adequate resources, a timetable for the implementation of the compliance measures, and the identification of an individual to serve as a compliance officer to ensure that each of the recommended and adopted elements is addressed. Once a commitment has been undertaken, a compliance officer should immediately be chosen to oversee the implementation of the compliance program.

The elements listed below provide a comprehensive and firm foundation upon which an effective compliance program may be built. Further, they are likely to foster the development of a corporate culture of compliance. The OIG recognizes that full implementation of all elements may not be immediately feasible for all pharmaceutical manufacturers. However, as a first step, a good faith and meaningful commitment on the part of the company's management will substantially contribute to the program's successful implementation. As the compliance program is implemented, that commitment should filter down through management to every employee and contractor of the pharmaceutical manufacturer, as applicable for the particular individual.

At a minimum, a comprehensive compliance program should include the following elements:

(1) The development and distribution of written standards of conduct, as well as written policies, procedures and protocols that verbalize the company's commitment to compliance (*e.g.*, by including adherence to the compliance

program as an element in evaluating management and employees) and address specific areas of potential fraud and abuse, such as the reporting of pricing and rebate information to the federal health care programs, and sales and marketing practices;

(2) The designation of a compliance officer and other appropriate bodies (*e.g.*, a corporate compliance committee) charged with the responsibility for developing, operating, and monitoring the compliance program, and with authority to report directly to the board of directors and/or the president or CEO;

(3) The development and implementation of regular, effective education and training programs for all affected employees;

(4) The creation and maintenance of an effective line of communication between the compliance officer and all employees, including a process (such as a hotline or other reporting system) to receive complaints or questions, and the adoption of procedures to protect the anonymity of complainants and to protect whistleblowers from retaliation;

(5) The use of audits and/or other risk evaluation techniques to monitor compliance, identify problem areas, and assist in the reduction of identified problems;

(6) The development of policies and procedures addressing the non-employment or retention of individuals or entities excluded from participation in federal health care programs, and the enforcement of appropriate disciplinary action against employees or contractors who have violated company policies and procedures and/or applicable federal health care program requirements; and

(7) The development of policies and procedures for the investigation of identified instances of noncompliance or misconduct. These should include directions regarding the prompt and proper response to detected offenses, such as the initiation of appropriate corrective action and preventive measures and processes to report the offense to relevant authorities in appropriate circumstances.

B. Written Policies and Procedures

In developing a compliance program, every pharmaceutical manufacturer should develop and distribute written compliance standards, procedures, and practices that guide the company and the conduct of its employees in day-to-day operations. These policies and procedures should be developed under the direction and supervision of the compliance officer, the compliance committee, and operational managers. At a minimum, the policies and procedures should be provided to all employees who are affected by these policies, and to any agents or contractors who may furnish services that impact federal health care programs (*e.g.*, contractors involved in the co-promotion of a manufacturer's products).

1. Code of Conduct

Although a clear statement of detailed and substantive policies and procedures is at the core of a compliance program, the OIG recommends that pharmaceutical manufacturers also develop a general corporate statement of ethical and compliance principles that will guide the company's operations. One common expression of this statement of principles is the code of conduct. The code should function in the same fashion as a constitution, *i.e.*, as a document that details the fundamental principles, values, and framework for action within an organization. The code of conduct for a pharmaceutical manufacturer should articulate the company's expectations of commitment to compliance by management, employees, and agents, and should summarize the broad ethical and legal principles under which the company must operate. Unlike the more detailed policies and procedures, the code of conduct should be brief, easily readable, and cover general principles applicable to all employees.

As appropriate, the OIG strongly encourages the participation and involvement of the pharmaceutical manufacturer's board of directors, CEO, president, members of senior management, and other personnel from various levels of the organizational structure in the development of all aspects of the compliance program, especially the code of conduct. Management and employee involvement in this process communicates a strong and explicit commitment by management to foster compliance with applicable federal health care program requirements. It also communicates the need for all employees to comply with the organization's code of conduct and policies and procedures.

2. Specific Risk Areas

This section is intended to help prudent pharmaceutical manufacturers identify areas of their operations that present potential risk of liability under several key federal fraud and abuse statutes and regulations.[6] This section focuses on areas that are currently of concern to the enforcement community and is not intended to address all potential risk areas for pharmaceutical manufacturers. Importantly, the identification of a particular practice or activity in this section is not intended to imply that the practice or activity is necessarily illegal in all circumstances or that it may not have a valid or lawful purpose underlying it.

This section addresses the following areas of significant concern for pharmaceutical manufacturers: (1) Integrity of data used by state and federal governments to establish payment amounts; (2) kickbacks and other illegal remuneration; and (3) compliance with laws regulating drug samples.

This guidance does not create any new law or legal obligations, and the discussions that follow are not intended to present detailed or comprehensive summaries of lawful and unlawful activity. Rather, these discussions should be used as a starting point for a manufacturer's legal review of its particular practices and for development of policies and procedures to reduce or eliminate potential risk.

a. Integrity of Data Used To Establish or Determine Government Reimbursement. Many federal and state health care programs establish or ultimately determine reimbursement rates for pharmaceuticals, either prospectively or retrospectively, using price and sales data directly or indirectly furnished by pharmaceutical manufacturers. The government sets reimbursement with the expectation that the data provided are complete and accurate. The knowing submission of false, fraudulent, or misleading information is actionable. A pharmaceutical manufacturer may be liable under the False Claims Act[7] if government reimbursement (including, but not limited to, reimbursement by Medicare and Medicaid) for the manufacturer's product depends, in whole or in part, on information generated or reported by the manufacturer, directly or indirectly, and the manufacturer has knowingly (as defined in the False Claims Act) failed to generate or report such information completely and accurately. Manufacturers may also be liable for civil money penalties under various laws, rules and regulations. Moreover, in some circumstances, inaccurate or incomplete reporting may be probative of liability under the federal anti-kickback statute.

Where appropriate, manufacturers' reported prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or

other price concessions or similar benefits offered to some or all purchasers. Any discount, price concession, or similar benefit offered on purchases of multiple products should be fairly apportioned among the products (and could potentially raise anti-kickback issues). Underlying assumptions used in connection with reported prices should be reasoned, consistent, and appropriately documented, and pharmaceutical manufacturers should retain all relevant records reflecting reported prices and efforts to comply with federal health care program requirements.

Given the importance of the Medicaid Rebate Program, as well as other programs that rely on Medicaid Rebate Program benchmarks (such as the 340B Program [8]), manufacturers should pay particular attention to ensuring that they are calculating Average Manufacturer Price and Best Price accurately and that they are paying appropriate rebate amounts for their drugs.[9]

In sum, pharmaceutical manufacturers are responsible for ensuring the integrity of data they generate that is used for government reimbursement purposes.

b. Kickbacks and Other Illegal Remuneration—*A. General Considerations.* Pharmaceutical manufacturers, as well as their employees and agents, should be aware of the federal anti-kickback statute and the constraints it places on the marketing and promotion of products reimbursable by the federal health care programs, including, but not limited to, Medicare and Medicaid. In the health care sector, many common business activities, including, for example, sales, marketing, discounting, and purchaser relations, potentially implicate the anti-kickback statute. Pharmaceutical manufacturers and their employees and agents should be aware that the anti-kickback statute prohibits in the health care industry some practices that are common in other business sectors. In short, practices that may be common or longstanding in other businesses are not necessarily acceptable or lawful when soliciting federal health care program business.

The anti-kickback statute is a criminal prohibition against payments (in any form, whether the payments are direct or indirect) made purposefully to induce or reward the referral or generation of federal health care business. The anti-kickback statute addresses not only the offer or payment of anything of value for patient referrals, but also the offer or payment of anything of value in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or ordering of any item or service reimbursable in whole or part by a federal health care program. The statute extends equally to the solicitation or acceptance of remuneration for referrals. Liability under the anti-kickback statute is determined separately for each party involved. In addition to criminal penalties, violators may be subject to civil monetary sanctions and exclusion from the federal health care programs. Under certain circumstances, a violation of the anti-kickback statute may give rise to liability under the False Claims Act.

Although liability under the anti-kickback statute ultimately turns on a party's intent, it is possible to identify arrangements or practices that may present a significant potential for abuse. Initially, a manufacturer should identify any remunerative relationship between itself (or its representatives) and persons or entities in a position to generate federal health care business for the manufacturer directly or indirectly. Persons or entities in a position to generate federal health care business include, for example, purchasers, benefit managers, formulary committee members, group purchasing organizations (GPOs), physicians and certain allied health care professionals, and pharmacists. The next step is to determine whether any *one* purpose of the remuneration may be to induce or reward the referral or recommendation of business payable in whole or in part by a Federal health care program. Importantly, a lawful purpose will not legitimize a payment that also has an unlawful purpose.

Although any arrangement satisfying both tests requires careful scrutiny from a manufacturer, the courts have identified several potentially aggravating considerations that can be useful in identifying arrangements at greatest risk of prosecution. In particular, manufacturers should ask the following questions, among others, about any problematic arrangements or practices they identify:

- 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?

Manufacturers that have identified problematic arrangements or practices can take a number of steps to reduce or eliminate the risk of an anti-kickback violation. Detailed guidance relating to a number of specific practices is available from several sources. Most importantly, the anti-kickback statute and the corresponding regulations establish a number of "safe harbors" for common business arrangements, including personal services and management contracts, 42 CFR 1001.952(d), warranties, 42 CFR 1001.952(g), discounts, 42 CFR 1001.952(h), employment, 42 CFR 1001.952(i), GPOs, 42 CFR 1001.952(j), and certain managed care and risk sharing arrangements, 42 CFR 1001.952(m), (t), and (u). *Safe harbor protection requires strict compliance with all applicable conditions set out in the relevant safe harbor.* Although compliance with a safe harbor is voluntary and failure to comply with a safe harbor does not mean an arrangement is illegal, many arrangements can be structured to fit in safe harbors, and we recommend that pharmaceutical manufacturers structure arrangements to fit in a safe harbor whenever possible. Other available guidance includes special fraud alerts and advisory bulletins issued by the OIG identifying and discussing particular practices or issues of concern and OIG advisory opinions issued to specific parties about their particular business arrangements. Parties may apply for an OIG advisory opinion using the procedures set out at 42 CFR part 1008. The safe harbor regulations (and accompanying **Federal Register** preambles), fraud alerts and bulletins, advisory opinions (and instructions for obtaining them), and other guidance are available on the OIG web site at *http://oig.hhs.gov.*

B. Key Areas of Potential Risk. The following discussion highlights several known areas of potential risk. The propriety of any particular arrangement can only be determined after a detailed examination of the attendant facts and circumstances. *The identification of a given practice or activity as "suspect" or as an area of "risk" does not mean it is necessarily illegal or unlawful, or that it*

cannot be properly structured to fit in a safe harbor. Nor does it mean that the practice or activity is not beneficial from a clinical, cost, or other perspective. Rather, the areas identified below are those areas of activity that have a potential for abuse based on historical law enforcement experience and that should receive close scrutiny from manufacturers. The discussion highlights potential risks under the anti-kickback statute arising from pharmaceutical manufacturers' relationships with three groups: purchasers (including those using formularies) and their agents; persons and entities in a position to make or influence referrals (including physicians and other health care professionals); and sales agents.

(1) Relationships with Purchasers and their Agents—(a) Discounts and Other Remuneration to Purchasers. Pharmaceutical manufacturers offer purchasers a variety of price concessions and other remuneration to induce the purchase of their products. Purchasers include direct purchasers (*e.g.*, hospitals, nursing homes, pharmacies, some physicians), as well as indirect purchasers (*e.g.*, health plans). Inducements offered to purchasers potentially implicate the anti-kickback statute if the purchased products are reimbursable to the purchasers, in whole or in part, directly or indirectly, by any of the federal health care programs. 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.

Discounting arrangements are prevalent in the pharmaceutical industry and deserve careful scrutiny particularly because of their potential to implicate the Best Price requirements of the Medicaid Rebate Program. Because the Medicaid Rebate Program in many instances requires that states receive rebates based on the Best Price offered by a pharmaceutical manufacturer to other purchasers, manufacturers have a strong financial incentive to hide *de facto* pricing concessions to other purchasers to avoid passing on the same discount to the states. Because of the potential direct and substantial effect of such practices on federal health care program expenditures and the interest of some manufacturers in avoiding price concessions that would trigger rebates to the states, any remuneration from a manufacturer to a purchaser, however characterized, should be carefully scrutinized.

Discounts. Public policy favors open and legitimate price competition in health care. Thus, the anti-kickback statute contains an exception for discounts offered to customers that submit claims to the federal health care programs, if the discounts are properly disclosed and accurately reported. *See* 42 U.S.C. 1320a–7b(b)(3)(A); 42 CFR 1001.952(h). However, to qualify for the exception, the discount must be in the form of a *reduction in the price* of the good or service based on an arms-length transaction. In other words, the exception covers only reductions in the product's price. Moreover, the regulations provide that the discount must be given at the time of sale or, in certain cases, set at the time of sale, even if finally determined subsequent to the time of sale (*i.e.*, a rebate).

Manufacturers offering discounts should thoroughly familiarize themselves, and have their sales and marketing personnel familiarize themselves, with the discount safe harbor at 42 CFR 1001.952(h) (and, if relevant, the safe harbors for price reductions in the managed care context, 42 CFR 1001.952(m), (t), and (u)). In particular, manufacturers should pay attention to the discount safe harbor requirements applicable to "sellers" and "offerors" of discounts. Under the safe harbor, sellers and offerors have specific obligations that include (i) informing a customer of any discount and of the customer's reporting obligations with respect to that discount, and (ii) refraining from any action that would impede a customer's ability to comply with the safe harbor. To fulfill the safe harbor requirements, manufacturers will need to know how their customers submit claims to the federal health care programs (*e.g.*, whether the customer is a managed care, cost-based, or charge-based biller). Compliance with the safe harbor is determined separately for each party.

Product Support Services. Pharmaceutical manufacturers sometimes offer purchasers certain support services in connection with the sale of their products. These services may include billing assistance tailored to the purchased products, reimbursement consultation, and other programs specifically tied to support of the purchased product. Standing alone, services that have no substantial independent value to the purchaser may not implicate the anti-kickback statute. However, if a manufacturer provides a service having no independent value (such as limited reimbursement support services in connection with its own products) in tandem with another service or program that confers a benefit on a referring provider (such as a reimbursement guarantee that eliminates normal financial risks), the arrangement would raise kickback concerns. For example, the anti-kickback statute would be implicated if a manufacturer were to couple a reimbursement support service with a promise that a purchaser will pay for ordered products only if the purchaser is reimbursed by a federal health care program.

Educational Grants. Pharmaceutical manufacturers sometimes provide grant funding for a wide range of educational activities. 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.

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.

Research Funding. 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.

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.

Other remuneration to purchasers. As already noted, 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. Selective offers of remuneration (*i.e.*, offers made to some but not all purchasers) may increase potential risk if the selection criteria relate directly or indirectly to the volume or value of business generated. In addition, manufacturers may contract with purchasers to provide services to the manufacturer, such as data collection services. These contracts should be structured whenever possible to fit in the personal services safe harbor; in all cases, the remuneration should be fair market value for legitimate, reasonable, and necessary services.

(b) Formularies and Formulary Support Activities. To help control drug costs while maintaining clinical appropriateness and quality of patient care, many purchasers of pharmaceutical products, including indirect purchasers such as health plans, have developed drug formularies to promote rational, clinically appropriate, safe, and cost-effective drug therapy. Formularies are a well-established tool for the effective management of drug benefits. The formulary development process—typically overseen by a committee of physicians, pharmacists, and other health care professionals—determines the drugs that are covered and, if tiered benefit levels are utilized, to which tier the drugs are assigned. So long as the determination of clinical efficacy and appropriateness of formulary drugs by the formulary committee precedes, and is paramount to, the consideration of costs, the development of a formulary is unlikely to raise significant issues under the anti-kickback statute.

Formulary support activities, including related communications with patients and physicians to encourage compliance, are an integral and essential component of successful pharmacy benefits management. Proper utilization of a formulary maximizes the cost-effectiveness of the benefit and assures the quality and appropriateness of the drug therapy. When provided by a PBM, these services are part of the PBM's formulary and benefit management function—a service provided to its customers—and markedly different from its purchasing agent/price negotiator role. Most importantly, the benefits of these formulary support activities inure directly to the PBM and its customers through lower costs.

To date, Medicare and Medicaid involvement with outpatient drug formularies has been limited primarily to Medicaid and Medicare managed care plans. In light of the safe harbors under the anti-kickback statute for those managed care arrangements, the financial arrangements between health plans and pharmaceutical manufacturers or, where the pharmacy benefit is managed by a PBM, the arrangements among the three parties, have received relatively little scrutiny. However, as federal program expenditures for, and coverage of, outpatient pharmaceuticals increase, scrutiny under the anti-kickback statute has also increased. Several practices appear to have the potential for abuse.

• *Relationships with formulary committee members.* Given the importance of formulary placement for a manufacturer's products, unscrupulous manufacturers and sales representatives may attempt to influence committee deliberations. Any remuneration from a manufacturer or its agents directly or indirectly to person in a position to influence formulary decisions related to the manufacturer's products are suspect and should be carefully scrutinized. Manufacturers should also review their contacts with sponsors of formularies to ensure that price negotiations do not influence decisions on clinical safety or efficacy.

• *Payments to PBMs.* Any rebates or other payments by drug manufacturers to PBMs that are based on, or otherwise related to, the PBM's customers' purchases *potentially* implicate the anti-kickback statute. Protection is available by structuring such arrangements to fit in the GPO safe harbor at 42 CFR 1001.952(j). That safe harbor requires, among other things, that the payments be authorized in advance by the PBM's customer and that all amounts actually paid to the PBM on account of the customer's purchases be disclosed in writing at least annually to the customer. In addition, arrangements with PBMs that assume risk may raise different issues; depending on the circumstances, protection for such arrangements may be available under the managed care safe harbors at 42 CFR 1001.952(m), (t) and (u).

• *Formulary placement payments.* Lump sum payments for inclusion in a formulary or for exclusive or restricted formulary status are problematic and should be carefully scrutinized.

In addition, some manufacturers provide funding for purchasers' or PBMs' formulary support activities, especially communications with physicians and patients. While the communications may indirectly benefit the manufacturer, the primary economic beneficiary is typically the formulary sponsor. In other words, the manufacturer's dollars appear to replace dollars that would or should be spent by the sponsor. To the extent the manufacturers' payments are linked to drug purchases directly or indirectly, they potentially implicate the anti-kickback statute. Among the questions that should be examined by a manufacturer in connection with these activities are: Is the funding tied to specific drugs or categories? If so, are the categories especially competitive? Is the formulary sponsor funding similar activities for other drug categories? Has funding of PBM activities increased as rebates are increasingly passed back to PBM customers?

(c) Average Wholesale Price. The "spread" is the difference between the amount a customer pays for a product and the amount the customer receives upon resale of the product to the patient or other payer. In many situations under the federal programs, pharmaceutical manufacturers control not only the amount at which they sell a product to their customers, but also the amount those customers who purchase the product for their own accounts and thereafter bill the federal health care programs will be reimbursed. To the extent that a manufacturer controls the "spread," it controls its customer's profit.

Average Wholesale Price (AWP) is the benchmark often used to set reimbursement for prescription drugs under the Medicare Part B program. For covered drugs and biologicals, Medicare Part B generally reimburses at "95 percent of average wholesale price." 42 U.S.C. 1395u(o). Similarly many state Medicaid programs and other payers base reimbursement for drugs and biologicals on AWP. Generally, AWP or pricing information used by commercial price reporting services to determine AWP is reported by pharmaceutical manufacturers.

If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers' profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated. Unlike *bona fide* discounts, which transfer remuneration from a seller to a buyer, manipulation of the AWP transfers remuneration to a seller's immediate customer from a subsequent purchaser (the federal or state government). Under the anti-kickback statute, offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business. In other words, it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the "spread" to induce customers to purchase its product.

In the light of this risk, we recommend that manufacturers review their AWP reporting practices and methodology to confirm that marketing considerations do not influence the process. Furthermore, manufacturers should review their marketing practices. The conjunction of manipulation of the AWP to induce customers to purchase a product with active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute. Active marketing of the spread includes, for example, sales representatives promoting the spread as a reason to purchase the product or guaranteeing a certain profit or spread in exchange for the purchase of a product.

(2) Relationships with Physicians and Other Persons and Entities in a Position to Make or Influence Referrals. Pharmaceutical manufacturers and their agents may have a variety of remunerative relationships with persons or entities in a position to refer, order, or prescribe—or influence the referral, ordering, or prescribing of—the manufacturers' products, even though the persons or entities may not themselves purchase (or in the case of GPOs or PBMs, arrange for the purchase of) those products. These remunerative relationships potentially implicate the anti-kickback statute. The following discussion focuses on relationships with physicians, but the same principles would apply when evaluating relationships with other parties in a position to influence referrals, including, without limitation, pharmacists and other health care professionals.

Manufacturers, providers, and suppliers of health care products and services frequently cultivate relationships with physicians in a position to generate business for them through a variety of practices, including gifts, entertainment, and personal services compensation arrangements. These activities have a high potential for fraud and abuse and, historically, have generated a substantial number of anti-kickback convictions. There is no substantive difference between remuneration from a pharmaceutical manufacturer or from a durable medical equipment or other supplier—if the remuneration is intended to generate any federal health care business, it potentially violates the anti-kickback statute.

Any time a pharmaceutical manufacturer provides anything of value to a physician who might prescribe the manufacturer's product, the manufacturer should examine whether it is providing a valuable tangible benefit to the physician with the intent to induce or reward referrals. For example, if goods or services provided by the manufacturer eliminate an expense that the physician would have otherwise incurred (*i.e.*, have independent value to the physician), or if items or services are sold to a physician at less than their fair market value, the arrangement may be problematic if the arrangement is tied directly or indirectly to the generation of federal health care program business for the manufacturer. Moreover, under the anti-kickback statute, neither a legitimate purpose for an arrangement (*e.g.*, physician education), nor a fair market value payment, will necessarily protect remuneration if there is also an illegal purpose (*i.e.*, the purposeful inducement of business).

In light of the obvious risks inherent in these arrangements, whenever possible prudent manufacturers and their agents or representatives should structure relationships with physicians to fit in an available safe harbor, such as the safe harbors for personal services and management contracts, 42 CFR 1001.952(d), or employees, 42 CFR 1001.952(i). *An arrangement must fit squarely in a safe harbor to be protected.* In addition, arrangements that do not fit in a safe harbor should be reviewed in light of the totality of all facts and circumstances, bearing in mind the following factors, among others:

- *Nature of the relationship between the parties.* What degree of influence does the physician have, directly or indirectly, on the generation of business for the manufacturer? Does the manufacturer have other direct or indirect relationships with the physician or members of the physician's group?
- *Manner in which the remuneration is determined.* Does the remuneration take into account, directly or indirectly, the volume or value of business generated (*e.g.*, is the remuneration only given to persons who have prescribed or agreed to prescribe the manufacturer's product)? Is the remuneration conditioned in whole or in part on referrals or other business generated? Is there any service provided other than referrals?
- *Value of the remuneration.* Is the remuneration more than trivial in value, including all gifts to any individual, entity, or group of individuals? [10] Do fees for services exceed the fair market value of any legitimate, reasonable, and necessary services rendered by the physician to the manufacturer?
- *Potential federal program impact of the remuneration.* Does the remuneration have the potential to affect costs to any of the federal health care programs or their beneficiaries or to lead to overutilization or inappropriate utilization?
- *Potential conflicts of interest.* Would acceptance of the remuneration diminish, or appear to diminish, the objectivity of professional judgment? Are there patient safety or quality of care concerns? If the remuneration relates to the dissemination of information, is the information complete, accurate, and not misleading?

These concerns are addressed in the PhRMA Code on Interactions with Healthcare Professionals (the "PhRMA Code"), adopted on April 18, 2002, which provides useful and practical advice for reviewing and structuring these relationships. (The PhRMA Code is available through PhRMA's Web site at *http://www.phrma.org.*) Although compliance with the PhRMA Code will not protect a manufacturer as a matter of law under the anti-kickback statute, it 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.

The following paragraphs discuss in greater detail several common or problematic relationships between manufacturers and physicians, including "switching" arrangements, consulting and advisory payments, payments for detailing, business courtesies and other gratuities, and educational and research activities.

• *Switching"* arrangements. As noted in the OIG's 1994 Special Fraud Alert (59 FR 65372; December 19, 1994), product conversion arrangements (also known as "switching" arrangements) are suspect under the anti-kickback statute. Switching arrangements involve pharmaceutical manufacturers offering physicians or others cash payments or other benefits each time a patient's prescription is changed to the manufacturer's product from a competing product. This activity clearly implicates the statute, and, while such programs may be permissible in certain managed care arrangements, manufacturers should review very carefully any marketing practices utilizing "switching" payments in connection with products reimbursable by federal health care programs.

Consulting and advisory payments. Pharmaceutical manufacturers frequently engage physicians and other health care professionals to furnish personal services as consultants or advisers to the manufacturer. 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.

At a minimum, manufacturers should periodically review arrangements for physicians' services to ensure that: (i) The arrangement is set out in writing; (ii) there is a legitimate need for the services; (iii) the services are provided; (iv) the compensation is at fair market value; and (v) all of the preceding facts are documented prior to payment. In addition, to further reduce their risk, manufacturers should structure services arrangements to comply with a safe harbor whenever possible.

Payments for detailing. 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.

Business Courtesies and Other Gratuities. Pharmaceutical companies and their employees and agents often engage in a number of other arrangements that offer benefits, directly or indirectly, to physicians or others in a position to make or influence referrals. Examples of remunerative arrangements between pharmaceutical manufacturers (or their representatives) and parties in a position to influence referrals include:

• Entertainment, recreation, travel, meals, or other benefits in association with information or marketing presentations; and

• Gifts, gratuities, and other business courtesies.

As discussed above, these arrangements potentially implicate the anti-kickback statute if any one purpose of the arrangement is to generate business for the pharmaceutical company. While the determination of whether a particular arrangement violates the anti-kickback statute depends on the specific facts and circumstances, compliance with the PhRMA Code with respect to these arrangements should substantially reduce a manufacturer's risk.

Educational and Research Funding. In some cases, manufacturers contract with physicians to provide research services 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. Research contracts that originate through the sales or marketing functions—or that are offered to physicians in connection with sales contacts—are particularly suspect. Indicia of questionable research include, for example, research initiated or directed by marketers or sales agents; research that is not transmitted to, or reviewed by, a manufacturer's science component; research that is unnecessarily duplicative or is not needed by the manufacturer for any purpose other than the generation of business; and post-marketing research used as a pretense to promote product. Prudent manufacturers will develop contracting procedures that clearly separate the awarding of research contracts from marketing or promotion of their products.

In addition, pharmaceutical manufacturers also provide other funding for a wide range of physician educational and research activities. Manufacturers should review educational and research grants to physicians similarly to educational and research grants to purchasers (described above). As with grants to purchasers, the OIG recognizes that many grant-funded activities are legitimate and beneficial. When evaluating educational or research grants provided by manufacturers to physicians, manufacturers should determine if the funding is based, in any way, expressly or implicitly, on the physician's referral of the manufacturer's product. If so, the funding plainly implicates the anti-kickback statute. In addition, the manufacturer should determine whether the funding is for *bona fide* educational or research purposes. Absent unusual circumstances, grants or support for educational activities sponsored and organized by medical professional organizations raise little risk of fraud or abuse, provided that the grant or support is not restricted or conditioned with respect to content or faculty.

Pharmaceutical manufacturers often provide funding to other sponsors of continuing medical education (CME) programs. Manufacturers should take steps to ensure that neither they, nor their representatives, are using these activities to channel improper remuneration to physicians or others in a position to generate business for the manufacturer or to influence or control the content of the program.[13] In addition, manufacturers and sponsors of educational programs should be mindful of the relevant rules and regulations of the Food and Drug Administration. Codes of conduct promulgated by the CME industry may provide a useful starting point for manufacturers when reviewing their CME arrangements.

(3) Relationships with Sales Agents. In large part, a pharmaceutical manufacturer's commitment to an effective fraud and abuse compliance program can be measured by its

commitment to training and monitoring its sales force. A pharmaceutical manufacturer should: (i) Develop a regular and comprehensive training program for its sales force, including refresher and updated training on a regular basis, either in person or through newsletters, memoranda, or the like; (ii) familiarize its sales force with the minimum PhRMA Code standards and other relevant industry standards; (iii) institute and implement corrective action and disciplinary policies applicable to sales agents who engage in improper marketing; (iv) avail itself of the advisory opinion process if it has questions about particular practices used by its sales force; and (v) establish an effective system for tracking, compiling, and reviewing information about sales force activities, including, if appropriate, random spot checking.

In addition, manufacturers should carefully review their compensation arrangements with sales agents. Sales agents, whether employees or independent contractors, are paid to recommend and arrange for the purchase of the items or services they offer for sale on behalf of the pharmaceutical manufacturer they represent. Many arrangements can be structured to fit in the employment or personal services safe harbor. Arrangements that cannot fit into a safe harbor should be carefully reviewed. Among the factors that should be evaluated are:

- The amount of compensation;
- The identity of the sales agent engaged in the marketing or promotional activity (*e.g.*, is the agent a "white coat" marketer or otherwise in a position of exceptional influence);
- The sales agent's relationship with his or her audience;
- The nature of the marketing or promotional activity;
- The item or service being promoted or marketed; and
- The composition of the target audience.

Manufacturers should be aware that a compensation arrangement with a sales agent that fits in a safe harbor can still be evidence of a manufacturer's improper intent when evaluating the legality of the manufacturer's relationships with persons in a position to influence business for the manufacturer. For example, if a manufacturer provides sales employees with extraordinary incentive bonuses and expense accounts, there may well be an inference to be drawn that the manufacturer intentionally motivated the sales force to induce sales through lavish entertainment or other remuneration.

c. Drug Samples. The provision of drug samples is a widespread industry practice that can benefit patients, but can also be an area of potential risk to a pharmaceutical manufacturer. The Prescription Drug Marketing Act of 1987 (PDMA) governs the distribution of drug samples and forbids their sale. 21 U.S.C. 353(c)(1). A drug sample is defined to be a unit of the drug "that is not intended to be sold * * * and is intended to promote the sale of the drug." 21 U.S.C. 353(c)(1). Failure to comply with the requirements of PDMA can result in sanctions. In some circumstances, if the samples have monetary value to the recipient (*e.g.*, a physician) and are used to treat federal health care program beneficiaries, the improper use of samples may also trigger liability under other statutes, including the False Claims Act and the anti-kickback statue.

Pharmaceutical manufacturers should closely follow the PDMA requirements (including all documentation requirements). In addition, manufacturers can minimize their risk of liability by: (i) Training their sales force to inform sample recipients in a meaningful manner that samples may not be sold or billed (thus vitiating any monetary value of the sample); (ii) clearly and conspicuously labeling individual samples as units that may not be sold (thus minimizing the ability of recipients to advertently or inadvertently commingle samples with purchased product); and (iii) including on packaging and any documentation related to the samples (such as shipping notices or invoices) a clear and conspicuous notice that the samples are subject to PDMA and may not be sold. Recent government enforcement activity has focused on instances in which drug samples were provided to physicians who, in turn, sold them to the patient or billed them to the federal health care programs on behalf of the patient.

C. Designation of a Compliance Officer and a Compliance Committee

1. Compliance Officer

Every pharmaceutical manufacturer should designate a compliance officer to serve as the focal point for compliance activities.[12] This responsibility may be the individual's sole duty or added to other management responsibilities, depending upon the size and resources of the company and the complexity of the task. If the individual has additional management responsibilities, the pharmaceutical manufacturer should ensure that the individual is able to dedicate adequate and substantive time and attention to the compliance functions. Similarly, if the compliance officer delegates some of the compliance duties, he or she should, nonetheless, remain sufficiently involved to fulfill the compliance oversight function.

Designating a compliance officer with the appropriate authority is critical to the success of the program, necessitating the appointment of a high-level official with direct access to the company's president or CEO, board of directors, all other senior management, and legal counsel. The compliance officer should have sufficient funding, resources, and staff to perform his or her responsibilities fully. The compliance officer should be able to effectuate change within the organization as necessary or appropriate and to exercise independent judgment. Optimal placement of the compliance officer within the organization will vary according to the particular situation of a manufacturer.[13]

Coordination and communication with other appropriate individuals or business units are the key functions of the compliance officer with regard to planning, implementing or enhancing, and monitoring the compliance program. The compliance officer's primary responsibilities should include:

- Overseeing and monitoring implementation of the compliance program;[14]
- Reporting on a regular basis to the company's board of directors, CEO or president, and compliance committee (if applicable) on compliance matters and assisting these individuals or groups to establish methods to reduce the company's vulnerability to fraud and abuse;
- Periodically revising the compliance program, as appropriate, to respond to changes in the company's needs and applicable federal health care program requirements, identified weakness in the compliance program, or identified systemic patterns of noncompliance;
- Developing, coordinating, and participating in a multifaceted educational and training program that focuses on the elements of the compliance program, and seeking to ensure that all affected employees and management understand and comply with pertinent federal and state standards;
- Ensuring that independent contractors and agents, particularly those agents and contractors who are involved in sales and marketing activities, are aware of the requirements of the company's compliance program with respect to sales and marketing activities, among other things;
- Coordinating personnel issues with the company's Human Resources/

Personnel office (or its equivalent) to ensure that the List of Excluded Individuals/Entities [15] has been checked with respect to all employees and independent contractors;

- Assisting the company's internal auditors in coordinating internal compliance review and monitoring activities;
- Reviewing and, where appropriate, acting in response to reports of noncompliance received through the hotline (or other established reporting mechanism) or otherwise brought to his or her attention (*e.g.*, as a result of an internal audit or by corporate counsel who may have been notified of a potential instance of noncompliance);
- Independently investigating and acting on matters related to compliance. To that end, the compliance officer should have the flexibility to design and coordinate internal investigations (*e.g.*, responding to reports of problems or suspected violations) and any resulting corrective action (*e.g.*, making necessary improvements to policies and practices, and taking appropriate disciplinary action) with various company divisions or departments;
- Participating with the company's counsel in the appropriate reporting of any self-discovered violations of federal health care program requirements; and
- Continuing the momentum and, as appropriate, revision or expansion of the compliance program after the initial years of implementation.[16]

The compliance officer must have the authority to review all documents and other information relevant to compliance activities. This review authority should enable the compliance officer to examine interactions with government programs to determine whether the company is in compliance with federal health care program reporting and rebate requirements and to examine interactions with health care professionals that could violate kickback prohibitions or other federal health care programs requirements. Where appropriate, the compliance officer should seek the advice of competent legal counsel about these matters.

2. Compliance Committee

The OIG recommends that a compliance committee be established to advise the compliance officer and assist in the implementation of the compliance program.[17] When developing an appropriate team of people to serve as the pharmaceutical manufacturer's compliance committee, the company should consider a variety of skills and personality traits that are expected from the team members. The company should expect its compliance committee members and compliance officer to demonstrate high integrity, good judgment, assertiveness, and an approachable demeanor, while eliciting the respect and trust of company employees. These interpersonal skills are as important as the professional experience of the compliance officer and each member of the compliance committee.

Once a pharmaceutical manufacturer chooses the people who will accept the responsibilities vested in members of the compliance committee, the company needs to train these individuals on the policies and procedures of the compliance program, as well as how to discharge their duties. The OIG recognizes that some pharmaceutical manufacturers (*e.g.*, small companies or those with limited budgets) may not have the resources or the need to establish a compliance committee. However, when potential problems are identified at such companies, the OIG recommends the creation of a "task force" to address the particular issues. The members of the task force may vary depending upon the area of concern. For example, if the compliance officer identifies issues relating to improper inducements to the company's purchasers or prescribers, the OIG recommends that a task force be organized to review the arrangements and interactions with those purchasers or prescribers. In essence, the compliance committee is an extension of the compliance officer and provides the organization with increased oversight.

D. Conducting Effective Training and Education

The proper education and training of officers, directors, employees, contractors, and agents, and periodic retraining of personnel at all levels are critical elements of an effective compliance program. A pharmaceutical manufacturer must take steps to communicate effectively its standards and procedures to all affected personnel by requiring participation in appropriate training programs and by other means, such as disseminating publications that explain specific requirements in a practical manner. These training programs should include general sessions summarizing the manufacturer's compliance program, written standards, and applicable federal health care program requirements. All employees and, where feasible and appropriate, contractors should receive the general training. More specific training on issues, such as (i) the anti-kickback statute and how it applies to pharmaceutical sales and marketing practices and (ii) the calculation and reporting of pricing information and payment of rebates in connection with federal health care programs, should be targeted at those employees and contractors whose job requirements make the information relevant. The specific training should be tailored to make it as meaningful as possible for each group of participants.

Managers and employees of specific divisions can assist in identifying specialized areas that require training and in carrying out such training. Additional areas for training may also be identified through internal audits and monitoring and from a review of any past compliance problems of the pharmaceutical manufacturer or similarly situated companies. A pharmaceutical manufacturer should regularly review its training and, where appropriate, update the training to reflect issues identified through audits or monitoring and any relevant changes in federal health care program requirements. Training instructors may come from outside or inside the organization, but must be qualified to present the subject matter involved and sufficiently experienced in the issues presented to adequately field questions and coordinate discussions among those being trained. Ideally, training instructors should be available for follow-up questions after the formal training session has been conducted.

The pharmaceutical manufacturer should train new employees soon after they have started working. Training programs and materials should be designed to take into account the skills, experience, and knowledge of the individual trainees. The compliance officer should document any formal training undertaken by the company as part of the compliance program. The company should retain adequate records of its training of employees, including attendance logs, descriptions of the training sessions, and copies of the material distributed at training sessions.

The OIG suggests that all relevant personnel (*i.e.*, employees as well as agents of the pharmaceutical manufacturer) participate in the various educational and training programs of the company. For example, for sales representatives who are responsible for the sale and marketing of the company's products, periodic training in the anti-kickback statute and its safe harbors should be required. Employees should be required to have a minimum number of educational hours per year, as appropriate, as part of their employment responsibilities.

The OIG recognizes that the format of the training program will vary depending upon the size and resources of the pharmaceutical manufacturer. For example, a company with limited resources or whose sales force is widely dispersed may want to create a videotape or computer-based program for each type of training session so new employees and employees outside of central locations can receive training in a timely manner. If videos or computer-based programs are used for compliance training, the OIG suggests that the company make a qualified individual available to field questions from trainees. Also, large pharmaceutical manufacturers may find training via the Internet or video conference capabilities to be a cost-effective means of reaching a large number of employees. Alternatively, large companies may include training sessions as part of regularly scheduled regional meetings.

The OIG recommends that participation in training programs be made a condition of continued employment and that failure to comply with training requirements should result in disciplinary action. Adherence to the training requirements as well as other provisions of the compliance program should be a factor in the annual evaluation of each employee.

E. Developing Effective Lines of Communication

1. Access to Supervisors and/or the Compliance Officer

In order for a compliance program to work, employees must be able to ask questions and report problems. Supervisors play a key role in responding to employee concerns and it is appropriate that they serve as a first line of communications. Pharmaceutical manufacturers should consider the adoption of open-door policies in order to foster dialogue between management and employees. In order to encourage communications, confidentiality and non-retaliation policies should also be developed and distributed to all employees.[18]

Open lines of communication between the compliance officer and employees are equally important to the successful implementation of a compliance program and the reduction of any potential for fraud and abuse. In addition to serving as a contact point for reporting problems and initiating appropriate responsive action, the compliance officer should be viewed as someone to whom personnel can go to get clarification on the company's policies. Questions and responses should be documented and dated and, if appropriate, shared with other staff so that compliance standards or polices can be updated and improved to reflect any necessary changes or clarifications. Pharmaceutical manufacturers may also consider rewarding employees for appropriate use of established reporting systems as a way to encourage the use of such systems.

2. Hotlines and Other Forms of Communication

The OIG encourages the use of hotlines, e-mails, newsletters, suggestion boxes, and other forms of information exchange to maintain open lines of communication. In addition, an effective employee exit interview program could be designed to solicit information from departing employees regarding potential misconduct and suspected violations of company policy and procedures. Pharmaceutical manufacturers may also identify areas of risk or concern through periodic surveys or communications with sales representatives about the current marketing environment. This could provide management with insight about and an opportunity to address conduct occurring in the field, either by the company's own sale representatives or those of other companies.

If a pharmaceutical manufacturer establishes a hotline or other reporting mechanism, information regarding how to access the reporting mechanism should be made readily available to all employees and independent contractors by including that information in the code of conduct or by circulating the information (*e.g.*, by publishing the hotline number or e-mail address on wallet cards) or conspicuously posting the information in common work areas. Employees should be permitted to report matters on an anonymous basis.

Reported matters that suggest substantial violations of compliance policies or applicable Federal health care program requirements should be documented and investigated promptly to determine their veracity and the scope and cause of any underlying problem. The compliance officer should maintain a detailed log that records such reports, including the nature of any investigation, its results, and any remedial or disciplinary action taken. Such information, redacted of individual identifiers, should be summarized and included in reports to the board of directors, the president or CEO, and compliance committee. Although the pharmaceutical manufacturer should always strive to maintain the confidentiality of an employee's identity, it should also make clear that there might be a point where the individual's identity may become known or need to be revealed in certain instances. The OIG recognizes that protecting anonymity may be infeasible for small companies. However, the OIG believes all employees, when seeking answers to questions or reporting potential instances of fraud and abuse, should know to whom to turn for a meaningful response and should be able to do so without fear of retribution.

F. Auditing and Monitoring

An effective compliance program should incorporate thorough monitoring of its implementation and an ongoing evaluation process. The compliance officer should document this ongoing monitoring, including reports of suspected noncompliance, and provide these assessments to company's senior management and the compliance committee. The extent and frequency of the compliance audits may vary depending on variables such as the pharmaceutical manufacturer's available resources, prior history of noncompliance, and the risk factors particular to the company. The nature of the reviews may also vary and could include a prospective systemic review of the manufacturer's processes, protocols, and practices or a retrospective review of actual practices in a particular area.

Although many assessment techniques are available, it is often effective to have internal or external evaluators who have relevant expertise perform regular compliance reviews. The reviews should focus on those divisions or departments of the pharmaceutical manufacturer that have substantive involvement with or impact on federal health care programs (such as the government contracts and sales and marketing divisions) and on the risk areas identified in this guidance. The reviews should also evaluate the company's policies and procedures regarding other areas of concern identified by the OIG (*e.g.*, through Special Fraud Alerts) and federal and state law enforcement agencies. Specifically, the reviews should evaluate whether the: (1) Pharmaceutical manufacturer has policies covering the identified risk areas; (2) policies were implemented and communicated; and (3) policies were followed.

G. Enforcing Standards Through Well-Publicized Disciplinary Guidelines

An effective compliance program should include clear and specific disciplinary policies that set out the consequences of violating the law or the pharmaceutical manufacturer's code of

conduct or policies and procedures. A pharmaceutical manufacturer should consistently undertake appropriate disciplinary action across the company in order for the disciplinary policy to have the required deterrent effect. Intentional and material noncompliance should subject transgressors to significant sanctions. Such sanctions could range from oral warnings to suspension, termination or other sanctions, as appropriate. Disciplinary action also may be appropriate where a responsible employee's failure to detect a violation is attributable to his or her negligence or reckless conduct. Each situation must be considered on a case-by-case basis, taking into account all relevant factors, to determine the appropriate response.

H. Responding to Detected Problems and Developing Corrective Action Initiatives

Violation of a pharmaceutical manufacturer's compliance program, failure to comply with applicable federal or state law, and other types of misconduct threaten the company's status as a reliable, honest, and trustworthy participant in the health care industry. Detected but uncorrected misconduct can endanger the reputation and legal status of the company. Consequently, upon receipt of reasonable indications of suspected noncompliance, it is important that the compliance officer or other management officials immediately investigate the allegations to determine whether a material violation of applicable law or the requirements of the compliance program has occurred and, if so, take decisive steps to correct the problem.[19] The exact nature and level of thoroughness of the investigation will vary according to the circumstances, but the review should be detailed enough to identify the root cause of the problem. As appropriate, the investigation may include a corrective action plan, a report and repayment to the government, and/or a referral to criminal and/or civil law enforcement authorities.

Reporting

Where the compliance officer, compliance committee, or a member of senior management discovers credible evidence of misconduct from any source and, after a reasonable inquiry, believes that the misconduct may violate criminal, civil, or administrative law, the company should promptly report the existence of misconduct to the appropriate federal and state authorities[20] within a reasonable period, but not more than 60 days,[21] after determining that there is credible evidence of a violation.[22] Prompt voluntary reporting will demonstrate the pharmaceutical manufacturer's good faith and willingness to work with governmental authorities to correct and remedy the problem. In addition, reporting such conduct will be considered a mitigating factor by the OIG in determining administrative sanctions (*e.g.*, penalties, assessments, and exclusion), if the reporting company becomes the subject of an OIG investigation.[23]

When reporting to the government, a pharmaceutical manufacturer should provide all information relevant to the alleged violation of applicable federal or state law(s) and the potential financial or other impact of the alleged violation. The compliance officer, under advice of counsel and with guidance from the governmental authorities, could be requested to continue to investigate the reported violation. Once the investigation is completed, and especially if the investigation ultimately reveals that criminal, civil or administrative violations have occurred, the compliance officer should notify the appropriate governmental authority of the outcome of the investigation, including a description of the impact of the alleged violation on the operation of the applicable federal health care programs or their beneficiaries.

III. Conclusion

In today's environment of increased scrutiny of corporate conduct and increasingly large expenditures for prescription drugs, it is imperative for pharmaceutical manufacturers to establish and maintain effective compliance programs. These programs should foster a culture of compliance that begins at the executive level and permeates throughout the organization. This compliance guidance is designed to provide assistance to all pharmaceutical manufacturers as they either implement compliance programs or re-assess existing programs. The essential elements outlined in this compliance guidance can be adapted to the unique environment of each manufacturer. It is the hope and expectation of the OIG that the resulting compliance programs will benefit not only federal health care programs and their beneficiaries, but also pharmaceutical manufacturers themselves.

Dated: April 23, 2003.

Janet Rehnquist,

Inspector General.

Endnotes

1. The term "Federal health care programs," as defined in 42 U.S.C. 1320a–7b(f), includes any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States government or any state health plan (e.g., Medicaid or a program receiving funds from block grants for social services or child health services). In this document, the term "federal health care program requirements" refers to the statutes, regulations and other rules governing Medicare, Medicaid, and all other federal health care programs.

2. *See* 66 FR 31246 (June 11, 2001), "Notice for Solicitation of Information and Recommendations for Developing a Compliance Program Guidance for the Pharmaceutical Industry."

3. *See* 67 FR 62057 (October 3, 2002), "Draft OIG Compliance Program Guidance for Pharmaceutical Manufacturers."

4. 42 U.S.C. 1320a–7b(b).

5. In addition, the compliance program elements and potential risk areas addressed in this compliance program guidance may also have application to manufacturers of other products that may be reimbursed by federal health care programs, such as medical devices and infant nutritional products.

6. In addition, pharmaceutical manufacturers should be mindful that many states have fraud and abuse statutes—including false claims, anti-kickback and other statutes—that are not addressed in this guidance.

7. The False Claims Act (31 U.S.C. 3729–33) prohibits knowingly presenting (or causing to be presented) to the federal government a false or fraudulent claim for payment or approval. Additionally, it prohibits knowingly making or using (or causing to be made or used) a false record or statement to get a false or fraudulent claim paid or approved by the federal government or its agents, like a carrier, other claims processor, or state Medicaid program.

8. The 340B Program, contained as part of the Public Health Services Act and codified at 42 U.S.C. 256b, is administered by the Health Resources and Services Administration (HRSA).

9. 42 U.S.C. 1396r–8. Average Manufacturer Price and Best Price are defined in the statute at 42 U.S.C. 1396r–8(k)(1) and 1396r–8(c)(1), respectively. CMS has provided further guidance on these terms in the National Drug Rebate Agreement and in Medicaid Program Releases available through its Web site at *http://www.hcfa.gov/medicaid/drugs/drug.mpg.htm.*

10. In this regard, pharmaceutical manufacturers should note that the exception for non-monetary compensation under the Stark law (42 U.S.C. 1395nn; 42 CFR 411.357(k)) is not a basis for protection under the anti-kickback statute.

11. CME programs with no industry sponsorship, financing, or affiliation should not raise anti-kickback concerns, although tuition payments by manufacturers (or their representatives) for persons in a position to influence referrals (e.g., physicians or medical students) may raise concerns.

12. It is also advisable to designate as a compliance officer an individual with prior experience or knowledge of compliance and

operational issues relevant to pharmaceutical manufacturers.

13. The OIG believes it is generally not advisable for the compliance function to be subordinate to the pharmaceutical manufacturer's general counsel, or comptroller or similar financial officer. Separation of the compliance function helps to ensure independent and objective legal reviews and financial analysis of the company's compliance efforts and activities. By separating the compliance function from the key management positions of general counsel or chief financial officer (where the size and structure of the pharmaceutical manufacturer make this a feasible option), a system of checks and balances is established to more effectively achieve the goals of the compliance program.

14. For companies with multiple divisions or regional offices, the OIG encourages coordination with each company location through the use of a compliance officer located in corporate headquarters who is able to communicate with parallel compliance liaisons in each division or regional office, as appropriate.

15. As part of its commitment to compliance, a pharmaceutical manufacturer should carefully consider whether to hire or do business with individuals or entities that have been sanctioned by the OIG. The List of Excluded Individuals and Entities can be checked electronically and is accessible through the OIG's Web site at: *http://oig.hhs.gov*.

16. There are many approaches the compliance officer may enlist to maintain the vitality of the compliance program. Periodic on-site visits of regional operations, bulletins with compliance updates and reminders, distribution of audiotapes, videotapes, CD ROMs, or computer notifications about different risk areas, lectures at management and employee meetings, and circulation of recent articles or publications discussing fraud and abuse are some examples of approaches the compliance officer may employ.

17. The compliance committee benefits from having the perspectives of individuals with varying responsibilities and areas of knowledge in the organization, such as operations, finance, audit, human resources, legal, and sales and marketing, as well as employees and managers of key operating units. The compliance officer should be an integral member of the committee. All committee members should have the requisite seniority and comprehensive experience within their respective departments to recommend and implement any necessary changes to policies and procedures.

18. In some cases, employees sue their employers under the False Claims Act's *qui tam* provisions after a failure or apparent failure by the company to take action when the employee brought a questionable, fraudulent, or abusive situation to the attention of senior corporate officials. Whistleblowers must be protected against retaliation, a concept embodied in the provisions of the False Claims Act. *See* 31 U.S.C. 3730(h).

19. Instances of noncompliance must be determined on a case-by-case basis. The existence or amount of a *monetary* loss to a federal health care program is not solely determinative of whether the conduct should be investigated and reported to governmental authorities. In fact, there may be instances where there is no readily identifiable monetary loss, but corrective actions are still necessary to protect the integrity of the health care program.

20. Appropriate federal and state authorities include the OIG, the Criminal and Civil Divisions of the Department of Justice, the U.S. Attorney in relevant districts, the Food and Drug Administration, the Federal Trade Commission, the Drug Enforcement Administration and the Federal Bureau of Investigation, and the other investigative arms for the agencies administering the affected federal or state health care programs, such as the state Medicaid Fraud Control Unit, the Defense Criminal Investigative Service, the Department of Veterans Affairs, HRSA, and the Office of Personnel Management (which administers the Federal Employee Health Benefits Program).

21. In contrast, to qualify for the "not less than double damages" provision of the False Claims Act, the provider must provide the report to the government within 30 days after the date when the provider first obtained the information. 31 U.S.C. 3729(a).

22. Some violations may be so serious that they warrant immediate notification to governmental authorities prior to, or simultaneous with, commencing an internal investigation. By way of example, the OIG believes a provider should report misconduct that: (1) Is a clear violation of administrative, civil, or criminal laws; (2) has a significant adverse effect on the quality of care provided to federal health care program beneficiaries; or (3) indicates evidence of a systemic failure to comply with applicable laws or an existing corporate integrity agreement, regardless of the financial impact on federal health care programs.

23. The OIG has published criteria setting forth those factors that the OIG takes into consideration in determining whether it is appropriate to exclude an individual or entity from program participation pursuant to 42 U.S.C. 1320a–7(b)(7) for violations of various fraud and abuse laws. *See* 62 FR 67392 (December 24, 1997).

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BILLING CODE 4152–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

National Evaluation of the Comprehensive Community Mental Health Services for Children and Their Families Program: Phase Three—(OMB No. 0930–0209, revision)—SAMHSA's Center for Mental Health Services is conducting Phase III of the national evaluation of the Comprehensive Community Mental Health Services for Children and Their Families Program. Phase III collects data on child mental health outcomes, family life, and service system development and performance. Data are being collected on 22 funded systems of care, and approximately 5,100 children and families. Data collection for this evaluation will be conducted over a 5½-year period.

The core of service system data are currently collected every 18 months throughout the evaluation period. Service delivery and system variables of interest include the following: Maturity of system of care development, adherence to the system of care program model, and client service experience. The length of time that individual families will participate in the study ranges from 18 to 36 months depending on when they enter the evaluation.

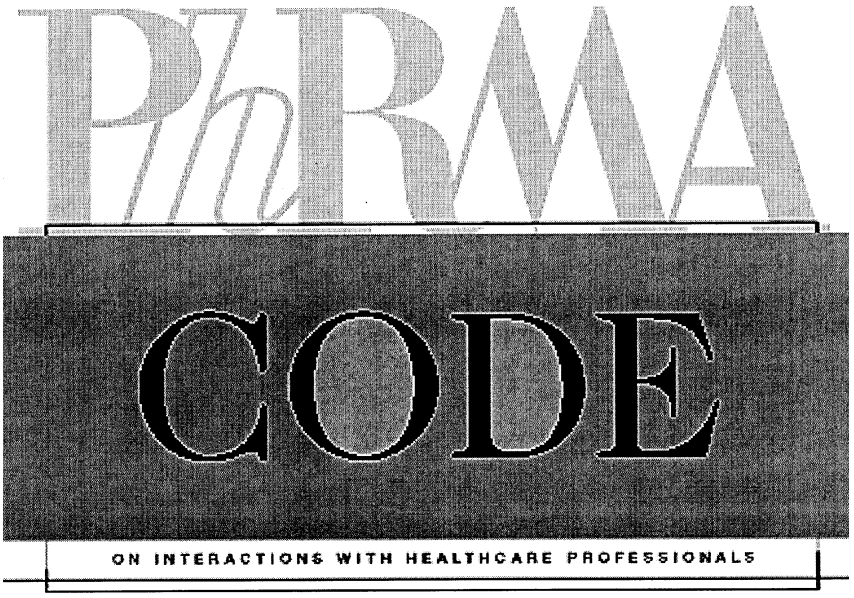
Child and family outcomes of interest will be collected at intake and during subsequent follow-up sessions at six-month intervals. The outcome measures include the following: Child symptomatology and functioning, family functioning, material resources, and caregiver strain. In addition, a treatment effectiveness study will examine the relative impact of an evidence-based treatment within one system of care.

The average annual respondent burden is estimated below. The estimate reflects the average number of respondents in each respondent category, the average number of responses per respondent per year, the average length of time it will take for each response, and the total average annual burden for each category of respondent, and for all categories of respondents combined.

This revision to the currently approved information collection activities involves: (1) Extension of the data collection period for an additional 18 months to cover an additional sixth year of grant funding in the 22 currently funded systems of care (and a six-month no-cost extension for the evaluation), (2) the addition of a family-driven study to assess the extent of family involvement in service planning, (3) the elimination of the longitudinal comparison study and the addition of a treatment effectiveness study in two sites

APPENDIX C

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PHRMA) 2002 "CODE ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS"


PhRMA
CODE
ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS

Preamble

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents research-based pharmaceutical and biotechnology companies. Our members develop and market new medicines to enable patients to live longer and healthier lives.

Ethical relationships with healthcare professionals are critical to our mission of helping patients by developing and marketing new medicines. An important part of achieving this mission is ensuring that healthcare professionals have the latest, most accurate information available regarding prescription medicines, which play an ever-increasing role in patient healthcare. This document focuses on our interactions with healthcare professionals that relate to the marketing of our products.

Effective marketing of medicines ensures that patients have access to the products they need and that the products are used correctly for maximum patient benefit. Our relationships with healthcare professionals are critical to achieving these goals because they enable us to –

- inform healthcare professionals about the benefits and risks of our products,
- provide scientific and educational information,
- support medical research and education, and
- obtain feedback and advice about our products through consultation with medical experts.

In interacting with the medical community, we are committed to following the highest ethical standards as well as all legal requirements. We are also concerned that our interactions with healthcare professionals not be perceived as inappropriate by patients or the public at large. This Code is to reinforce our intention that our interactions with healthcare professionals are to benefit patients and to enhance the practice of medicine. The Code is based on the principle that a healthcare professional's care of patients should be based, and should be perceived as being based, solely on each patient's medical needs and the healthcare professional's medical knowledge and experience.

Therefore, PhRMA adopts, effective July 1, 2002, the following voluntary Code on relationships with healthcare professionals. This Code addresses interactions with respect to marketed products and related pre-launch activities. It does not address relationships with clinical investigators relating to pre-approval studies.

1

Basis of Interactions

Our relationships with healthcare professionals are intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing healthcare professionals about products, providing scientific and educational information, and supporting medical research and education.

2

Informational Presentations by or on Behalf of a Pharmaceutical Company

7

Informational presentations and discussions by industry representatives and others speaking on behalf of a company provide valuable scientific and educational benefits. In connection with such presentations or discussions, occasional meals (but no entertainment/recreational events) may be offered so long as they: (a) are modest as judged by local standards; and (b) occur in a venue and manner conducive to informational communication and provide scientific or educational value. Inclusion of a healthcare professional's spouse or other guests is not appropriate. Offering "take-out" meals or meals to be eaten without a company representative being present (such as "dine & dash" programs) is not appropriate.

3

Third-Party Educational or Professional Meetings

- Continuing medical education (CME) or other third-party scientific and educational conferences or professional meetings can contribute to the improvement of patient care and therefore, financial support from companies is permissible. Since the giving of any subsidy directly to a healthcare professional by a company may be viewed as an inappropriate cash gift, any financial support should be given to the conference's sponsor which, in turn, can use the money to reduce the overall conference registration fee for all attendees. In addition, when companies underwrite medical conferences or meetings other than their own, responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the organizers of the conferences or meetings in accordance with their guidelines.

- Financial support should not be offered for the costs of travel, lodging, or other personal expenses of non-faculty healthcare professionals attending CME or other third-party scientific or educational conferences or professional meetings, either directly to the individuals attending the conference or indirectly to the conference's sponsor (except as set out in section 6 below). Similarly, funding should not be offered to compensate for the time spent by healthcare professionals attending the conference or meeting.

- Financial support for meals or receptions may be provided to the CME sponsors who in turn can provide meals or receptions for all attendees. A company also may provide meals or receptions directly at such events if it complies with the sponsoring organization's guidelines. In either of the above situations, the meals or receptions should be modest and be conducive to discussion among faculty and attendees, and the amount of time at the meals or receptions should be clearly subordinate to the amount of time spent at the educational activities of the meeting.

- A conference or meeting shall mean any activity, held at an appropriate location, where (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentations(s) should be the highlight of the gathering), and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented.

4

Consultants

It is appropriate for consultants who provide services to be offered reasonable compensation for those services and to be offered reimbursement for reasonable travel, lodging, and meal expenses incurred as part of providing those services. Compensation and reimbursement that would be inappropriate in other contexts can be acceptable for bona fide consultants in connection with their consulting arrangements. Token consulting or advisory arrangements should not be used to justify compensating healthcare professionals for their time or their travel, lodging, and other out-of-pocket expenses. The following factors support the existence of a bona fide consulting arrangement (not all factors may be relevant to any particular arrangement):

- a written contract specifies the nature of the services to be provided and the basis for payment of those services;
- a legitimate need for the services has been clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants;
- the criteria for selecting consultants are directly related to the identified purpose and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular healthcare professionals meet those criteria;
- the number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified purpose;
- the retaining company maintains records concerning and makes appropriate use of the services provided by consultants;
- the venue and circumstances of any meeting with consultants are conducive to the consulting services and activities related to the services are the primary focus of the meeting, and any social or entertainment events are clearly subordinate in terms of time and emphasis.

It is not appropriate to pay honoraria or travel or lodging expenses to non-faculty and non-consultant attendees at company-sponsored meetings including attendees who participate in interactive sessions.

5

Speaker Training Meetings

It is appropriate for healthcare professionals who participate in programs intended to recruit and train speakers for company sponsored speaker bureaus to be offered reasonable compensation for their time, considering the value of the type of services provided, and to be offered reimbursement for reasonable travel, lodging, and meal expenses, when (1) the participants receive extensive training on the company's drug products and on compliance with FDA regulatory requirements for communications about such products, (2) this training will result in the participants providing a valuable service to the company, and (3) the participants meet the criteria for consultants (as discussed in part 4.a. above).

6

Scholarships and Educational Funds

15

Financial assistance for scholarships or other educational funds to permit medical students, residents, fellows, and other healthcare professionals in training to attend carefully selected educational conferences may be offered so long as the selection of individuals who will receive the funds is made by the academic or training institution. "Carefully selected educational conferences" are generally defined as the major educational, scientific, or policy-making meetings of national, regional, or specialty medical associations.

7

Educational and Practice-Related Items

- Items primarily for the benefit of patients may be offered to healthcare professionals if they are not of substantial value ($100 or less). For example, an anatomical model for use in an examination room primarily involves a patient benefit, whereas a VCR or CD player does not. Items should not be offered on more than an occasional basis, even if each individual item is appropriate. Providing product samples for patient use in accordance with the Prescription Drug Marketing Act is acceptable.

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

- Items intended for the personal benefit of healthcare professionals (such as floral arrangements, artwork, music CDs or tickets to a sporting event) should not be offered.

- Payments in cash or cash equivalents (such as gift certificates) should not be offered to healthcare professionals either directly or indirectly, except as compensation for bona fide services (as described in parts 4 and 5). Cash or equivalent payments of any kind create a potential appearance of impropriety or conflict of interest.

8

Independence and Decision Making

19

No grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items should be provided or offered to a healthcare professional in exchange for prescribing products or for a commitment to continue prescribing products. Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a healthcare professional's prescribing practices.

9

Adherence to Code

Each member company is strongly encouraged to adopt procedures to assure adherence to this Code.

PhRMA

Q.

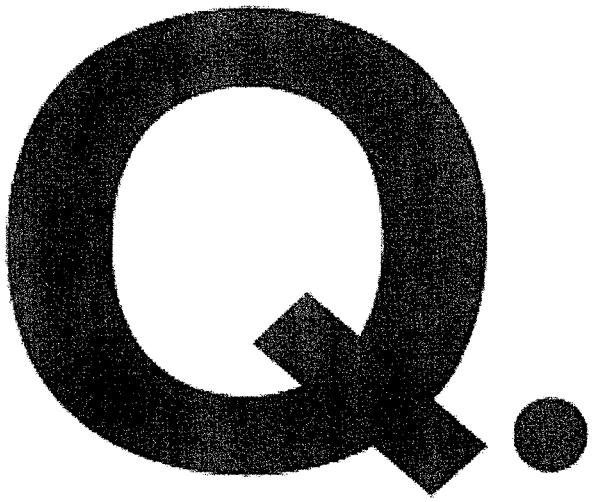
Under the Code, may items such as stethoscopes be offered to health-care professionals?

23

A.

Yes, because these items primarily benefit patients, so long as the items are not of substantial value and are only occasionally offered to the healthcare professional. Items that are of more than minimal value and do not primarily benefit patients are also not permitted even if they bear a company or product name.

PhRMA



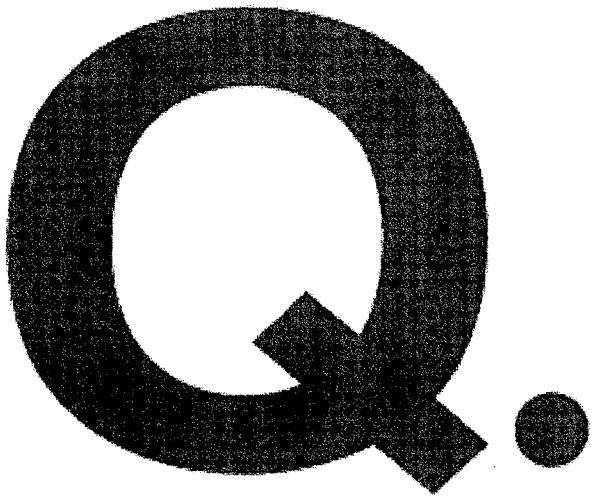
Under the Code, may golf balls and sports bags be provided if they bear a company or product name?

25

A.

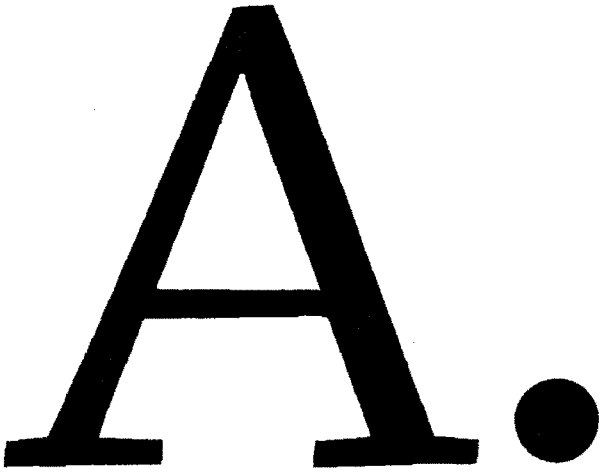
No. Golf balls and sports bags, even if of minimal value, do not primarily entail a benefit to patients and are not primarily associated with the healthcare professional's practice, even if they bear the name of a company or product.

PhRMA



Under the Code, may healthcare professionals be provided with gasoline for their cars if they are provided with product information at the same time?

27



No. Items intended for the personal benefit of a healthcare professional should not be offered.

PhRMA

Q.

The Code says that informational presentations and discussions may be accompanied by occasional, modest meals. What types of presentations and meals would this include?

29

A.

An informational presentation or discussion may be accompanied by a modest meal provided that the venue and manner of presentation/discussion is conducive to a scientific or educational interchange. For example, if a medical or scientific expert (who is a consultant to or employee of the company) is providing information about recently obtained study data to an audience of healthcare professionals, this could be done over lunch or dinner at a quiet restaurant providing the meal was of modest value as judged by local standards.

Following the same logic, if a sales representative is providing substantial scientific or educational information regarding a company's products to one or a few healthcare practitioners, this could also be done during a modest meal which could be at or outside of a physician's office.

However, if the nature or location of the meal would not facilitate communication of the information, then a meal would not be appropriate. Further, the use of modest meals on more than an occasional basis would not be appropriate.

PhRMA

Q.

A representative of Company X provides pizza for the staff of a medical office. Is this consistent with the Code?

31

A.

This would be consistent with the Code if the representative will provide an informational presentation to the medical staff in conjunction with the meal of modest value, so long as the location of the presentation is conducive to a scientific or educational communication. Merely dropping off food for the office staff, however, would not be consistent with the Code.

PhRMA

Q.

A representative of Company X invites physicians to meet to hear a scientific and educational presentation about a new drug at the café at a nearby bookstore. Coffee and cake are provided by the representative and, following the presentation (which is in small groups), each physician is given a gift certificate for books in the amount of $30. Does this conform to the Code?

33

A.

No. While the presentation may present scientific or educational information and the coffee and cake may appropriately be provided, an open-ended gift certificate is a cash equivalent. A medical textbook, a book on patient care, or a gift certificate redeemable solely for a medical textbook or book on patient care could be provided if it is not of substantial value.

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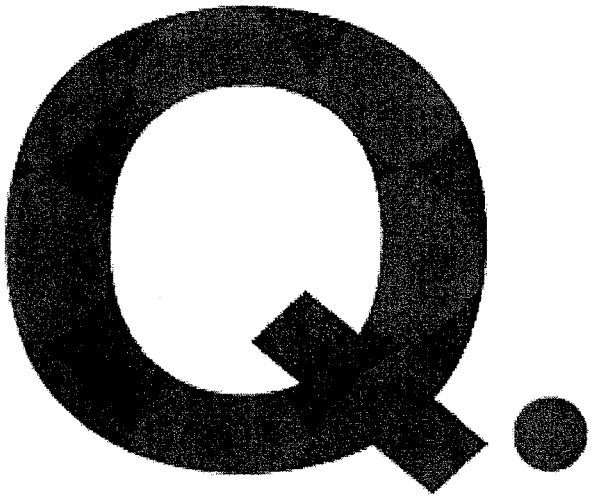

Company C invites 30 physicians to a corporate suite at a professional baseball game for a 45-minute scientific and educational presentation followed by a buffet and the three-hour game. Does this conform to the Code?

35

A.

No. A modest buffet meal accompanying a scientific or educational presentation would be acceptable. However, the provision of entertainment and/or recreational activities, including entertainment at sporting events in connection with an educational or scientific presentation or discussion, is inconsistent with the Code.

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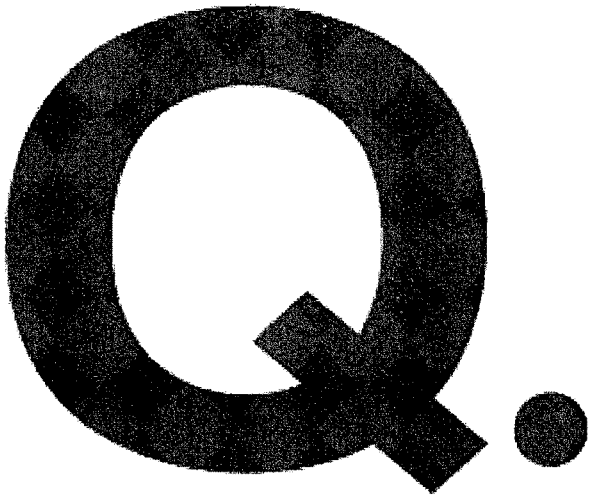

Under what circumstances would the Code permit a company to provide entertainment or recreational activities directly to health-care practitioners?

A.

Companies may provide modest entertainment or recreational activities to healthcare practitioners in a context where those practitioners are providing a legitimate service to the companies, such as when they act as bona fide consultants on an advisory board or are trained at a speaker-training meeting.

Companies should generally not provide entertainment or recreational activities to healthcare practitioners. Thus, companies should not invite healthcare professionals to sporting events, concerts, or shows, or provide them with recreational activities such as hunting, fishing, boating, ski trips, or golf outings, even if those entertainment events or recreational activities are used to facilitate informational interchanges between the company representative and the healthcare professional. Similarly, it would be inappropriate to provide these types of entertainment and recreational events in conjunction with promotional scientific presentations by medical experts.

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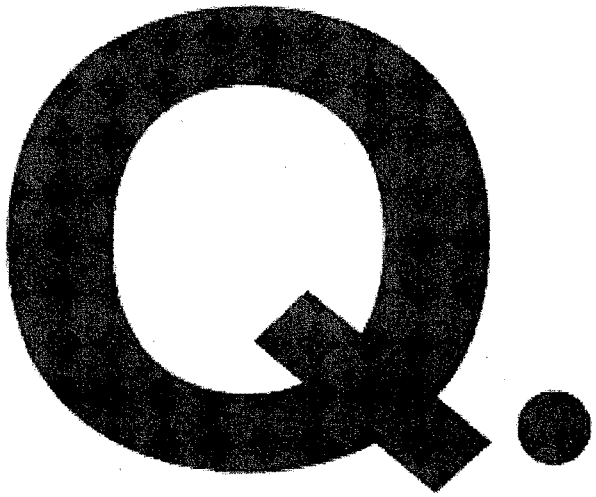

Company A retains a small group of 15 nationally known physicians regarding a therapeutic area relevant to company A's products to advise on general medical and business issues and provide guidance on product development and research programs for those products. These physicians are paid significant fees, but those fees are typical of the fees paid to thought leaders in this therapeutic area. They normally meet once or twice a year at resort locations to discuss the latest product data, research programs and Company plans for the product(s). Does this comply with the Code? If it does, is it appropriate to pay for the spouse of the healthcare professional to attend, as well?

39

A.

This arrangement appears to comply with the Code. The number of advisors seems reasonably small. The advisors seem to have been selected based on their expertise in the areas where advice is needed. While the consultants are paid significant fees, these appear to be reasonable under the circumstances. Finally, while holding consultant meetings at resort locations is not prohibited, the facilities chosen should be conducive to the services provided as well as reasonable and appropriate to the conduct of the meeting.

It would not be appropriate to pay for the cost of the spouse of the advisor. If the spouse attends, it should be at the cost of the advisor.

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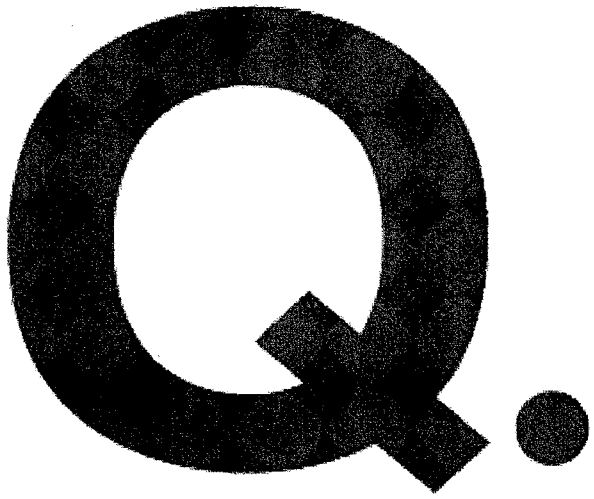

Company A invites 300 physicians/consultants to a two-day and one-night speaker-training program at a regional golf resort. All attendees are compensated for their participation and their expenses are reimbursed. Prospective speakers are selected based on recommendations of the Company's district managers and an assessment of their qualifications by the Company's medical or scientific personnel. Each of the attendees is required to sign an agreement in advance covering the services they will provide. They are educated by a faculty on the full range of data surrounding the disease state and the Company's drug product, on presentation skills, and on FDA regulatory requirements. The Company plans to use at least 280 participants as speakers over the coming year, and it needs to train 300 speakers in order to ensure that 280 will actually be available when needed. Training sessions take both days, and the Company provides for a few hours of golf and meals. Does this program conform to the Code? If so, is it appropriate to pay for a spouse of the healthcare professional, as well?

41

A.

This arrangement appears to comply with the Code. Speaker training is an essential activity because FDA holds companies accountable for the presentations of their speakers. In this case, the participants undergo extensive training that will result in a valuable service being provided to the company, and the arrangement meets reasonable indicia of a bona fide consulting relationship. While resort locations are not prohibited, the Company may want to consider whether it would be more appropriate to hold the training session at a non-resort location. In this case, the number of speakers being trained is important; if significantly more participants were trained than were to be used as speakers, this arrangement would not comply with the Code.

The amount of time spent training speakers should be reasonable in relation to the material that has to be covered. The compensation offered to prospective speakers, including the value of any entertainment, should be evaluated to assure that it is reasonable compensation for that time.

It would not be appropriate to pay for the cost of the spouse of the healthcare professional. If the spouse attends, it should be at the cost of the healthcare professional.

PhRMA

Q.

A sales representative invites a physician out for a round of golf and lunch following the golf. The physician is very busy and is difficult to see in her office. The cost of the golf and the lunch combined are $65. Does this comply with the code?

43

A.

No. It is inconsistent with the Code to provide entertainment or recreational activities such as golf.

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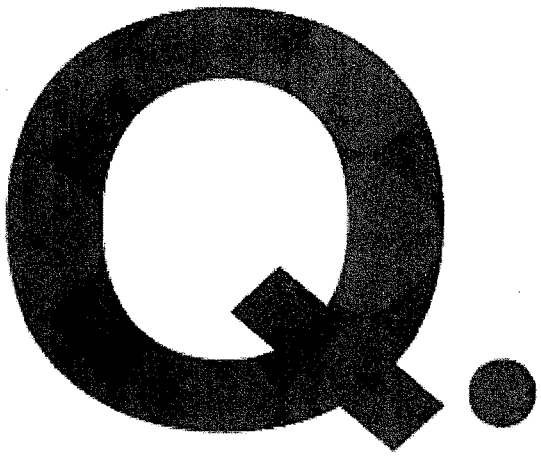

Under the Code, may a healthcare professional's spouse or other guest be included in a meal with a pharmaceutical company representative that is provided in connection with an informational presentation by or on behalf of the company, if the healthcare professional pays for the spouse or guest?

45

A.

No. The Code provides that it is not appropriate to include a spouse or guest at a meal in connection with an informational presentation, regardless of who pays for their meal, unless the spouse or guest would independently qualify as a healthcare professional for whom the informational presentation is appropriate.

PhRMA

Q.

Under the Code, what guidelines apply to financial support for meals and receptions in connection with the meeting of a major medical society or other third-party scientific and educational conferences and professional meetings?

A.

Guideline 3 of the Code addresses financial support for meals or receptions provided in connection with continuing medical education meetings. The same provisions apply to other third-party scientific and educational conferences and professional meetings.

PhRMA

Q.

Under the Code, may a company make a charitable contribution such as purchasing a table at a fundraising dinner or a foursome slot at a fundraising golf tournament?

49

A.

Yes, but the company may not invite healthcare professionals to attend the event at its expense. The company may use some or all of its allotment for its own employees, and return any unused portion to the sponsoring organization to use as it wishes.

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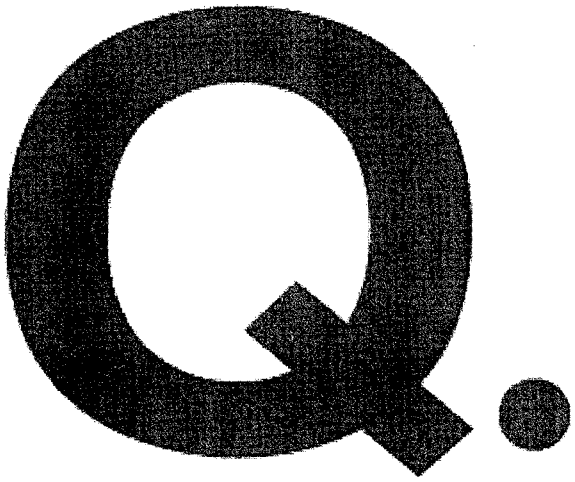

Under the Code, may a company compensate a consultant for bona fide services by providing an item with a legitimate patient benefit in lieu of paying an honorarium or fee?

A.

If the consulting arrangement otherwise complies with the Code, and the fair market value of the item represents reasonable compensation for the services provided, this may be permissible. However, it would be important to comply with all applicable recordkeeping and reporting requirements, just as with cash compensation. The written agreement for the consulting services should set forth the compensation and its fair market value, and disclose that this is taxable income.

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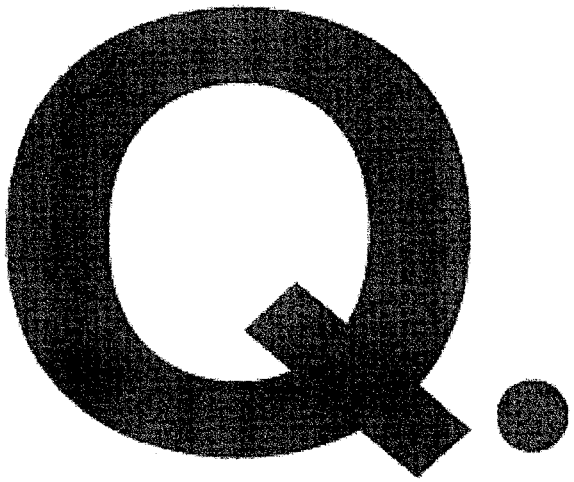

Does the Code apply to interactions with physician office managers, receptionists, and similar personnel who may not be healthcare professionals?

A.

Although the Code does not directly apply to persons who are not healthcare professionals, it would be difficult to separate a company's interactions with any of a physician's employees from those directly with the physician. Therefore, the Code should be followed under these circumstances.

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Revised January 2004

APPENDIX D

FOOD AND DRUG ADMINISTRATION (FDA) 1997 "GUIDANCE FOR INDUSTRY: INDUSTRY-SUPPORTED SCIENTIFIC AND EDUCATIONAL ACTIVITIES"

Guidance for Industry

Industry-Supported Scientific and Educational Activities

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Policy
November 1997

Guidance for Industry[1]

Industry-Supported Scientific and Educational Acivities

I. Background: Promotion, Education, and Independence

Two important sources of information on therapeutic products (human and animal drugs, biological products, and medical devices regulated by the Food and Drug Administration (FDA)) for health care professionals are: (1) Activities (programs and materials) performed by, or on behalf of, the companies that market the products; and (2) activities, supported by companies, that are otherwise independent from the promotional influence of the supporting company. Although both provide valuable and sometimes vital information to health care professionals, the programs and materials performed and disseminated by companies are subject to the labeling and advertising provisions of the Federal Food, Drug, and Cosmetic Act (the act), whereas the truly independent and nonpromotional industry-supported activities have not been subject to FDA regulation.[2]

This jurisdictional line is important because the constraints on advertising and labeling,[3] when applied to scientific and educational activities, can restrict the freedom of participants to discuss their data or express their views. In particular, discussions of unapproved uses, which can be an important component of scientific and educational activities, are not permissible in programs that are or can be (because the provider is not functionally independent) subject to substantive influence by companies that market products related to the discussion. Thus, the agency, has traditionally sought to avoid regulating activities that are produced

[1] This guidance has been prepared by FDA's Intra-Agency Working Group on Advertising and Promotion. This guidance represents the Agency's current thinking on industry-supported scientific and educational activities. It does not create or confer any rights for or on any person and does not operate to bind FDA or the industry. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

[2] In this context, the terms "independent" and "nonpromotional" are not mutually exclusive. The agency views independence as an indication of whether an activity is nonpromotional.

[3] These provisions require the company to ensure that the content does not promote unapproved uses, and that discussions of the company's products are not false or misleading and do not lack fair balance.

independently from the influence of companies marketing the products. The agency recognizes that industry-supported activities can be both nonpromotional and educational.

Demarcating the line between activities that are performed by or on behalf of the company, and thus, subject to regulation, and activities that are essentially independent of their influence has become more difficult due to the increasing role industry has played in supporting postgraduate and continuing education for health care professionals.

The agency traditionally has recognized the important public policy reasons not to regulate all industry-supported activities as advertising or labeling. To permit industry support for the full exchange of views in scientific and educational discussions, including discussions of unapproved uses, FDA has distinguished between those activities supported by companies that are nonpromotional and otherwise independent from the substantive influence of the supporting company and those that are not. Those activities that have been deemed by the agency to be independent from influence by the supporting company and nonpromotional have not been treated as advertising or labeling, and have not been subjected to the agency's regulatory scrutiny.

In determining whether an activity is independent of the substantive influence of a company, the agency examines whether and to what extent the company is in a position to influence the presentation of information related to its products or otherwise transform an ostensibly independent program into a promotional vehicle. FDA is concerned that companies may influence the content of educational programs both directly and indirectly. Directly, by being involved in the selection of speakers or in the treatment of topics. Indirectly, through the nature of the relationship between the company and the provider (e.g., if the provider has reason to believe that future financial support from the company depends upon producing programs that promote the company's products.)

FDA is responsible for seeing that scientific and educational activities that are not intended to be promotional are designed to be truly independent from substantive influence by the marketers of regulated products. The agency recognizes, however, that the primary responsibility for overseeing the process of postgraduate and continuing professional education and scientific exchange lies with the scientific and health

care communities and accrediting organizations. Accordingly, FDA will work closely with scientific and professional health care communities and accrediting organizations to help ensure that provider activities are independent.

The agency is providing this guidance to describe the agency's enforcement policy with regard to scientific and educational activities supported by industry. The guidance seeks to clarify the distinction drawn by the agency between scientific and educational activities that FDA considers nonpromotional and those that the agency considers promotional, and to provide guidance on how industry may support such activities without subjection to regulation under the labeling and advertising provisions of the act.

This guidance applies only to those company-supported activities that relate to the supporting company's products or to competing products. A company-supported educational activity or part thereof that does not relate to the company's products or a competing product, or suggest a use for the company's products, would not be considered a promotional activity under this guidance.

II. Guidance: Industry-Supported Scientific and Educational Activities

FDA has not regulated and does not intend to regulate, under the labeling and advertising provisions of the act, industry-supported scientific and educational activities that are independent of the influence of the supporting company. Companies and providers who wish to ensure that their activities will not be subject to regulation should design and carry out their activities free from the supporting company's influence and bias, based on the factors considered in evaluating activities and determining independence, as described below. These factors are provided to furnish guidance on the design and conduct of such activities, so that they will be educational and nonpromotional in nature. These factors will be considered as part of an overall evaluation of an activity; no individual factor is likely by itself to stimulate an action based on lack of independence.

A. Factors Considered in Evaluating Activities and Determining Independence

FDA will consider the following factors in evaluating programs and activities and determining independence:

(1) Control of Content and Selection of Presenters and Moderators

The agency will consider whether the provider has maintained full control over the content of the program, planning of the program's content, and over the selection of speakers and moderators. In so doing, the agency will look at whether the supporting company has engaged in scripting, targeting points for emphasis, or other actions designed to influence the program's content. In addition, the agency will consider if the company has suggested speakers who are or were actively involved in promoting the company's products or who have been the subject of complaints or objections with regard to presentations that were viewed as misleading or biased in favor of the company's products.

(2) Disclosures

The agency will consider whether there was meaningful disclosure, at the time of the program, to the audience of: (1) The company's funding of the program; (2) any significant relationship between the provider, presenters or moderators, and the supporting company (e.g., employee, grant recipient, owner of significant interest or stock); and (3) whether any unapproved uses of products will be discussed;

(3) The Focus of the Program

The agency will consider whether the intent of the company and the provider is to produce an independent and nonpromotional activity that is focussed on educational content and free from commercial influence or bias. The agency will also consider whether the title of the activity fairly and accurately represents the scope of the presentation.

The agency also will look at the focus of the activity to determine if the central theme is based on a single product marketed by the company or a competing product, except when existing treatment options are so limited as to preclude any meaningful discussion of alternative therapies. This is not to suggest that each treatment option must be discussed with precisely equal emphasis. However, emphasis on a newer or, in the view of the presenter, more beneficial treatment modality should be provided in the context of a discussion of all reasonable and relevant options.

(4) Relationship Between Provider and Supporting Company

The agency will consider whether there are legal, business, or other relationships between the company and the provider that could place the company in a position whereby it may exert influence over the content of the activity (e.g., a provider that is owned by, or is not viable without the support of, the company supporting the activity).

(5) Provider Involvement in Sales or Marketing

The agency will consider whether individuals employed by the provider and involved in designing or conducting scientific or educational activities are also involved in advising or otherwise assisting the company with respect to sales or marketing of the company's product.

(6) Provider's Demonstrated Failure to Meet Standards

The agency will consider whether the provider has a history of conducting programs that fail to meet standards of independence, balance, objectivity, or scientific rigor when putting on ostensibly independent educational programs.

(7) Multiple Presentations

The agency will consider whether multiple presentations of the same program are held.[5]

(8) Audience Selection

The agency will consider whether invitations or mailing lists for supported activities are generated by the sales or marketing departments of the supporting company, or are intended to reflect sales or marketing goals (e.g., to reward high prescribers of the company's products, or to influence "opinion leaders").

(9) Opportunities for Discussion

In the case of a live presentation, the agency will consider whether there was an opportunity for meaningful discussion or questioning provided during the program.

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[5] FDA recognizes that some repeat programs can serve public health interests. The Department of Health and Human Services sometimes actively encourages multiple presentations on selected urgent topics.

(10) Dissemination

The agency will consider whether information about the supporting company's product presented in the scientific or educational activity is further disseminated after the initial program, by or at the behest of the company, other than in response to an unsolicited request or through an independent provider as discussed herein.

(11) Ancillary Promotional Activities

The agency will consider whether there are promotional activities, such as presentations by sales representatives or promotional exhibits, taking place in the meeting room.

(12) Complaints

The agency will consider whether any complaints have been raised by the provider, presenters, or attendees regarding attempts by the supporting company to influence content.

B. Additional Considerations

The foregoing list of factors is not intended to be exhaustive and other factors may be appropriate for consideration in a particular case.

One means of documenting the measures taken to ensure independence of an activity is to have a written agreement between the provider and the supporting company. This document should reflect that the provider will be solely responsible for designing and conducting the activity, and that the activity will be educational, nonpromotional, and free from commercial bias. While not required, a written agreement, coupled with the factors described above, can provide valuable evidence as to whether an activity is independent and nonpromotional.

III. FDA'S Cooperation With Major Accrediting Organizations

FDA recognizes the important role accrediting organizations can play in ensuring that industry-sponsored educational activities are independent and nonpromotional. The agency also recognizes the importance of avoiding undue Government interference in postgraduate and continuing education for health

care professionals, as the agency seeks to ensure that company promotional activities meet applicable legal requirements. Thus, the agency will continue to work with major accrediting organizations to monitor company-supported educational activities conducted by their accredited providers.

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