Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

PROMOTION OF PRESCRIPTION DRUGS THROUGH PAYMENTS AND GIFTS

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EXECUTIVE SUMMARY

PURPOSES

The purposes of this study are to (1) describe the range of drug promotion practices that involve physicians receiving money or other items of value from pharmaceutical companies, (2) assess the vulnerabilities such practices present, and (3) examine the responses of government and private groups to inappropriate or illegal practices.

BACKGROUND

Much attention has focused recently on pharmaceutical companies' promotional techniques. The Senate Labor and Human Resources Committee conducted hearings in December 1990 that highlighted questionable promotional practices. At these hearings, the American Medical Association (AMA) and the Pharmaceutical Manufacturers Association (PMA) testified about ethical guidelines that the AMA had just adopted and the PMA had fully endorsed to help their members avoid potentially unethical situations.

We focus in this report on many drug promotion techniques that have been used recently and on the potential hazards each presents to physicians and the practice of good medicine. Because this report is not based on a statistically valid sample of physicians, we are not reporting on the extent of promotional practices involving money or other items of value.

Our data were gathered from (1) interviews with physicians and pharmacists in six hospitals, (2) ethical guidelines produced by various medical professional and industry groups, and (3) a review of relevant academic and professional literature and mass media.

This is the first of several reports on prescription drug promotion we plan to issue. An upcoming report will focus on the current prevalence of promotional practices involving pharmaceutical companies offering money or other items of value to physicians. Another report will evaluate the scientific merit and validity of prescription drug advertising in medical journals.

FINDINGS

Pharmaceutical companies offer money and other items of value to physicians for a range of purposes, from sponsoring important educational activities to actively promoting their products. Offers that have been used for promotional purposes fall into four major categories.

1. **Studies** - Pharmaceutical companies ask physicians to participate in many types of studies on FDA-approved drugs. The companies offer a wide variety of payments for physicians' involvement, including per patient cash reimbursement, medical equipment, large grants, and trips.

2. **Speaking Engagements** - Pharmaceutical companies ask physicians to speak on topics ranging from complex surgical procedures to the positive attributes of the companies' products. In return, speakers receive compensation in the form of honoraria and travel expenses.

3. **Program Attendance** - Pharmaceutical companies offer monetary payments, travel expenses, accommodations, meals, entertainment, and recreational activities to physicians for listening to and participating in programs ranging from descriptions of the latest academic medical research to round-table discussions about a particular product.

4. **Gifts** - Pharmaceutical companies offer physicians such gifts as items useful in medical practice, meals, promotional gadgets, valuable trips, and prizes.

Promotional practices involving items of value appear to affect physicians' prescribing decisions.

- Studies have shown that physicians' prescribing practices are affected by promotional efforts of pharmaceutical companies.

- Experts warn about the obligation a pharmaceutical company's gift or financial arrangement imposes on a physician to prescribe the company's drugs.

- Many of the physicians we spoke with acknowledged that these types of drug promotion have affected their prescribing decisions and expressed concern about the obligations imposed by money and other items of value.

The medical community and the pharmaceutical industry consider certain promotional practices involving offers of money and other items of value to be inappropriate.

- Guidelines recently developed by AMA/PMA and other medical specialty groups advise members on specific promotions to be avoided.

- Most of the physicians we spoke with view some aspects of accepting money and other items of value to be inappropriate.

It is unclear what effect recently developed ethical guidelines will have on pharmaceutical companies and physicians.

- The guidelines do not specifically define acceptable and unacceptable sponsorship of and participation in studies.

- The guidelines are not backed by any enforcement mechanisms.

The Department of Health and Human Services has recently undertaken new efforts to curb illegal and inappropriate promotional practices.

- The Office of Inspector General is currently investigating its first group of kickback cases involving promotional practices of pharmaceutical companies.

- The Food and Drug Administration has often commented on and forced changes in the **content** of promotional material, but thus far it has not addressed the **methods** of promotion. The FDA is drafting guidelines on scientific education and has expressed interest in regulating the use of research funding for promotional purposes.

CONCLUSION

Although it is not clear how prevalent illegal or inappropriate promotional activities are, the concerns raised by the practices described in this report warrant further monitoring of drug promotion.

TABLE OF CONTENTS

INTRODUCTION

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The purposes of this report are to (1) describe the range of drug promotion practices that involve physicians receiving money or other items of value from pharmaceutical companies, (2) assess the vulnerabilities such practices present, and (3) examine the government's and the industry's responses to inappropriate or illegal practices.

BACKGROUND

Much attention has focused recently on pharmaceutical companies' promotional techniques. The Senate Labor and Human Resources Committee conducted hearings in December 1990 that highlighted questionable promotional practices. At the hearings, the Committee released a report that surveyed selected pharmaceutical firms. Expenditures by these companies for symposia, reminder items, and samples have skyrocketed since 1976 (the last time a similar survey was conducted). Expenditures for gifts have also increased. The report spurred the Committee to look into specific promotional practices.

Among the practices described in testimony by witnesses from the academic and medical community were the following[1]:

* A widely publicized program sponsored by Wyeth-Ayerst Laboratories. The company developed a "Patient Profile Program," ostensibly to gather information on the types of patients who were taking Inderal LA (propanalol hydrochloride). Physicians participating in the program were eligible to receive honoraria in collecting information on their patients taking Inderal LA. The honoraria ranged from medical textbooks to free airline tickets, depending on the number of patients enrolled. Massachusetts's Medicaid Fraud Control Unit began criminal proceedings against Wyeth-Ayerst under State anti-kickback statutes, but settled the case out of court for $195,000.

* A CIBA-GEIGY-sponsored seminar held in a Caribbean resort that touted their new product called Estraderm (estradiol transdermal system). The company paid all expenses for attendees and their spouses including airfare and first-class hotel accommodations and meals.

* Numerous programs in which physicians were paid (usually $100) to attend either promotional seminars or round-table discussions on companies' products.

Witnesses spoke of how expensive these promotions were and of their direct effects on prescribing decisions. These practices were roundly criticized by hearing participants and committee members.

At these hearings, the American Medical Association (AMA) and the Pharmaceutical Manufacturers Association (PMA) testified about ethical guidelines that the AMA had just adopted and the PMA had fully endorsed to help their members avoid potentially unethical situations. Previous guidelines had not been specific about which practices should be avoided, leaving much interpretation up to individual physicians and manufacturers. The new guidelines delineate several particular practices to avoid.

The hearings raised the public's awareness of issues that have been publicized several times over the last three decades. As early as the 1960's, congressional hearings exposed widespread questionable promotional practices. Senator Edward M. Kennedy sponsored a series of hearings in the 1970's around these same issues and, partly as a result, introduced S. 1831 in 1977. This bill's enactment would have resulted in a fairly comprehensive reform of pharmaceutical regulation. Among other things, it would have prohibited "the transfer . . . of any gift, product, premium, prize, or other things of value" from a person in the drug industry to any physician or pharmacist "if the purpose of such transfer is to influence the prescribing, administering, or dispensing of any such drug." The bill was passed overwhelmingly in the Senate, but died in the House of Representatives. No legislation was introduced in the recent hearings.

Our focus in this report is to summarize many of the problems highlighted by the hearings and to detail some drug promotion techniques involving money or other items of value that have been used recently. We will evaluate the potential hazards these practices present to physicians and the practice of good medicine. We will then summarize and evaluate the government, industry, and medical establishment responses to inappropriate and/or illegal practices.

METHODOLOGY

To collect descriptions of pharmaceutical companies' drug promotion techniques and medical professionals' perspectives on these practices, we conducted detailed interviews with 68 physicians and 7 pharmacists who practice in hospitals. [In the coming months, a questionnaire will be mailed to a sample of approximately 1,000 physicians to gather statistically significant information about the prevalence of various offers.] We asked about research, education, and other activities involving money and other items of value being offered to physicians by pharmaceutical

companies. To evaluate how these practices could affect the prescribing decisions and integrity of medical care, we supplemented our interview information with numerous academic and professional journal articles on the subject.
To determine the response of industry and the medical establishment to inappropriate or illegal promotional activities, we contacted over 20 medical professional organizations and inquired about their ethical guidelines (see Appendix C). We received 10 official statements or guidelines. We also reviewed recent academic and business literature and mass media related to this topic and conducted discussions with key government officials.

About the Interviews

Our interviews were conducted at one teaching hospital and one community hospital within each of the following metropolitan areas: Boston, Massachusetts; Los Angeles, California; and Charlotte, North Carolina. The cities were chosen on the basis of geographic dispersion, size differences, and differences in health service availability. We chose the largest teaching hospital and the largest community (nonteaching) hospital available in each city. The physicians and pharmacists we interviewed were picked by the chief executive officer of each hospital (Appendix C details the selection criteria). We spoke with medical professionals in hospitals to be able to profile hospital responses to inappropriate or illegal drug promotion.

In general, our interviews focused on practices both in and out of the hospital setting. We asked some questions to hospital committee members and pharmacists about hospital-specific activity, but most of our questions focused on interactions between medical professionals and pharmaceutical companies.

Our interviews were conducted prior to the publication of the new AMA guidelines and covered physicians' experiences from up to five years prior to the interviews. This means that information we gathered cannot be used to test the effectiveness of the new guidelines or to discern any effects the recent wave of publicity might have had on promotional practices.

This is the first of several reports we plan to issue on prescription drug promotion. Because we have not yet assessed the extent of problematic practices, we do not make recommendations here. Instead, we have developed conclusions that indicate further courses of inquiry. An upcoming report will focus on the current prevalence of promotional practices involving pharmaceutical companies offering money or other items of value to physicians. The report will summarize results of a national survey of physicians and will include recommendations on how HHS should respond to inappropriate or illegal practices. Another report will evaluate the accuracy, truthfulness, and educational value of prescription drug advertising in medical journals. Our findings will be based on assessments of advertisements made by physicians and pharmacists who serve as peer reviewers for major medical journals.

FINDINGS

Pharmaceutical companies offer money and other items of value to physicians for a range of purposes, from sponsoring important educational activities to actively promoting their products. Offers that have been used for promotional purposes fall into four major categories.

1. **Studies** - Pharmaceutical companies ask physicians to participate in many types of studies on FDA-approved drugs. The companies offer a wide variety of payments for physicians' involvement, including per patient cash reimbursement, medical equipment, large grants, and trips.

Pharmaceutical companies sponsor studies for a variety of purposes. Commonly, companies conduct post-marketing research for the stated purpose of discovering scientifically relevant information about FDA-approved drugs. Although most studies have designs and methods that allow for these stated purposes to be addressed, some studies are either explicitly intended to promote or have the effect of promoting companies' drugs.

Physicians we interviewed seem to agree that studies can have promotional[2] purposes as well as the stated purposes. Of the 68 physicians we spoke with, 9 mentioned (without being asked) that they had been approached to participate in studies that had promotional purposes as well as the stated purposes. Examples of the comments we heard include: "Drug companies couldn't care less about the outcomes of comparative studies. They only are into it to market the drug to get doctors familiar with it," and "post-approval studies . . . are of questionable scientific validity. They're primarily aimed at marketing." Appendix A describes some of the studies recounted to us that appear promotional.

Pharmaceutical companies use studies for promotional purposes in several ways: (1) they sponsor studies which are intended to familiarize physicians with the drug so that they will use it in the future; (2) they give physicians direct incentives to prescribe certain drugs; and (3) they compensate physicians generously for time spent doing research. It is often difficult to make distinctions between the scientific and promotional purposes of studies, but observers can make informed judgments by looking at the financial arrangements, the design and methodology of the studies, and the source of control of the study design and publishing.

Financial Arrangements

Pharmaceutical companies use financial arrangements in studies for promotional purposes in a variety of ways. First, the companies can reimburse physicians for time spent doing research more generously than is necessary to get them to conduct the study. Sometimes payment is based on the amount of work required; sometimes it is not. Per patient reimbursement offered to the physicians we interviewed varied from $5 to $4,800, and grants to a physician or institution varied from $400 to $150,000. There was no obvious correlation between the amount of money offered and the apparent effort required. Other offers of payment included a trip to Hawaii, a computer, and medical equipment. Second, pharmaceutical companies can give direct incentives to prescribe certain drugs by paying the physician according to the number of patients he or she enrolls. For example, some physicians we interviewed have been offered payments on the basis of the number of new patients (patients who have never used the study drug) they put on the study, and others have been offered payments on the basis of the number of patients they switched from another drug. Third, payments are sometimes offered with strings attached. We interviewed a pharmacist who is a member of a hospital's formulary committee. He described how one pharmaceutical company offered large research grants in exchange for a physician requesting inclusion of one of the company's drugs in the hospital formulary.

Design and Methodology of Studies

Physicians are involved in studies that have a range of stated purposes:

* **New Uses** - testing new uses or new administration of a drug;
* **Effectiveness** - testing the effectiveness of a drug for its labeled use;
* **Comparison** - comparing one drug to a competitor's drug or to the treatment of choice;
* **Side Effects** - screening patients for unknown side effects; and
* **Marketing** - assisting in developing marketing plans and testing marketing effectiveness.

The methods used vary in two main respects: use of a control group and blinding of the selection of test drug or control drug. Control groups can be:

* **Placebo** - treatment that has no chemical effect on the patient;
* **Other Control** - treatment of choice or a competitor's drug; or
* **No control.**

Placement on the control versus study drug can be:

* **Blinded** - done without the patient being aware of the choice or
* **Open label** - done with both the patient and the physician being aware of the choice.

Some studies that encourage the physician to prescribe the study drug are not designed to discover scientifically relevant results. Others may provide scientific data, but also promote the company's drug. Studies that use unacceptable scientific

methods or require the physician to switch therapies from a competitor's drug are likely being used to promote the drugs to the physician-investigator. So-called surveillance studies, which use open label designs and/or do not have control groups, are not usually acceptable for generalizing about effectiveness or the advantages of one drug over another,[3] but they are widely used to screen for side effects. Surveillance studies, however, may contain some elements of promotion, depending on the financial arrangements and the stated purposes of the study.

The following table describes how different combinations of methods are used for each stated purpose.

TABLE 1

Types of Studies

NEW USES	EFFECTIVENESS	COMPARISON	SIDE EFFECTS	MARKETING
1. Blinded, placebo control	1. Blinded, placebo control	1. Blinded, other control	*1. Open label, no control*	*1. Open label, no control*
2. Open label, no control	*2.* Blinded, other control	*2. Open label, other control*		
	3. Open label, other control			
	4. Open label, no control			

Note: Italics indicate the methods more likely to be used for promotional purposes.

Control of Design and Publishing

Pharmaceutical companies either sponsor independent research or generate their own protocols, methodologies, and other aspects of research designs, and choose which physicians they wish to involve. Their control can extend to the publishing of study findings; sometimes, pharmaceutical companies' scientists control the writing of articles for medical journals. Promotional studies are much more likely than not to have pharmaceutical company control of the research design and/or publishing.

2. **Speaking Engagements** - Pharmaceutical companies ask physicians to speak on topics ranging from complex surgical procedures to the positive attributes of the companies' products. In return, speakers receive compensation in the form of honoraria and travel expenses.

Pharmaceutical companies are involved in almost every aspect of physicians' continuing education. Almost all these programs can be forums for physician-speakers who are sponsored or paid by pharmaceutical companies.[4] Depending on the meeting, physicians may speak on highly academic subjects or may promote specific products. Pharmaceutical companies support speakers by either contributing

money to an institution's or organization's education fund or paying the speaker directly.

Pharmaceutical companies use sponsorship of speakers for promotional purposes in two ways: they give physicians slides, notes, and/or a full text of a speech, which are slanted toward the companies' products; or they pay the physicians very generous fees to speak on any topic (often the most influential physicians are paid the most).

In our interviews, we heard about sponsorship of speakers that appears to have been done for promotional purposes. One example was a Los Angeles gynecologist's experience. He showed us a notebook full of slides and presentation material that a pharmaceutical company had given to him. The slides and material showed GnRH agonists in general and the company's drug specifically in a favorable light. An attached letter from the product manager said, we "share your excitement in this new class of compounds and we appreciate your continued support. We feel we have a winner with [the product]!" The physician refused to use these slides and stopped speaking for the company.

Though it is difficult to judge what level of fees is excessive, physicians we spoke with mentioned being paid up to $1,000 for speaking locally and over $2,000 for speaking out of town. These fees are much higher than the typical honoraria of $100-$500 per speech.

3. **Program Attendance** - Pharmaceutical companies offer monetary payments, travel expenses, accommodations, meals, entertainment, and recreational activities to physicians for listening to and participating in programs ranging from descriptions of the latest academic medical research to round-table discussions about a particular product.

Pharmaceutical company support of continuing medical education includes not only support for the speakers but also support for attendees. The companies supply meals in connection with hospital meetings and provide receptions and meals at large regional or national medical organization conferences. In addition, physicians we interviewed spoke about special outings, baby-sitting services, transportation, and trinkets that were offered at these meetings.

Pharmaceutical companies also sponsor their own meetings and conferences. These range from highly educational research presentations to discussions about the companies' latest marketing material. The companies at these meetings sometimes pay for all expenses incurred by the attendee, including airfare, hotel, meals, entertainment, and recreational activities. In addition, some companies cover all or some expenses for a spouse or guest to attend the conference. They also occasionally offer honoraria for attendees, ranging from $50 to $500.

Although many of these programs are widely recognized as legitimate medical education, the financial support given attendees is inherently promotional, since it is not earned in any way. The support seems even more directly promotional when discussions are focused primarily on the sponsoring company's products as opposed to a particular disease state, or programs are held in resort locations, or the topics, speakers, and attendees are all chosen by the sponsoring company, or there is a high ratio of free time and organized recreational activity to lecture and discussion time, or additional guests are invited to attend.

One physician from the Los Angeles area described his experiences with pharmaceutical company sponsorship of educational meetings. He had attended all-expense-paid programs in many locations (for example, Phoenix, Tucson, Orlando, Banff, and St. Thomas). He was most concerned, however, about a conference he attended over one weekend at a Beverly Hills hotel at which accommodations, meals, and travel expenses were paid by the sponsoring company. He and twenty other physicians from around the country came to hear a renowned colleague speak. The speaker ended up strongly advocating the use of a drug that was not yet on the market. In return for his time, the physician received $500 from the company.

4. **Gifts** - Pharmaceutical companies give physicians such gifts as items useful in medical practice, meals, promotional gadgets, valuable trips, and prizes.

Pharmaceutical sales representatives offer physicians gifts of all types when they meet with them. These gifts are not given as payment for conducting research, acting as a consultant, or making presentations for the company, but are presented to physicians as part of a sales visit or marketing package. Many of these gifts are useful in the physicians' offices, either for medical practice or for running of the office. Some gifts are simply inexpensive promotional items, others are more valuable and serve no obvious professional purpose. The following table lists items that were offered by pharmaceutical sales representatives or through the mail to physicians we interviewed.

TABLE 2
Gifts

PROMOTIONAL ITEMS USEFUL FOR MEDICAL PRACTICE	PROMOTIONAL ITEMS OF LITTLE VALUE	PROMOTIONAL ITEMS OF SIGNIFICANT VALUE
Appointment books	Breath mints	Deep sea fishing trips
Calendars	Candy	Drawings for prizes
Clocks	Coffee cup with candy in it	Drugs for personal/family use
Drugs for patient use	Golf balls	Meals in restaurants
Educational material	Jump rope	Tickets to sporting events and theater
Flashlights	Key chains	Wine
Literature searches	Meals/snacks in the hospital	
Medical equipment	Mugs	
Note pads	Socks	
Pencils	Toys	
Pens		
Pointers		
Post-it™ notes		
Rulers		
Textbooks		
Trays		

Promotional practices involving items of value appear to affect physicians' prescribing decisions.

- Studies have shown that physicians' prescribing practices are affected by promotional efforts of pharmaceutical companies.

Research has shown that physicians depend on commercial sources of information, particularly for new drugs. Hemminki conducted a comprehensive review of the literature on the factors affecting drug prescribing in 1975 and found that commercial sources of information play a significant role in the decisions physicians make.[5] Many other articles have described how promotion increases prescribing.[6] Other articles describe how first news of a drug usually comes from commercial sources.[7] Bowman and Pearle note that the funding source for continuing medical education seminars at a university medical center can affect prescribing.[8] For three different companies' seminars, the sponsor's product was more frequently prescribed by physicians after they attended than before. One article disputes these studies, however, and claims that increasing promotion does not affect demand for prescription drugs.[9]

Many of these articles relied on physician self-reporting, but one important study did not. Avorn and colleagues showed that doctors believed in the superiority of two heavily promoted drugs over alternative forms of therapy, despite overwhelming scientific evidence to the contrary.[10] The study showed that doctors did not acknowledge commercial sources of information to be important factors in their prescribing decisions. They concluded that these doctors must have been relying on promotional rather than scientific material in forming opinions about these drugs.

This study demonstrated two important points: physicians are often unaware of the importance of commercial sources of information on their prescribing decisions and drug promotion can influence physicians to make irrational prescribing decisions.

- Experts warn about the obligations a pharmaceutical company's gift or financial arrangement imposes on a physician to prescribe the company's drugs.

Chren and colleagues discuss in detail the relationship set up between doctors and drug companies by gift giving.[11] Although physicians may regard themselves as unable to be bought, the acceptance of a gift places obligations on them. The authors conclude that a gift need not be contingent on behavior in order to affect prescribing decisions. Instead, they speak of more subtle consequences: "Whenever a physician accepts a gift from a drug company, an implicit relationship is established between the physician and the company or its representative. Inherent in the relationship is an obligation to respond to the gift; this obligation may influence the physician's decisions with regard to patient care."

Goldfinger warns against the minor obligations that accepting a free trip to a resort location to attend a CME seminar might confer.[12] He asks, "Isn't it a bit sleazy to take the corsage without at least yielding its sender a place on one's dance card?"

An American Medical Association Report of the Council on Ethical and Judicial Affairs describes two recent studies that examined the promotional influence of gift giving.[13] One says that salespeople give gifts to potential buyers because they believe the gifts impose obligations to respond and therefore will increase sales.[14] The other shows how the accepting of a gift, even a small one, positively affects the receiver's perception of a company's product.[15]

Even if a gift is simply a matter of supporting legitimate continuing medical education, the presentation of the material can be biased. Drug company sponsorship of continuing medical education can slant the content of material presented toward the positive aspects of the sponsoring company's drug.[16]

- Many of the physicians we spoke with acknowledged that these types of drug promotion have affected their prescribing decisions and expressed concern about the subsequent obligations that money and other items of value impose.

Of the 12 physicians who responded to our question about the effect of pharmaceutical company-sponsored research funding on their prescribing decisions, 4 reported that they use the study drug more than they did prior to starting the study. Of the 68 physicians we spoke with, 22 said their attendance at pharmaceutical company-sponsored meetings could lead to changes in their prescribing decisions, although many of these doctors qualified their responses to note that this would occur only if the information presented was of sufficient force and credibility. The

physicians who responded that they would not change their prescribing were asked a follow-up question about why companies might sponsor programs that did not result in prescribing changes favoring the sponsor. Of the 33 physicians responding, 14 said that there must be some who, unlike themselves, do switch drugs as a result of attending programs and 14 also said that companies sponsor these programs as a form of advertising, promotion, or enhancing name recognition. Only 7 physicians said the purpose of the programs was as stated: to educate doctors about the companies' products and make them aware of new product development.

In responding to a question about whether financial offers can have inappropriate effects on prescribing behavior, most physicians we spoke with responded yes (42 of 68 physicians). Another 14 said that it depends on the individual. One Charlotte area physician responded, "A doctor who tells you he's not influenced is naive or lying." A Los Angeles area director of medicine at a large teaching hospital agreed that financial offers can have an effect on prescribing decisions and said, "I am amazed at the number of physicians who don't believe this." A Boston area physician simply said that there is an implied quid quo pro with offers of money, travel, and other material goods. A Charlotte area internist talked about how a gift obligates the physician to pay attention to the sales representative. One obstetrician from Charlotte was up front about the potential obligation: "If someone paid me to go to San Francisco, I'd feel obligated to write prescriptions for them."

The medical community and the pharmaceutical industry consider certain promotional practices involving offers of money and other items of value to be inappropriate.

- Guidelines recently developed by AMA/PMA and other medical specialty groups advise members on specific promotions to be avoided.

On December 3, 1990, the American Medical Association revised its ethical code to incorporate new guidelines on gifts to physicians from the industry.[17] The Pharmaceutical Manufacturers Association endorsed these guidelines in full. These guidelines (see Appendix B) define acceptable and unacceptable offers in some areas. The following are specified by the guidelines as offers that are not appropriate for physicians to accept or pharmaceutical companies to offer:

* Gifts of cash
* Gifts that are not related to the physician's work or that do not entail benefits to the patient
* The cost of travel, lodging, and other personal expenses of physicians attending meetings
* Subsidies to compensate for the physician's time attending a meeting
* Token consulting arrangements
* Gifts with strings attached

Although most of the medical organizations we contacted provided us with guidelines that do not specify practices to avoid,[18] those received from some other groups do single out unacceptable practices (see Appendix B for complete texts):

* **American Surgical Association:** Giving papers or lectures that are promotional. Accepting money, gifts, and gratuities as a reward for participating in promotional activities.[19]

* **American College of Obstetricians and Gynecologists (ACOG):** Letting provision of research funds affect the experimental design, methodology, or results of studies.[20]

* **American College of Cardiology:** Accepting large gifts. Accepting dinners or entertainment given to discuss a representative's product.[21]

* **Infectious Diseases Society of America (IDSA):** Accepting research funding directly from the pharmaceutical company rather than having the funding flow through an institution.[22]

Two groups characterize ethical activities as follows:

* **The Accreditation Council for Continuing Medical Association** states that funding for CME programs should be made in the form of an educational grant to the sponsor of the program. Full disclosure of sponsorship should be made. Sponsors should not pay for travel, lodging, honoraria, or personal expenses of attendees.[23]

* **The Vanderveer Group,** which provides communication services for the pharmaceutical industry, recently adopted a code of principles in response to the AMA/PMA guidelines. The code limits items of value given to physicians in return for attending events to articles useful for medical practice.[24]

- Most of the physicians we spoke with view some aspects of accepting money and other items of value to be inappropriate.

Over 80 percent (51 of 62 responding to the question) of the physicians we interviewed identified at least one type or aspect of educational programs they considered inappropriate, while over 70 percent (50 of 68 responding to the question) identified at least one type or aspect of drug company sponsored research as such.[25] Popular responses were very general: the most common type of research thought to be inappropriate were studies designed to market a drug or those which had no scientific merit, while the loosely defined term "junket" was mentioned most frequently as an inappropriate educational program.

However, some specific features of both educational programs and research were mentioned by physicians we interviewed as being inappropriate. The following specific pharmaceutical company activities were mentioned by physicians we interviewed as being inappropriate: paying the audience to attend an educational program (mentioned by 15 respondents), conducting discussions on a single product (13 mentions), influencing what a speaker says at an educational program (12 mentions), paying travel expenses to attend an educational program (9 mentions), sponsoring one-sided or biased presentations (8 mentions), selecting the speakers (5 mentions), paying physicians to attend focus group sessions (4 mentions), controlling the release or publishing of study data (4 mentions), analyzing the study data (3 mentions), and paying per case reimbursement for studies (2 mentions).

It is unclear what effect recently developed ethical guidelines will have on pharmaceutical companies and physicians.

The press and academic community have focused much attention on the issues raised here. Publications as diverse as the *American Journal of Hospital Pharmacists* and *SELF* magazine have detailed potentially inappropriate promotional practices and their relation to the AMA/PMA guidelines.[26] At least one pharmaceutical company has responded to the wave of publicity by publishing a statement of principles. Merck Sharp & Dohme (MSD)[27] placed a two-page ad in major medical journals detailing the principles guiding its promotional activities. These essentially echo the AMA/PMA guidelines. MSD has asked physicians to evaluate whether the company is indeed in compliance with these guidelines and whether its principles follow those of the AMA guidelines. The AMA's general counsel has stated that he perceives practices to have changed significantly because of the guidelines: "The major gifts to physicians that raised the most controversy, lodging and travel to educational events are, for the large part, over."[28]

- The guidelines do not specifically define acceptable and unacceptable sponsorship of and participation in studies.

The AMA/PMA guidelines, which are the focus of much of the publicity, speak to study sponsorship and participation in two subsections:

* "It is appropriate for consultants who provide genuine services to receive reasonable compensation. . . . Token consulting or advisory arrangements cannot be used to justify the compensation of physicians for their time or their travel, lodging, and other out-of-pocket expenses."

* "No gifts should be accepted if there are strings attached. For example, physicians should not accept gifts if they are given in relation to the physician's prescribing practices."

The guidelines, however, do not clarify what distinguishes genuine services from token consulting or advisory arrangements or whether study reimbursement based on the number of patients enrolled constitutes a "strings attached" gift.

ACOG's guidelines do not allow pharmaceutical companies to control the design of studies or the publishing of data, and the IDSA guidelines would rule out direct funding of research by pharmaceutical companies. But these guidelines, despite having been released several years ago, are not widely known or publicized and are directed only to a limited number of specialists.

- The guidelines are not backed by any enforcement mechanisms.

The American Medical Association has no enforcement authority. The AMA has decided at least one promotion was in violation of the guidelines since the publishing of the guidelines. Their response has been to write to the physicians known to be involved to advise them that they are violating their profession's code of ethics.[29] At the Senate hearings, the AMA stated that it expected most state and local licensing boards would adopt the guidelines in full and thus would be able to sanction doctors who were outside the guidelines. It is not clear, however, what effect incorporating the guidelines into state medical board codes would have,[30] nor is there any requirement that the boards incorporate these guidelines into their ethical codes.

The Pharmaceutical Manufacturers Association plans to enforce its guidelines in the same manner as it has the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) Code of Pharmaceutical Marketing Practices. That is, when the PMA receives a complaint, it sends the complaint to the PMA member that is the subject of the alleged breach, and the PMA member responds in writing. Gerald Mossinghoff, president of the PMA, has said that this "procedure has resulted in satisfactory resolution of each and every alleged breach of the IFPMA Code by PMA members over the years."[31] But these complaints and responses are not generally public information, nor is any kind of disciplinary action taken if a promotion falls outside the code. One promotion that began prior to the release of the guidelines, but included activities that took place in early May clearly is in violation of the PMA guidelines. PMA deferred judgement on this promotion to the AMA because of the start date of the promotion.[32]

Other organizations are explicit in recognizing that they have no ability or desire to enforce their guidelines. For example:

* "The [Infectious Diseases] Society [of America] recognizes its inability to legislate the morals of its members and of those with whom they interact."[33]

* "The position presented here by the American Surgical Association does not connote any direct restriction or punitive action."[34]

* "Because recommendations in individual cases nearly always have to be based on reasoned judgments rather than on rote application of an encyclopedic set of rules, our [the American College of Cardiology's] attention should focus on guidelines rather than rules."[35]

The Department of Health and Human Services has recently undertaken new efforts to curb illegal and inappropriate promotional practices.

- The HHS Office of Inspector General (OIG) is currently investigating its first group of kickback cases involving promotional practices of pharmaceutical companies.

The Medicare and Medicaid anti-kickback provisions (42 U.S.C. 1320a-7b) apply to financial transactions between pharmaceutical companies and physicians. The law reads in part:

> "Whoever . . . solicits or receives any remuneration . . . in cash or in kind . . . in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good . . . for which payment may be made [by Medicare or Medicaid] shall be guilty of a felony . . . Whoever offers or pays any remuneration . . . in cash or in kind to any person to induce such person . . . to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good . . . for which payment may be made [by Medicare or Medicaid] shall be guilty of a felony."

Traditional applications of this law involve cases in which doctors are paid remunerations to refer patients to certain laboratories or specialists. But the law also applies to a doctor who is paid remunerations to prescribe or otherwise recommend a drug which is covered by Medicare or Medicaid.

The OIG is currently investigating Wyeth-Ayerst's "Patient Profile Program" (see p. 1) and is collecting information about many other promotional programs offered by numerous pharmaceutical companies. Investigators have expressed a desire to expand the choice of remedies and penalties available to punish violators of the law and protect the Medicare and State health care programs.

- The Food and Drug Administration (FDA) has often commented on and forced changes in the <u>content</u> of promotional material, but thus far, it has not addressed the <u>methods</u> of promotion. The FDA is drafting guidelines on scientific education and has expressed interest in regulating the use of research funding for promotional purposes.

The FDA is charged with regulating the content of all packaging and advertising material related to pharmaceutical drugs. They have interpreted this authority to

include all forms of drug promotion. Promotional material must be balanced in its presentation of indications and contraindications, effects, and side effects. It may not include unsubstantiated claims of superiority or discuss uses that have not been approved by the FDA. The FDA focuses most of its promotional oversight attention on journal advertising. It also attempts to monitor educational programs (again for content), but has limited resources for this purpose.

The FDA has no control over the financial relationships between manufacturers and physicians, although it can and does use these financial relationships to determine whether particular statements are promotion (which the FDA can regulate) or scientific communication (which it cannot regulate).

The new Commissioner of the FDA believes the FDA can play an important role in preventing physicians and others from being misled by promotional activities.[36] In this regard, he has sought and received approval to add staff to the Division of Drug Advertising and Labeling to allow more resources for promotion oversight.[37] Central in this staff development has been the appointment of a new director of the Division. The new Director has stated the importance of regulating "promotional activities in the guise of scientific exchanges."[38] The FDA is also active in gathering information about various types of promotion, such as company sponsorship at medical meetings.[39] As part of this effort, the FDA is planning to set up a hot line for physicians and pharmacists to phone if they are aware of inappropriate promotional practices.[40]

In addition, the FDA is drafting guidelines for scientific education,[41] which should significantly clarify what is viewed as promotion versus what is viewed as education. The FDA has expressed interest in regulating the use of studies for promotional purposes. One of its officials recently talked about how open label studies "can present problems in that they can represent an effort to promote . . . an unapproved use."[42] He said the Advertising Division would have no hesitation in halting clinical studies and calling for revised protocols when they promote unapproved uses.

CONCLUSION

Although it is not clear how prevalent illegal or inappropriate promotional activities are, the concerns raised by the practices described in this report warrant further monitoring of drug promotion.

Drug promotion activities warrant continued attention for many reasons. Direct adverse effects on prescribing decisions may occur as a result of promotional activities. Some practices may indeed be illegal, violating the Medicare and Medicaid anti-kickback statutes. Additionally, acceptance of promotion-related money or other items of value from pharmaceutical companies has the appearance of impropriety. This appearance is damaging to the public's confidence in the medical profession. Although our interviews indicate that potentially inappropriate practices may be widespread, more recent activities (the AMA/PMA guidelines) appear to have changed the way promotion is conducted. If, however, the guidelines prove ineffective because of weaknesses mentioned in this report, inappropriate or illegal promotions could continue. To keep abreast of changes related to these activities, the OIG will continue its research in this area and will formally survey physicians to determine the current prevalence of promotional practices involving payments and gifts. In addition, the OIG will continue to pursue cases against apparent violators of the Medicare and Medicaid anti-kickback statutes.

APPENDIX A

Descriptions of Studies Used for Promotional Purposes

Some of the studies that were described to us appear to have encouraged the physician to prescribe the company's drug. The following are examples:

* One gastroenterologist from the Los Angeles area was involved in conducting a study examining the relative effectiveness of four dosing regimes for one ulcer treatment. The maker of the drug approached the physician with a study methodology, which included a requirement that the patients involved in the study be currently taking another drug. The study was being conducted in multiple sites around the country, was not controlled, and did not require blinding. The physician was being paid by the company on the basis of the number of patients he enrolled.

* A cardiologist who practices in the Charlotte area conducted a study looking into the efficacy and side effects of one company's beta blocker. The company offered the physician $100 per patient to collect what the physician called only a few pieces of data. The company designed the methodology, which included no controls and was open label. The study was conducted in multiple sites throughout the country. The physician did not think the results were scientifically relevant or useful; the company, he said, was not trying to do real research, but was using this as a marketing method.

* An infectious disease specialist in the Boston area was invited to participate as an investigator in a nationwide trial of the efficacy and safety of a new intravenous form of an approved antibiotic drug. The drug's IV form was about to be approved at the time (the study would not start until after the drug was approved). The investigator was to enroll 10 patients having certain diagnoses and fill out a "brief two-page Clinical Evaluation Form." In return, the physicians involved were to receive $30 for each completed form and Category II Continuing Medical Education credits. The results were to be analyzed and written up by scientists at the company.

* An oncology specialist in the Charlotte area was asked to give an ulcer medication to patients free of charge and collect minimal information on the patients. The sponsoring company was not planning to publish the results of the study, and they offered him a piece of medical equipment as, according to the physician, "a prize" for participating. He refused to do the study, because he did not consider it good science.

APPENDIX B

Ethical Guidelines

Report as filed by the House of Delegates on December 4, 1990

American Medical Association

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

Report: F
(I-90)

Subject: Opinion of the Council on Ethical and Judicial Affairs--Gifts to Physicians from Industry

Presented by: Richard J. McMurray, MD, Chairman

Referred to: Reference Committee on Amendments to Constitution and Bylaws
(David B. Carmichael, Jr., MD, Chairman)

The Council on Ethical and Judicial Affairs submits the following opinion to the House of Delegates for its information and recommends that this report be filed.

GIFTS TO PHYSICIANS FROM INDUSTRY. Many gifts given to physicians by companies in the pharmaceutical, device and medical equipment industries serve an important and socially beneficial function. For example, companies have long provided funds for educational seminars and conferences. However, there has been growing concern about certain gifts from industry to physicians. Some gifts that reflect customary practices of industry may not be consistent with principles of medical ethics. To avoid the acceptance of inappropriate gifts, physicians should observe the following guidelines:

1. Any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value. Accordingly, textbooks, modest meals and other gifts are appropriate if they serve a genuine educational function. Cash payments should not be accepted.

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

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

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

5. Scholarship or other special funds to permit medical students, residents and fellows to attend carefully selected educational conferences may be permissible as long as the selection of students, residents or fellows who will receive the funds is made by the academic or training institution.

6. No gifts should be accepted if there are strings attached. For example, physicians should not accept gifts if they are given in relation to the physician's prescribing practices. In addition, when companies underwrite medical conferences or lectures other than their own, responsibility for and control over the selection of content, faculty, educational methods and materials should belong to the organizers of the conferences or lectures.

acog committee opinion

Committee on Ethics

Number 45—October 1985

Guidelines for Relationships Between Industry and the American College of Obstetricians and Gynecologists and Its Fellows

The American College of Obstetricians and Gynecologists recognizes that companies in the health care industry, such as manufacturers of pharmaceuticals and medical devices, assist the College in pursuit of its educational goals and objectives through sponsorship and financial support of various medical educational programs.

In the course of such interactions, there is the possibility that company expenditures will generate some degree of bias unrelated to product merit, creating the actuality or the appearance of inappropriate and undue influence. When any product promotion leads to inappropriate or unbalanced medical advice or recommendation to patients, an ethical problem exists. The public holds physicians to a high standard of medical advice, and such advice should be as accurate, balanced, complete, and devoid of bias as possible.

Industry-physician interactions can be divided into three major types, as characterized in the following paragraphs. Ethical implications specific to these types of interactions suggest areas in which the College and its Fellows should particularly strive to be circumspect.

1. *Product promotion to individual physicians by advertising, personal communication, and provision of samples.* The physician has an obligation to go beyond the information provided through advertising in selecting the best product for care of the patient.
2. *Company promotion to individual physicians and groups of physicians, such as medical specialty societies, by provision of noneducational gifts, parties, trips, and services.* Company promotional practices directed to individual physicians or to professional groups without concomitant educational benefits have the potential for unduly influencing physicians and generating a sense of obligation which could prejudice optimal health care. The College has promulgated guidelines to clarify its relationship to these activities. Individual physicians are responsible for their own behavior as it relates to noneducational promotions and should be aware of the potential for ethical problems generated by such promotions.
3. *Company promotion to individual physicians and groups, including specialty societies, hospitals, and medical schools, through the support of educational activities, honorary awards, research grants, and development contracts.* Whenever there is a relationship between the College and industry in the educational area, it is desirable for the College and its Districts and Sections to establish basic principles governing industry's participation in the support and sponsorship of educational activities. Support of educational programs and the provision of awards, grants, and contracts may be accepted by the College and its members if such support is offered in accordance with the following guidelines:

   a. Awards should be based on merit (societal, educational, or scientific) and should be granted on a competitive basis.

   b. No obligation should be imposed or implied by the provision of funds. Provision of funds should not affect the experimental design, methodology, or results of grant-supported programs. No topic or speaker restrictions on educational programs should be accepted. Educational programs carried out with support from industry should present a balanced view of treatment options and should not be biased toward a specific product or procedure lest they be construed as a form of paid advertising.

   c. The sources of support and the relationship between these and the investigator or speaker should be a matter of public record and should be made explicit at the time of publication or presentation.

JACC Vol. 16, No. 1
July 1990:1–36

Task Force V: The Relation of Cardiovascular Specialists to Industry, Institutions and Organizations

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I. General

The delivery of cardiovascular care has undergone dramatic changes. New technologies, therapies and systems for health care delivery have emerged and have done so largely through cooperative efforts of our profession and industry. These developments have benefited our profession, the industry and, most importantly, our patients. Further development will require continued cooperative efforts. Yet such efforts are threatened by increasing concerns regarding the motives of those involved (1–3). Enormous amounts of money are involved in health care (approximately 12% of our gross national product or $550 billion in 1988). Physicians largely control how this money is allocated. Therefore it is not surprising that industry devotes much of its marketing to physicians to influence prescribing habits and purchase of their products. Physicians and their patients benefit from these activities when the relation between physicians and industry is based on ethical principles and mutual respect.

Ethical behavior ultimately is an individual decision but it must be appreciated that it is the perception by patients, health policy makers, the media, and others, of our ethical or unethical behavior that will determine society's response. The cardiovascular community (physicians, industry, institutions and organizations) has a special obligation to help define the boundaries of ethical behavior in their relations. A guiding principle for physicians must be that their decisions about patient care are determined by the health needs of the patient and not based on inappropriate monetary, scientific or academic gains. Physicians must not be influenced by any incentives that would cause them to act in a manner contrary to their best professional judgment. What follows are guidelines to assist those who must make decisions relating to ethical behavior and conflicts of interest in this area.

II. Industry-Sponsored Programs or Conferences

A. General

Much of our educational activity is financially supported by industry. In general this has been beneficial for physician education, and continued support for these activities should be encouraged. However, the primary objective of such programs must be educational. Programs should not be used to promote the products of the sponsor. Selection of topics and discussants should be determined by the medical director of the program or the staff to which the presentation is to be made. Honoraria for faculty participants should be in keeping with the participants' contributions. Honoraria and inducements for audience attendees should not be accepted. Payment of expenses for attendees may be acceptable in situations consistent with educational objectives with appropriate accreditation. For example, appropriate situations are those in which the attendees are faculty participants and in which the program control and selection of attendees is determined by physicians, without restriction by industry. Lavish entertainment and gifts are inappropriate. Expenses should not be paid or reimbursed for spouses or guests of attendees. Provision of meals as part of a meeting is an acceptable practice. Speakers sponsored by industry should be identified in the program or at the time of the presentation.

B. Industry-Initiated Conferences

Particular attention should be given to conferences organized and conducted directly by industry. Physicians participating as faculty in such meetings have an obligation to present scientifically balanced information. They are frequently well recognized leaders in the field whose recommendations are readily accepted. Their comments must not be subject to approval or censored by the sponsoring com-

pany. It is acceptable to have a reputable and accredited teaching institution endorse the conference. The program chairman should be responsible for final selection of topics and discussants. Conferences devoted to a single drug or device produced by the sponsoring company may be appropriate if no other treatment alternatives are available or special procedures are required for proper utilization. However, conferences devoted to a single drug or device in therapeutic categories in which other equivalent treatments are available should be discouraged unless strict guidelines are enforced; for example, the conference is advertised as such and attendees pay their own tuition or expenses, or both, to attend.

Those invited to attend an industry-initiated program should not expect or accept inducements to attend. High quality industry-sponsored programs do not require inducements to obtain attendees. The practice of accepting cash incentives to attend is to be condemned.

C. Physician-Initiated Programs

Many educational programs are physician initiated but totally or partially sponsored by industry and frequently held at resorts or attractive locations as an inducement for physician attendance. Many such conferences could not be held if it were not for industry support, and acknowledgment of that support is appropriate. It is particularly important that these programs are organized and conducted primarily as educational events. The program chairman should be responsible for selection of topics and discussants. Attendees not participating as faculty should pay tuition and travel expenses.

D. Industry and Trainees

Previous comments pertaining to physicians and their relation to the health care industry also apply to physicians in training. However, the latter may be particularly susceptible to marketing efforts. Supervising physicians, particularly directors of training programs, should take an active role to assure that ethical principles are adhered to by all parties. Pharmaceutical companies frequently provide meals at educational programs conducted for physicians in training. Representatives of the companies are often permitted to briefly present product information at these conferences. This is an acceptable practice if all pharmaceutical companies that wish to participate have equal opportunities to do so and if supervising physicians are in attendance to ensure a balanced presentation. The direct personal acceptance of meals or entertainment at functions without a significant educational component is discouraged.

III. Publications Sponsored by Industry

Most scientific journals receive significant financial support from industry advertising. Such support is necessary and appropriate if it does not influence editorial decisions. Furthermore, publication of proceedings of educational programs supported by industry is common practice. Publication of these proceedings may be of value, but there is the potential for the presentation of biased information. Publication of these proceedings should be subject to peer review in a manner similar to that of unsponsored manuscripts submitted to that journal. Proceedings to be published directly by industry should undergo review by the faculty involved or an independent group of authorities.

IV. Gifts

Gifts to physicians may represent appropriate gestures or inappropriate acts. The principles to be employed are the reasonableness of the gift or payment for the service rendered and the gift's effect on physician decision making. The following examples are used to illustrate these concepts.

Small gifts. Physicians frequently receive small items, such as pens, notepads or appointment books, from industry representatives. These usually are given when the representative discusses their company's product with the physician. Industry views these items as important for product recognition. This is acceptable practice.

Large gifts. It is an increasingly common practice to encourage physicians to use a certain product by linking the use of that product to inappropriately valuable gifts and financial or other rewards. For example, physicians may receive financial incentives such as frequent flyer programs or direct cash payment if they prescribe a specific drug brand for a small number of patients and then complete a short form describing the result. These "studies" rarely have scientific value and are designed primarily to encourage physicians to prescribe the drug. Provision of the drug free to the patient does not justify this practice.

Reimbursement for surveillance studies. However, it is appropriate to reimburse physicians participating in legitimate postmarketing surveillance studies (phase IV) that are guided by protocols approved by institutional review boards. These studies can be an important part of the continuing development of a product.

Hospitality suites at medical meetings. These are commonly provided and are acceptable if they are primarily used for social functions.

Consultation fees for physicians' services. These are acceptable practice provided the fee is commensurate with the services performed.

Market research focus groups. These are common practice. Individuals are usually paid for participation in the focus group, which is an acceptable practice if physicians'

JACC Vol. 16, No. 1
July 1990:1-36

comments are uninfluenced by the sponsoring organization and honoraria are in keeping with the service provided.

General guidelines for giving and accepting gifts. Anything given to physicians by industry should not be 1) a reward for selecting a specific product; 2) an incentive for selecting a product other than on scientific grounds (educational material about a product is an acceptable form of incentive); 3) out of proportion to a need, for example, foreign trips to view a facility or equipment. The recommendations of the Royal College of Physicians that acceptable gifts are those that are "inexpensive and related to the practice of medicine" are appropriate: ". . . a useful criterion of acceptability may be—would you be willing to have these arrangements generally known?" (4). Physicians should not accept or demand lavish gifts such as dinner or entertainment to discuss a representative's product.

V. Physician Ownership of Health Care Facilities

The economic philosophy of our society not only supports but encourages individual economic investment. Physician participation in the ownership of health care facilities, such as imaging centers and mobile cardiac catheterization laboratories, is increasing. Although currently legal, there is considerable debate as to whether physician ownership of facilities to which they refer patients is ethical. The potential for unethical behavior or the appearance of a conflict of interest occurs whenever physicians gain financially from their patients' expenses for services the physician orders but does not provide directly. It appears that patients generally are unaware of their physician's involvement in these facilities. Physician involvement in such activities may be acceptable if these activities clearly improve patient care above that available in the community. It is mandatory that physicians disclose to their patients their financial interest in such facilities.

Unfortunately health care facilities are often developed in areas that already have adequate facilities. The introduction of new facilities without evidence of need will increase medical care costs—this in itself is unethical.

VI. Physicians' Relation to Institutions and Organizations

A. Institutions

Hospitals depend on physicians to maintain an adequate patient base. Today, a large number of hospital beds are unfilled and competition for patient revenue is intense. Increasingly, institutions are awarding incentives to physicians in order to attract patients. Physicians should determine where to refer their patients on the basis of the quality of care provided by an institution regardless of financial incentives to the physician.

As a result of the intense competition for patient revenue, physicians may be subject to pressures from institutions to increase such revenue. This is particularly true for physicians salaried by or under contract to institutions such as managed care facilities and faculty practice plans. The practice of publicly comparing physicians by revenue generated, hospital revenue saved or procedures ordered is often designed to enhance profits, with a disregard for the quality of patient care. Institutions should be concerned primarily with the quality of care provided by their physicians. Conversely, physicians must have an awareness of the financial pressures institutions are under and avoid unnecessary over- or underutilization of resources. Physicians have an obligation to cooperate with administrators in determining cost-effective strategies for their institution.

B. Organizations

Physicians are generally members of several professional organizations or societies. Physicians in positions that influence the activities or decisions of these organizations must avoid any potential conflict of interest. Organizations should insist on and physicians agree to disclosure of any arrangements they or their immediate families have with the corporate sector that could lead to conflicts of interest, for example, the holding of stock, equity interests, directorships or consulting relations with a company. Obviously physicians must avoid participating in decisions that affect companies in which they have financial arrangements. These precepts do not imply that physicians should not *have* financial relations with industry but that these relations must be revealed before situations occur in which there is potential conflict of interest.

VII. Physicians, Industry and Research

Physicians are indispensable to the health care research conducted by industry. The maintenance of scientific integrity by all parties in these endeavors is essential. Industry must utilize proper safeguards that assure that they do not influence results of the sponsored research. Physicians should not have arrangements with industry, such as stock or equity interests, that would result in financial advantage based on the results of the study.

The use of inside information for personal gain by physicians involved in research or data review is both illegal and unethical.

When participating as an investigator in industry-sponsored single investigator clinical research or multicenter trials the investigator 1) should not be given personal incentive payments or rewards for accomplishing a research protocol; 2) should not hold direct significant financial inter-

est of any kind in the product under investigation; 3) should have a role in choosing the safety and data monitoring committee; 4) may participate in "postmarketing (phase IV) research" of the product investigated; 5) must divulge payments to patients to the institutional review board; 6) may be considered as a "preferred" speaker relating to the clinical research; and 7) should be cautious about premature promotion of a drug through lectures, news media or other means.

VIII. Conclusions

The following are guidelines for ethical behavior of cardiovascular specialists relating to industry, institutions and organizations.

1. General

A guiding principle for physicians must be that their decisions about patient care are not based on monetary, scientific or academic gain. Physicians must not be influenced by external financial incentives in such a way that would cause them to act in a manner contrary to their best professional judgment.

2. Industry-sponsored programs or conferences

The primary objective of such programs must be educational, and the programs should not be used as promotional tools.

A. Industry-initiated conferences. Physicians participating as faculty members in such meetings have a special obligation to be sure that unbiased information is presented.

B. Physician-initiated programs. Programs must be organized and conducted primarily as educational programs. Industry should not specify speakers or topics. Attendees should pay tuition and travel expenses.

C. Industry and trainees. Supervising of physicians, particularly directors of training programs, should take an active role in assuring that ethical principles are adhered to by all parties and that material is presented in a balanced way.

3. Publications sponsored by industry

Publications should be subject to peer review.

4. Gifts from industry

Acceptable gifts are those that are "inexpensive and related to the practice of medicine . . .—a useful criterion of acceptability may be—would you be willing to have these arrangements generally known?" (4).

5. Physician ownership of health care facilities

Such ownership is acceptable if it clearly improves patient care above that which is available in the community. Disclosure of ownership to patients is mandatory.

6. Relation of physicians to institutions and organizations

A. Institutions referral. Physicians should base decisions of where to refer their patients on quality of care issues and the ability to provide better care, regardless of financial incentives to the physician.

B. Organizations. One must avoid participation in decisions affecting companies in which one has financial arrangements.

7. Physicians, industry and research

Physicians should not hold direct, significant financial interest of any kind (including equity interest) with a company whose product is under investigation.

Physicians hold a favored position in society because society perceives us as being unique. We have the ability to cure their diseases, alleviate their suffering, allay their anxieties and our rewards for doing so are considerable. Only as long as society perceives these to be our primary goals will we retain this favor of society.

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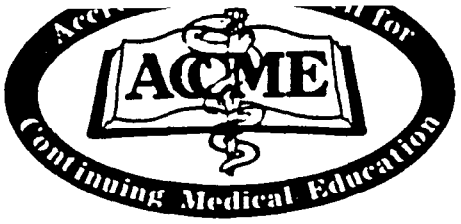

GUIDELINES FOR COMMERCIAL SUPPORT OF CONTINUING MEDICAL EDUCATION

(Revision of guidelines previously approved by ACCME: June, 1984)

PREAMBLE

The purpose of continuing medical education (CME) is to enhance the physician's ability to care for patients. It is the responsibility of the accredited sponsor of a CME activity to assure that the activity is designed primarily for that purpose.

Accredited sponsors often receive financial and other support from non-accredited commercial organizations. Such support can contribute significantly to the quality of CME activities. The purpose of these guidelines is to describe appropriate behavior of accredited sponsors in planning, designing, implementing, and evaluating certified CME activities for which commercial support is received.

GUIDELINES

1. Accredited sponsors are responsible for the content, quality, and scientific integrity of all CME activities certified for credit. Identification of continuing medical education needs, determination of educational objectives, and selection of content, faculty, educational methods and materials is the responsibility of the accredited sponsor. Similarly, evaluation must be designed and performed by the accredited sponsor.

2. The accredited sponsor is responsible for the quality, content, and use of enduring materials for purposes of CME credit. (For the definition, see ACCME "Guidelines for Enduring Materials.")

3. Presentations must give a balanced view of all therapeutic options. Use of generic names will contribute to this impartiality. If trade names are used, those of several companies should be used rather than only that of a single sponsoring company.

4. When commercial exhibits are part of the overall program, arrangements for these should not influence planning nor interfere with the presentation of CME activities. Exhibit placement should not be a condition of support for a CME activity.

5. The ultimate decision regarding funding arrangements for CME activities must be the responsibility of the accredited sponsor. Funds from a commercial source should be in the form of an educational grant made payable to the accredited sponsor for the support of programming. However, all support in

relation to the certified CME activity must be made with the full knowledge and approval of the accredited sponsor. Payment of reasonable honoraria and reimbursement of out-of-pocket expenses for faculty is customary and proper. Commercial support must be acknowledged in printed announcements and brochures, however, reference must not be made to specific products. Following the CME activity, upon request, the accredited sponsor should be prepared to report to each commercial supporter and other relevant parties, and each commercial supporter to the accredited sponsor, information concerning the expenditures of funds each has provided.

6. Commercially supported social events at CME activities should not compete with, nor take precedence over, the educational events.

7. An accredited sponsor shall have a policy on conflict of interest applicable to CME activities. All certified CME activities shall conform to this policy.

8. In an activity offered by an accredited sponsor it is not permissible to provide for travel, lodging, honoraria, or personal expenses for attendees. Subsidies for hospitality should not be provided outside of modest meals or social events that are held as a part of the activity.

   Scholarship or other special funding to permit medical students, residents, or fellows to attend selected educational conferences may be provided, as long as the selection of students, residents or fellows who will receive the funds is made either by the academic or training institution or by the accredited sponsor with the full concurrence of the academic or training institution.

Approved by the ACCME
March 16, 1991

These Guidelines were approved by the Joint Task Force on Pharmaceutical Industry/CME Provider Collaboration, February 15, 1991.

The American Surgical Association has considered the ethical implications of marketing practices of companies providing material necessary in the care of surgical patients. For years such companies have been benefactors of surgery through actions supporting teaching, graduate training of surgeons, and surgical research. Subsidies have emanated principally from corporate bodies and were provided to groups, societies, and academic departments, to promote good will toward corporate names.

In recent years the practice of concentrating on product promotion by targeting individual surgeons has been increasingly evident. It is the implications of this change in approach that has become a concern of the American Surgical Association. As a result, the Association feels the practice of providing direct payment to surgeons for the purposes of promoting a product is not in the best interest of patients, of the profession of surgery, or of the intended recipient of the subsidy, and must be considered as unethical practice if the enticement is accepted. The need for industry to promote its products is well understood, but to do so by attempted persuasion of individuals through unearned monetary or other reward has to be considered as a form of bribery. The promotional effort is aimed at influencing the judgment of the recipient who is paid for allowing himself to be subjected to the industry's promotional influence. The end result may be a loss of objectivity secondary to bias evoked by the enticement. Considering the importance of decisions impacting on the care of patients, this possibility is not acceptable. To distinguish between what is acceptable and what is not, the following position has been taken:

It is the position of the American Surgical Association that it is unethical for a surgeon to accept remuneration or material reward for participating in advertising or other product promotional activity of a health care-related industry, with no relationship to professional service rendered by the surgeon. "Remuneration or material reward" is meant to imply money, gifts, gratuities such as vacation, travel, or other emoluments. Acceptable "professional services rendered" include bona fide consultation services; legal testimony of qualified specialty consultants; product testing, evaluation, development, and experimental or

clinical research. Giving papers or lectures at the behest of a health care-related industry for the primary purpose of promoting a drug, an appliance, or any other health care supply item is not an acceptable professional service warranting remuneration.

The position presented here by the American Surgical Association does not connote any direct restriction or punitive action. For the reasons stated, it simply provides the guidelines for ethical behavior that have heretofore not been clearly stated. This action is taken with a full realization of the important role industry has played in collaborating with the medical community in the past and with the hope that future relationships and interactions will be both proper and mutually beneficial.

Chairmen of departments of surgery and surgical program directors are encouraged to support this position and to discourage unethical practices.

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Statement on Ethical Conduct in Research by the Infectious Diseases Society of America

It is stated in the By-Laws of the Infectious Diseases Society of America that individuals are elected to membership or fellowship "on the basis of evidence of high professional and ethical standards," and the Society considers ethical conduct to be an implicit requirement of continued membership. Provision exists also in the By-Laws for the expulsion of any member for cause. In an era of heightened concern over the ethical aspects of conduct in a highly complex society, involving relationships among individuals, educational institutions, hospitals, private corporations, and government, the Society has attempted to identify certain features of these relationships requiring careful consideration by the parties entering into them. The Society recognizes its inability to legislate the morals of its members and of those with whom they interact. It does expect, however, that each member recognize his/her full responsibility to the Society and to the medical profession to maintain standards of conduct that will stand full public scrutiny.

To assist members in achieving this desideratum, the Society has identified a number of areas where attention to the concepts and procedures set forth may help to avoid misunderstandings and perceptions of questionable or of improper conduct. This latter goal is best achieved, perhaps, through the use, whenever possible, of peer review and of full disclosure of relationships established for the furtherance of scientific investigation. To assist members who do not have suitable institutional affiliations for the purposes described, the Society should consider the establishment of committees or of panels to fulfill these functions for members who request them.

Research Proposals

Content: Whether initiated by the investigator or by another individual or agency, the proposal should be subjected to peer review by an acceptable agency that does not have a vested interest in the outcome of the investigation.

Human Subjects: Evidence of compliance with existing regulations should be documented for all research involving the participation of human subjects. Impartial review of all such proposals by a third party should be mandatory.

Funding: Whenever possible, defrayal of investigational costs should be institutionalized. Funds from the donor should flow through institutional channels (university, hospital) rather than being paid directly to the investigator. All financial transactions should be subject to audit and available for public disclosure if and when appropriate. Funds accepted for specific purposes should be utilized solely for those purposes and should not be diverted for personal or for institutional use for purposes other than those stipulated under the terms of the award.

Publication of Results: No contract should be entered into that restricts the prompt disclosure of findings that affect, in any way, the public welfare. Disclosure of support from a sponsor with a vested interest in the outcome of any investigation should always accompany oral presentation or publication of results.

Personal Conduct

Members of the Society should be constantly sensitive to the need not only to do no wrong but also to the need not to give the appearance of doing wrong.

(*A*) In fulfilling functions in which there may be the appearance of a conflict of interest, full disclosure of relationships among the involved parties should be made.

(*B*) Interactions between industry and members of the Society and their affiliated institutions may be mutually beneficial. Such relationships should always be disclosed by members of the Society who are involved in any governmental advisory or regulatory process. Because members of the Society most knowledgeable about a given drug or device and most frequently called upon to testify about it are often those most likely to have had some contact with its manufacturer, they are the ones also at greatest risk of finding themselves confronted with a conflict of interest. Such conflicts may arise

[*Editor's note.* This statement on ethical conduct was developed by a subcommittee appointed by the Council of the IDSA. It has the full endorsement of the Officers and Council members of the IDSA.]

out of subtle and seemingly insignificant relationships that are nonetheless open to varying interpretations when subjected to public scrutiny. If and when potential for conflict exists, a member should consider declining to testify unless such testimony is both essential to the public interest and is preceded by a statement describing all potential conflicts.

(*C*) Individuals should guard against excessive reimbursement for services to industry; e.g., honoraria for lectures, fees for consultation, and perquisites for attending meetings or other sponsored activities. Acceptance of such honoraria and fees should be in accordance with the regulations of the individual's primary employer.

(*D*) Individuals engaged in consultative or contractual activities with industry should recognize the implications of other financial relationships, such as the ownership of stock in companies they are advising.

(*E*) Individuals having financial relationships with industry should be equally careful in choosing the content of material for oral or written public presentation not subject to prior review as they are in preparation of material subject to editorial review prior to publication. Investigators should be especially sensitive to the potential conflict of interest arising from the written or verbal endorsement of products for the study of which they have received financial support from industry. While it is evident that peer review and opinion will rectify, in time, erroneous or biased views (the professional integrity of the faculties of the medical schools being probably the strongest ethical force in the system), harm may result in the interval between presentation and its rectification.

(*F*) Individuals whose speaking engagements are funded by industry should encourage industry to support institutions seeking speakers, so that the latter institutions may make their own selections and have direct financial dealings with speakers. Speakers receiving honoraria directly from entities that support their work or in which they have a financial interest should consider filing with their primary employer (or the Society) a periodic itemized accounting of such stipends, to be available for public scrutiny.

APPENDIX C

Methodological Notes

1. INTERVIEWS: We asked each CEO to arrange for us to speak with at least one of each of the following: the chief of the medical staff, the chief of pharmacy, the director or supervisor of medical education, the chief resident, the chief infectious disease specialist, a member of the institutional review board, a member of the ethics committee, a cardiologist, a gastroenterologist, a psychiatrist, an internist (preferably a geriatric specialist), a pediatrician, an obstetrics or gynecology specialist, and a surgeon.

2. GUIDELINES: We contacted or attempted to contact all the medical organizations listed in Sourcebook on Health Occupations to inquire about their guidelines. This amounted to almost 30 major medical organizations.

APPENDIX D

Endnotes

1. Senate Labor and Human Resources Committee hearings on Pharmaceutical Advertising, Marketing, and Promotional Practices, December 11-12, 1990.

2. By promotional, we mean any activity that is intended to change physicians' prescribing based on other than purely scientific information.

3. K. Feather, "Ask the FDA: Can We Use This Study Promotionally?" *Medical Marketing and Media*, April 1990, pp. 52, 54, 56.

4. Hospital grand rounds, department meetings, professional organization meetings, stand-alone educational and promotional seminars, dinner meetings, and round-table discussions are all forums for physician speakers who are sponsored by pharmaceutical companies.

5. E. Hemminki, "Review of Literature on the Factors Affecting Drug Prescribing," *Social Science & Medicine* 9 (1975): 111-116.

6. K. Leffler, "Persuasion or Information? The Economics of Prescription Drug Advertising," *Journal of Law and Economics* 24, no. 1 (1981): 45-74.; J. Lexchin, "Pharmaceutical Promotion in Canada: Convince Them or Confuse Them," *International Journal of Health Services* 17, no. 1 (1987): 77-89.; D. Christensen, and P. Bush, "Drug Prescribing: Patterns, Problems, and Proposals," *Social Science and Medicine* 15A (1981): 343-355.; E. Hemminki, "Review of Literature on the Factors Affecting Drug Prescribing," *Social Science and Medicine* 9 (1975): 111-116.; and G. Keele, "A Survey of the Effects of a Drug Promotion Campaign," *Journal of the Royal College of General Practitioners* 26 (1976): 382-386.

7. D. Christensen and A. Wertheimer, "Sources of Information and Influence on New Drug Prescribing Among Physicians in an HMO," *Social Science and Medicine* 13A (1979): 313-322. and M. Peay and E. Peay, "Differences among Practitioners in Patterns of Preference for Information Sources in the Adoption of New Drugs," *Social Science and Medicine* 18, no. 12 (1984): 1019-1025.

8. M. Bowman and D. Pearle, "Changes in Drug Prescribing Patterns Related to Commercial Company Funding of Continuing Medical Education," *The Journal of Continuing Education in the Health Professions* 8 (1988): 13-20.

9. J. Mackowiak and J.P. Gagnon, "Effects of Promotion on Pharmaceutical Demand," *Social Science and Medicine* 20, no. 11 (1985): 1191-1197.

10. J. Avorn, M. Chen, and R. Hartley, "Scientific Versus Commercial Sources of Influence on the Prescribing Behavior of Physicians," *American Journal of Medicine* 73 (1982): 4-8.

11. M. Chren, C.S. Landefeld, and T. Murray, "Doctors, Drug Companies and Gifts," *Journal of American Medical Association* 262, no. 24 (1989): 3448-3451.

12. S.E. Goldfinger, "A Matter of Influence," *New England Journal of Medicine* 316 (1987): 1408-1409.

13. Gifts to Physicians from Industry, American Medical Association, Council on Ethical and Judicial Affairs, Report G, Adopted 12/4/90.

14. R.E. Hite and J.A. Bellizzi, "Salespeople's Use of Entertainment and Gifts," *Industrial Marketing Management* 16 (1987): 279-285.

15. A. Shama and J.K. Thompson, "Gifts Build Goodwill and Market Share," *Journal of Retail Banking* 11 (1989): 55-59.

16. M. Bowman, "The Impact of Drug Company Funding on the Content of Continuing Medical Education," *MOBIUS* 6, no. 1 (1986): 66-69.

17. Council on Ethical and Judicial Affairs, "Gifts to Physicians From Industry," *Journal of the American Medical Association* 265, no. 4 (1991): 501.

18. The American Academy of Dermatology, the American Academy of Ophthalmology, the American College of Physicians, the American Osteopathic Association, and the American Psychiatric Association provided us with guidelines or bylaws dealing with conflicts of interest or gift arrangements from industry.

19. American Surgical Association, *Minutes of the One Hundred and Seventh Meeting*, April 27, 1987, pp. lxxvi - lxxvii.

20. American College of Obstetricians and Gynecologists Committee on Ethics, Guidelines for Relationships between Industry and the American College of Obstetricians and Gynecologists and Its Fellows, ACOG Committee Opinion, Number 45, October 1985.

21. C.R. Conti et al., "Task Force V: The Relation of Cardiovascular Specialists to Industry, Institutions and Organizations," *Journal of the American College of Cardiologists* 16, no. 1 (1990): 30-36.

22. Infectious Disease Society of America, "Statement on Ethical Conduct in Research by the Infectious Diseases Society of America," *Journal of Infectious Disease* 150 (1985): 792-793.

23. Accreditation Council for Continuing Medical Education, Guidelines for Commercial Support of Continuing Medical Education, Approved March 16, 1991.

24. "Vanderveer Group Adopts Code of Principles in Response to Hill Criticism of Physician Dinner Meetings and Honoraria; Code Outlines Restrictions on Gifts," *F-D-C Reports*, April 29, 1991.

25. Physicians were asked whether there were any kinds of pharmaceutical company sponsored education (and, separately, research) that they considered inappropriate. They were not required to have been involved in the education or research they were calling inappropriate.

26. Practices outlined include a $20,000 grant extended to a researcher by a pharmaceutical company to get a study favorable to the company's product published (*SELF*, March 1991); extraordinary marketing pressure placed on physicians to prescribe TPA (*Time*, March 18, 1991); a research project requiring collecting minimal information on at least five new patients in return for money (*Public Citizen*, March/April 1991); and a circus-like extravaganza put on by pharmaceutical companies at a hospital pharmacist convention in Las Vegas (*American Journal of Hospital Pharmacists* 48, 1991).

27. Merck Sharp & Dohme's ads appeared in the *Journal of the American Medical Association* and the *New England Journal of Medicine* in February, March, and April of 1991.

28. T. Randall, "AMA, Pharmaceutical Association Form 'Solid Front' on Gift-Giving Guidelines," *Journal of the American Medical Association* 265, no. 18 (May 8, 1991): 2304.

29. Collagen Corp. was planning on sending dermatologists who purchased high volumes of injectable collagen on an 8 day "educational cruise" in the South Pacific at the firms' expense in late June, 1991. The promotion was recently cancelled. See T. Randall, "Not All Drug Firms Subject to Gifts Guidelines, But, for Physicians, Their Gifts Are Still Taboo," *Journal of American Medical Association* 265: no. 18 (May 8, 1991): 2305 and T. Randall, "Promotional Cruise Scuttled in Ethics Storm, Wome Would-Be Cruisers Claim Financial Damages," *Journal of American Medical Association* 265: no. 22 (June 12, 1991): 2929.

30. The Federation of State Medical Boards currently does not even collect information on disciplinary actions taken as a result of financial conflict of interest or other financially oriented ethical violations. (Federation of State Medical Boards Disciplinary Code List, FSMB files.)

31. "MD-Promotion Guideline Implementation Described in Letter to Kennedy," *PMA Newsletter* 33, no. 5 (February 4, 1991): 2-3.

32. TAP Pharmaceuticals gave 700 physicians round-trip airfare, 4 nights' lodging, and registration fees to attend a ACOG meeting in May, 1991. The winners were selected in drawings held between August 1, 1990 and February 1, 1991. See T. Randall, "Some Promotions Began Before, But Extended Into, Grace Period of AMA/PMA Guidelines," *Journal of the American Medical Association* 265, no. 18 (May 8, 1991): 2309.

33. Infectious Disease Society of America, p. 792.

34. American Surgical Association, p. lxxvi.

35. W. Parmley et. al., "Task Force I: Background and General Principles," *Journal of the American College of Cardiology* 16, no. 1 (1990): 7-10.

36. Kessler, D. and Pines, W., "The Federal Regulation of Prescription Drug Advertising and Promotion," *Journal of the American Medical Association* 264, no. 18 (1990): 2409- 2415.

37. "Drug Advertising Regulatory Action By FDA Appears Likely: FDA Collecting Records on Repeat Offenders in Preparation for Setting Object Lesson," *F-D-C Reports*, February 18, 1991.

38. " . . . The Hit List," *PMA Newsletter* 33, no. 19 (May 13, 1991): 1.

39. "Authority Uncertain, FDA Tries to Enforce AMA Promotion Guidelines," *PMA Newsletter* 33, no. 12 (1991): 1.

40. "FDA Will Set Up Drug Promotion Abuse "Hotline" for Physicians and Pharmacists; Agency is Still Considering Criminal Prosecutions as Object Lesson." *F-D-C Reports* (April 29, 1991): 1-2.

41. "RX Drug Advertising Will Be Target of New FDA Enforcement Effort," *PMA Newsletter* 33, no. 9 (1991): 1.

42. "Open Label, 'Seeding' Studies for Unapproved Uses Will Be Regulated as Promotions; FDA is Watching Symposia Setting and Conflict of Interest Issues," *F-D-C Reports* (September 24, 1990): 16.