

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**PRESCRIPTION DRUG PROMOTION
INVOLVING PAYMENTS AND GIFTS:
PHYSICIANS' PERSPECTIVES**



**Richard P. Kusserow
INSPECTOR GENERAL**

OEI-01-90-00481

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EXECUTIVE SUMMARY

PURPOSE

The purpose of this study is to estimate to what extent physicians are offered gifts and payments from pharmaceutical companies.

BACKGROUND

There has been much attention paid recently to prescription drug promotion practices involving payments and gifts. In December 1990, the Senate Labor and Human Resources Committee held hearings that highlighted questionable promotional practices. At these hearings, the American Medical Association (AMA) announced the release of ethical guidelines on gifts to physicians from industry. The Pharmaceutical Manufacturers Association (PMA) immediately adopted these guidelines in full.

In August 1991, we reported the range of prescription drug promotion practices involving payments and gifts. We discussed the vulnerabilities such practices present and the responses of government and private groups to inappropriate and illegal practices.

We found that gifts and offers of value related to studies, speaking engagements, and program attendance are used by pharmaceutical companies to promote their drugs. We also found that promotional practices involving items of value appear to affect physicians' prescribing decisions. The medical community and the pharmaceutical industry consider certain promotional practices involving items of value to be inappropriate. It is unclear, however, what effect their recently developed ethical guidelines have had and will have on pharmaceutical companies and physicians. The Department of Health and Human Services (HHS) has taken initial action in controlling inappropriate or illegal activity. In particular, the Food and Drug Administration (FDA) has drafted guidelines defining the difference between scientific education and promotion.

We concluded in our first report that the concerns raised by our findings warranted further monitoring of prescription drug promotion. As part of that effort, we have selected a national random sample of approximately 1,000 physicians to inquire about items of value offered to them by pharmaceutical companies.

We asked physicians questions about the offers that had been extended to them in the previous 12 months. The period covered by our survey was fall 1990 to fall 1991. The objective of our study is not to evaluate the effectiveness of the **AMA/PMA** guidelines, which were in effect for most but not all of our survey period. We do, however, use the guidelines as reference points to classify the offers.

FINDINGS

Pharmaceutical companies offered gifts or payments on at least one occasion in the year prior to fall 1991 to 82 percent of physicians. Gifts most frequently offered included pens, notepads, pharmaceutical samples for personal or family use, meals, and drinks; payments most frequently offered included travel expenses and honoraria for attending educational programs, and compensation for participation in focus groups.

- ▶ Pharmaceutical companies offered gifts and payments on an average of 28 occasions to each physician and offered gifts and payments other than small gifts such as pens and notepads on an average of 13 occasions to each physician.
- ▶ According to physicians' estimates, the median value of all gifts and payments offered each physician was \$125.
- ▶ Pharmaceutical companies were more likely to offer gifts and payments to physicians who were frequent prescribers than to those who were infrequent prescribers.

In the year prior to fall 1991, pharmaceutical companies offered many physicians gifts or payments that are specifically defined by the current AMA/PMA guidelines as being inappropriate. These offers include gifts that bear no relation to the physician's work and payment of travel expenses or honoraria for attending educational programs or meetings.

- ▶ Pharmaceutical companies offered such gifts or payments at least once to 27 percent of physicians.
- ▶ Pharmaceutical companies offered such gifts or payments at least once to 36 percent of physicians who wrote at least 50 prescriptions a week.
- ▶ Some of these offers, in addition to being defined as inappropriate, may be illegal.

The AMA/PMA guidelines' definition of what is inappropriate is not precise in some cases. In the year prior to fall 1991, pharmaceutical companies offered many physicians gifts or payments that fall short of being in the guidelines.

- ▶ Pharmaceutical companies offered 51 percent of physicians pharmaceutical samples for their own or their family's use. These offers may have had no relation to the physicians' practice and may not have entailed benefits to patients.
- ▶ Pharmaceutical companies offered physicians compensation for involvement in different types of focus groups and studies. Some of these offers may have been token consulting arrangements or gifts with strings attached.

RECOMMENDATIONS

Although the findings of this study do not allow us to measure the effects of the **AMA/PMA** guidelines, the evidence of so many offers now seen as inappropriate raises some important conclusions. If most of these offers took place prior to the guidelines' promulgation, then these findings indicate that the guidelines addressed a significant problem and that continued attention to their adherence is necessary. If, however, some of the offers have taken place since the implementation of the guidelines, more attention should be paid to their adherence. Our recommendations focus on further clarifications the Department of Health and Human Services and the PMA should make on the interpretation of certain offers.

The Public Health Service (PHS), through the Food and Drug Administration (FDA), should finalize guidelines defining what it considers promotional activity and what it considers scientific interchange.

- ▶ These guidelines would clarify how important FDA considers gifts and payments associated with educational seminars and meetings to be in indicating promotional intent.

The Pharmaceutical Manufacturers Association should work with the American Medical Association to more specifically define lines of propriety in the remaining gray areas of their guidelines.

- ▶ Improved clarity is necessary in areas of market surveys, focus groups, and post-marketing surveillance research.

COMMENTS

We received written comments on our draft report from the Assistant Secretary for Health (PHS), the American Medical Association (AMA), the Pharmaceutical Manufacturers Association (PMA), the Accreditation Council for Continuing Medical Education (ACCME), and the Public Citizen Health Research Group (PCHRG). The full texts of these comments are in Appendix E. We also received notice of concurrence with no elaboration from the Assistant Secretary for Planning and Evaluation.

The PHS concurred with the recommendations of our report. They also made several technical comments resulting in our making slight changes in presentation, including more information about biasing effects. The AMA cited the importance of our study and had favorable comments about it. The PMA felt the report had significant methodological flaws and problems with the reporting of the results and conclusions. We addressed the **PMA's** comments about the presentation of the value of offers, but disagree with the remainder of their comments. The ACCME made supportive

comments. The PCHRG supported our findings. However, because they felt our findings demonstrated that the **AMA/PMA** guidelines have failed, they suggested that we recommend legislation banning gifts and payments extended for promotional purposes. Because we cannot draw conclusions about the effectiveness of the guidelines, we have not incorporated **PCHRG's** suggestion to recommend new legislation.

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INTRODUCTION

The purpose of this study is to estimate to what extent physicians are offered gifts and payments from pharmaceutical companies.

BACKGROUND

There has been much attention paid recently to prescription drug promotion practices involving payments and gifts. In December 1990, the Senate Labor and Human Resources Committee held hearings that highlighted questionable promotional practices. At these hearings, the American Medical Association (AMA) announced the release of ethical guidelines on gifts to physicians from industry. The Pharmaceutical Manufacturers Association (PMA) immediately adopted these guidelines in full.¹

In August 1991, we reported the range of prescription drug promotion practices involving payments and gifts.² We discussed the vulnerabilities such practices present and the responses of government and private groups to inappropriate and illegal practices.

We found that gifts and offers of value related to studies, speaking engagements, and program attendance are used by pharmaceutical companies to promote their drugs. We also found that promotional practices involving items of value appear to affect physicians' prescribing decisions.³ The medical community and the pharmaceutical industry consider certain promotional practices involving items of value to be inappropriate.⁴ It is unclear what effect their recently developed ethical guidelines have had and will have on pharmaceutical companies and physicians.⁵ The Department of Health and Human Services (HHS) has taken initial action in controlling inappropriate or illegal activity. In particular, the Food and Drug Administration (FDA) has drafted guidelines defining the difference between scientific education and promotion. The FDA has also set up a hotline for physicians and others to report questionable promotional practices.⁶

We concluded that the concerns raised by our findings warranted further monitoring of prescription drug promotion. As part of that effort, we undertook a national survey of physicians to inquire about items of value that had been offered to them by pharmaceutical companies. We mailed surveys to 997 physicians who bill the Medicare program. We received 617 usable responses from physicians in a wide variety of specialties and locations. For details on our sampling selection, survey methods, survey instrument, possible biases, and respondent profiles, see appendix B.

We asked physicians several background questions and then inquired about whether they had been offered a variety of gifts, promotional offers, research funding or payments, and payments or travel for attending or presenting at educational or other

programs. We asked about how often these offers had been presented and what their value was, and then whether there were obligations to prescribe drugs attached to the offer. For offers involving educational programs, we asked whether or not they were offered continuing medical education credits for the program.

We asked physicians questions about the offers that had been extended to them in the previous 12 months. The period covered by our survey was fall 1990 to fall 1991. The objective of our study is not to evaluate the effectiveness of the **AMA/PMA** guidelines, which were in effect for most but not all of our survey period. We do, however, use the guidelines as reference points to classify the offers.

We present all data without factoring in any biasing effects of a 38 percent nonresponse rate and false or incorrect reporting by respondents. As we argue in appendix B, these biasing effects are likely to cause underreporting of the frequency and size of the offers extended. Therefore, figures on frequency and size of offers in this report are likely to be conservative estimates.

Our review was conducted in accordance with the ***Interim Standards for Inspections*** issued by the President's Council on Integrity and Efficiency.

FINDINGS

Pharmaceutical companies offered gifts or payments on at least one occasion in the year prior to fall 1991 to 82 percent of physicians.

- ▶ Pharmaceutical companies offered gifts and payments on an average of 28 occasions to each physician and offered gifts and payments other than small gifts such as pens and notepads on an average of 13 occasions to each physician.

Pharmaceutical companies offered gifts or payments on at least one occasion in the past year to 82 percent (95 percent confidence interval is ± 3 percent) of physicians and on 5 or more occasions to 79 percent.⁷ These offers ranged from small gifts such as prescription pads and pens to major funding for research activity. On average, pharmaceutical companies offered gifts or payments 28 times (± 4) to each physician in the year prior to fall 1991.⁸ Most physicians (77 percent) were offered small gifts such as pens and prescription pads, but, on average, each physician was offered at least one more substantive gift or payment. Pharmaceutical companies offered gifts or payments other than small gifts to 71 percent of physicians; they extended these offers on an average of 13 occasions (± 3) to each physician.⁹ Commonly offered items included pharmaceutical samples for personal or family use (50 percent), meals or drinks (37 percent), and payment for participating in focus group sessions (18 percent). (See table 1 for more detail.)

- ▶ According to physicians' estimates, the median value of all gifts and payments offered each physician was \$125.

The value of the offers that pharmaceutical companies made to physicians ranged from \$0 to \$38,315. The median total dollar value physicians ascribed to items offered to them during the year was \$125.¹⁰ The median value of each offer was approximately \$10.¹¹ Three offers for research funding were \$20,000 or more.

Offers involving research and educational activities were worth more than those involving gifts. Compensation for research involving an experimental drug not yet approved by **FDA** had a median value of \$1,250 and travel and/or accommodation expenses to attend a program or meeting at which the physician did not present information had a median value of \$550. (See table 1 for detailed information.)

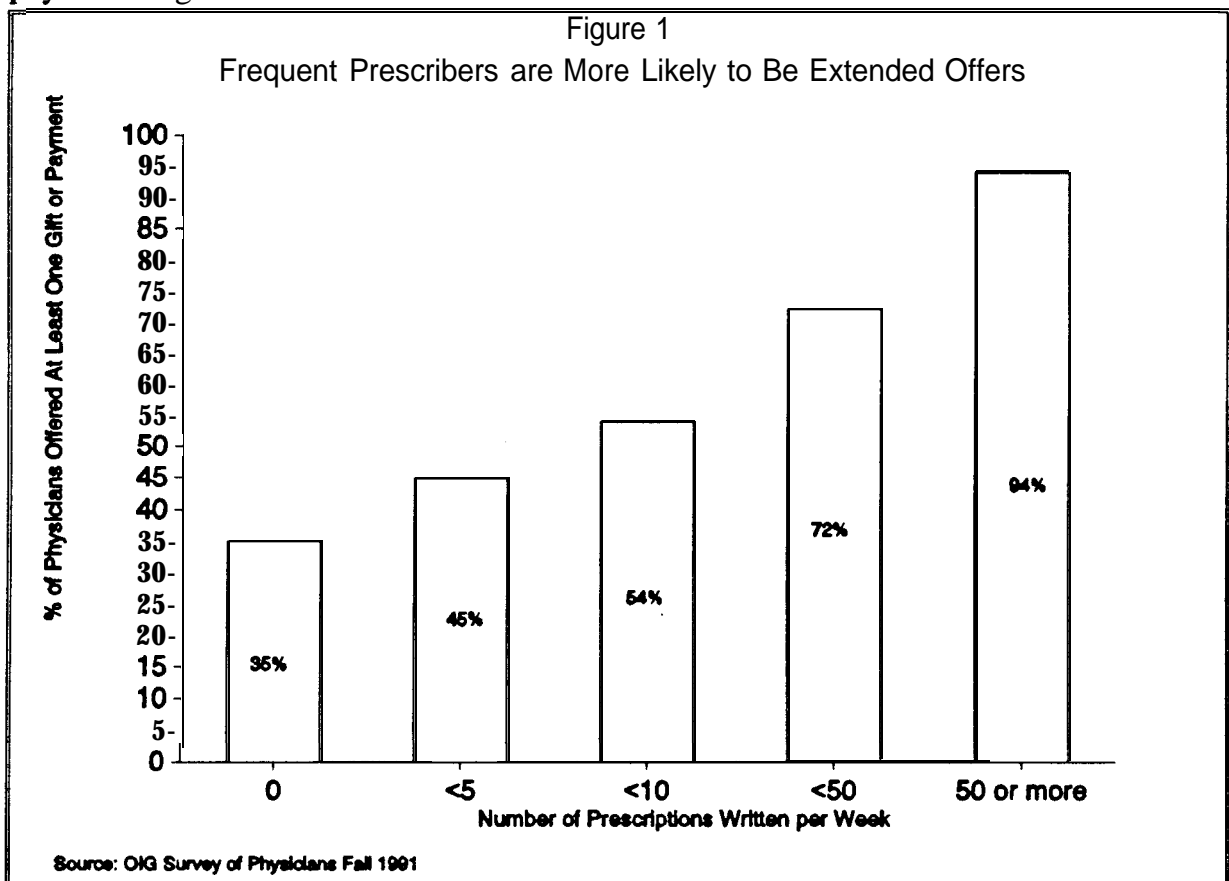
Table 1
Offers from Pharmaceutical Companies to Physicians

OFFER	NUMBER OF PHYSICIANS OFFERED (n=617)	PERCENT OF PHYSICIANS OFFERED	AVERAGE NUMBER OF OFFERS	MEDIAN TOTAL VALUE OF OFFERS
Small gifts such as pens and prescription pads	475	77%	20	\$12
Pharmaceutical samples for personal/family use	309	50%	9	\$50
Meals or drinks	227	37%	8	\$45
Compensation for participating in focus group sessions	114	18%	3	\$100
Medical texts	105	17%	2	\$50
Cash honoraria for attending educational programs at which the physician was not a presenter	67	11%	3	\$100
Travel and/or accommodation expenses for the physician to go to out-of-town programs at which he/she was not a presenter	67	11%	2	\$550
Travel/ accommodation expenses and/or honoraria for making presentations at educational programs	42	7%	2	\$500
Other gifts, tickets, and hospitality for attending educational programs at which the physician was not a presenter	39	6%	3	\$95
Entertainment or sporting event tickets	38	6%	2	\$50
Medical equipment	38	6%	3	\$75
Travel and/or accommodation expenses for a spouse or companion to accompany the physician to educational programs at which the physician was not a presenter	34	6%	1	\$375
Compensation for conducting studies that required recording clinical information	34	6%	1	\$162
Other items for personal family use	34	6%	5	\$20
Compensation for conducting studies that required prescribing the drug being studied to people who were not previously taking it	25	4%	2	\$200
Compensation for supervising or conducting clinical trials on experimental drugs not yet approved by FDA	23	4%	2	\$1,250
Compensation for conducting studies that required recording demographic, but not clinical information	15	2%	2	\$87
Office equipment	15	2%	3	\$20
Gifts of money	5	1%	1	\$80
OVERALL	509	82%	28	\$125

Source: OIG Survey of Physicians, Fall 1991.

- ▶ Pharmaceutical companies were more likely to offer gifts and payments to physicians who were frequent prescribers than to those who were infrequent prescribers.

We asked physicians how many prescriptions for drugs they write per week. Pharmaceutical companies offered at least one gift or payment to 89 percent of the physicians who write at least one prescription per week; they offered at least one gift or payment to 35 percent of the physicians who do not prescribe drugs (this difference is significant: chi-square value is 96 at 1 degree of freedom). They were also more likely to offer gifts and payments to physicians who frequently prescribe drugs than to physicians who less frequently prescribe drugs. For example, pharmaceutical companies offered at least one payment or gift to 94 percent of the physicians who write at least 50 prescriptions a **week**.¹² Figure 1 displays the relationship between number of prescriptions written and percent of physicians offered at least one payment or gift.



We also asked physicians to identify their primary specialty and classified their answers into forty-three specialties. Pharmaceutical companies extended offers to many physicians in high-prescribing specialties, such as internal medicine, family practice, dermatology, and cardiology. (See appendix C for more detailed information.)

In the year prior to fall 1991, pharmaceutical companies offered many physicians gifts or payments that are specifically defined by the current AMA/PMA guidelines as being inappropriate.

On December 3, 1990, the American Medical Association revised its ethical code to incorporate new guidelines on gifts to physicians from the industry.¹³ The Pharmaceutical Manufacturers Association endorsed these guidelines in full. These guidelines define acceptable and unacceptable offers in some areas. The following are specified 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

Some of these guidelines outline activities that are difficult (if not impossible) to examine in a survey of physicians. For example, it is difficult to distinguish between token and real consulting arrangements.¹⁴ However, we asked physicians whether they had been offered several items that are now clearly prohibited by the guidelines: gifts of cash, travel and/or accommodation expense for attending a meeting for the physician and for a spouse or companion, and certain gifts that are not related to the physician's work or that do not entail benefits to the patient.”

- ▶ Pharmaceutical companies offered gifts or payments explicitly defined by the current **AMA/PMA** guidelines as being inappropriate on at least one occasion to 27 percent of physicians.

Pharmaceutical companies offered entertainment or sporting event tickets to 6 percent of the physicians, other items for personal or family use to 6 percent, gifts of money to 1 percent, gifts that required the physician to prescribe a company's drug as a condition for receiving the offer to 1 percent, travel to and/or accommodations at a program at which the physician was not a presenter to 11 percent, a spouse or companion's travel to and/or accommodations at a program at which the physician was not a presenter to 6 percent, and cash honoraria for attending a program at which the physician was not a presenter to 11 percent. All of these offers were specifically defined by the PMA guidelines as being **inappropriate**.¹⁶

On average, the total value of the offers prohibited by the PMA guidelines was \$574 (median value was \$105). Pharmaceutical companies offered 4 percent of physicians gifts or payments outside of the guidelines on 10 or more occasions, including one

physician who was offered gifts or payments prohibited by the guidelines on 33 occasions.

- ▶ Pharmaceutical companies offered gifts or payments explicitly defined by the current **AMA/PMA** guidelines as being inappropriate on at least one occasion to 36 percent of physicians who wrote more than 50 prescriptions a week.

Physicians who are heavy prescribers of drugs were more frequently offered gifts and payments outside of the guidelines. For example, pharmaceutical companies offered such gifts or payments on at least one occasion in the last year to 30 percent of the physicians who write 5 or more prescriptions a week, 31 percent of the physicians who write 10 or more prescriptions a week, and 36 percent of the physicians who write 50 or more prescriptions a week.”

- ▶ Some of these offers, in addition to being defined as inappropriate, may be illegal.

The Medicare and Medicaid anti-kickback statute (42 U.S.C. **§ 1320a-7b(b)**) makes it a felony for a person or entity to knowingly and willfully offer, pay, solicit, or receive any remuneration with the intent to induce or in return for the ordering or furnishing of items or services paid for in whole or in part under the Medicare or Medicaid programs. A person or entity is also subject to exclusion from participation in the Medicare and Medicaid programs for a knowing and willful violation of the **anti-kickback** statute, 42 U.S.C. **§ 1320a- 7(b) (7)**.

The offering of compensation or gifts based on the number of prescriptions for pharmaceuticals which might be paid for by the Medicare and Medicaid programs could breach the anti-kickback statute. A total of 18 (nonresearch) offers of “remuneration” were made to physicians requiring the prescribing of a particular drug as a condition for receiving the offer. To the extent that these drugs were covered and reimbursed in whole or in part by the Medicare or Medicaid programs, the offering and receipt of such remuneration could be considered as violative of the **anti-kickback** statute.

In addition, the offers of compensation for conducting studies that required prescribing the drug being studied to people who were not previously taking it could, depending on the design of the study, be in violation of the anti-kickback provisions. Pharmaceutical companies made offers of this type to 4 percent of the physicians.

The AMA/PMA guidelines' definition of what is inappropriate is not precise in some cases. In the year prior to fall 1991, pharmaceutical companies offered many gifts or payments that fall into gray areas in the guidelines.

- ▶ Pharmaceutical companies offered 51 percent of physicians pharmaceutical samples for their own or their family's use. These offers may have had no relation to the physicians' practice and may not have entailed benefits to patients.

The **AMA/PMA** guidelines clearly disapprove of pharmaceutical companies offering any gift that is not related to the physician's work or that does not entail benefits to a patient. It is difficult to see how paying patients get any benefit from companies offering pharmaceutical samples to physicians for their own or their family's use. Yet, pharmaceutical companies offered 51 percent of the physicians pharmaceutical samples for their own or their family's use.¹⁸

- ▶ Pharmaceutical companies offered physicians compensation for involvement in different types of focus groups and studies. Some of these offers may have been token consulting arrangements or gifts with strings attached.

The **AMA/PMA** guidelines are vague in their definition of inappropriate or appropriate research funding by pharmaceutical companies, disapproving only of token consulting arrangements and gifts with strings attached." None of the questions we asked directly addressed these issues, but we did delineate several types of research funding.

Pharmaceutical companies offered 4 percent of physicians compensation for conducting studies that required prescribing the drug being studied to people who were not previously taking it. Some legitimate research protocols require the patients involved to be "virgin" patients to limit the biasing effects of a patient having used the drug previously. But, if the study is being done for promotional purposes and the use of research funding is simply to start patients on a particular drug, it could be seen as a gift with strings attached.

Pharmaceutical companies offered 2 percent of physicians compensation for conducting studies that required recording demographic, but not clinical information. This type of research could be seen as illegitimate scientific research and, therefore, may be token consulting.

Finally, focus groups could be used for purposes disapproved of by the **AMA/PMA** guidelines (see note 13 for a more detailed discussion). It is not clear whether some of these sessions were simply token consulting arrangements. Pharmaceutical companies offered 19 percent of the physicians compensation for participating in focus group sessions.

RECOMMENDATIONS

Although the findings of this study do not allow us to measure the effects of the AMA/PMA guidelines, the evidence of so many offers now seen as inappropriate raises some important conclusions. If most of these offers took place prior to the guidelines' promulgation, then these findings indicate that the guidelines addressed a significant problem and that continued attention to their adherence is necessary. If, however, some of the offers have taken place since the implementation of the guidelines, more attention should be paid to their adherence. Our recommendations focus on further clarifications the Department of Health and Human Services and the PMA should make on the interpretation of certain offers.

The public Health Service (PHS), through the Food and Drug Administration (FDA), should finalize guidelines defining what it considers promotional activity and what it considers scientific interchange.

The FDA has the responsibility for overseeing promotional activities of pharmaceutical manufacturers.²⁰ It released a draft concept paper in October 1991 on pharmaceutical company-supported activities in scientific or educational contexts.²¹ In this paper, FDA spells out the proposed conditions for educational seminars not to be seen as promotional. Included in this draft is a statement about gifts: "The following factors suggest promotional intent: (a. GIFTS) Inducements (other than perhaps meals or token gifts), e.g., travel or lodging subsidies, are provided to encourage attendance of the target audience." By making this statement an official guideline, FDA would clearly interpret many of the offers attached to seminars mentioned in our survey as indicating promotional intent. This type of policy statement would be very helpful in delineating FDA's opinion on certain gifts and payments.

The Pharmaceutical Manufacturers Association should work with the American Medical Association to more specifically define lines of propriety in the remaining gray areas of their guidelines.

Although we are unable to determine the effect of the guidelines on relations with industry that the American Medical Association developed and the Pharmaceutical Manufacturers Association adopted, the guidelines have clearly heightened awareness of the issues and have likely slowed the prevalence of inappropriate gifts and payments.²² For this reason, we feel it is important to expand the guidelines to more effectively define inappropriate activities in the areas of research and focus groups. Clarifying what determines a "string attached gift" or "token consulting arrangement" would allow the pharmaceutical industry to make clear cut decisions about what are and are not appropriate ways of conducting post-marketing and market research.

COMMENTS ON THE DRAFT REPORT

We received written comments from the Assistant Secretary for Health, the American Medical Association, the Pharmaceutical Manufacturers Association, the Accreditation Council for Continuing Medical Education, and Public Citizen Health Research Group. The full texts of these comments are in Appendix E. We also received notice of concurrence with no elaboration from the Assistant Secretary for Planning and Evaluation.

Assistant Secretary for Health

The Public Health Service concurred with the recommendations of our report. They were, however, concerned about our presentation of the value of offers made to physicians. They cited the positive skew in the distribution of values and suggested we address inconsistencies between the mean and median values. They noted that our discussion of potential bias did not include recall bias which they thought would tend to cause underreporting. They felt that our presentation of bias was not given adequate emphasis by virtue of its placement in a methodological appendix and suggested discussion in the text of these issues. They also had several technical comments.

We have changed our presentation of the value of offers to consistently reject the median values as opposed to mean, thus conservatively estimating the “average” value of the offers. We added information about the potential bias of short term recall and made clear our judgements about the overall bias direction. We included a brief summary of this information in the introduction to highlight its importance. We have addressed the other technical comments.

American Medical Association

The American Medical Association cited the importance of our study and had favorable comments about it. They also cited their continuing effort to clarify and make more specific their guidelines on gifts from industry to physicians. The AMA also noted the positive effects their guidelines have had on the ethical promotion of prescription drugs.

We welcome the American Medical Association³ efforts in continuing to clarify and make more specific their guidelines. We are particularly encouraged that the AMA has decided to address the complex ethical issues of physicians’ acceptance of fees for participation in market research focus groups and clinical research and their acceptance of pharmaceutical samples for personal use. We hope that the AMA guidelines have had the effects the AMA claims.

Pharmaceutical Manufacturers Association

The Pharmaceutical Manufacturers Association recommended that the final report not be published, citing methodological flaws and problems with the reporting of the results and conclusions. The PMA asked that we not use the results of our survey to draw conclusions about the effectiveness of their ethical guidelines. In particular, they felt that the timing of our survey made it impossible to measure the effectiveness of their guidelines. They also expressed concerns about the biasing effects of a response rate of 62 percent, though they did not speculate on the potential direction of the bias. They stated that our presentation interprets all payments and gifts as promotional. Finally, they felt that our presentation of the value of the gifts and payments offered was misrepresentative because of a positive skew in the distribution.

We do not agree that there are significant methodological flaws or problems with our presentation. Our survey was not intended to measure the effectiveness of the ethical guidelines produced by the AMA and agreed upon by the PMA. Because of concerns raised by us in our earlier report entitled "Prescription Drug Promotion Involving Payments and Gifts," we felt there was a significant lack of information available about how frequently or commonly physicians were offered any kind of payment or gift from pharmaceutical companies. As our purpose states, we conducted this survey to estimate the extent to which physicians are offered gifts and payments from pharmaceutical companies. We do not draw conclusions or speculate on the timing of the offers, but do point out the differing implications of our findings if the offers were extended prior to or after the promulgation of the guidelines.

We are convinced that the response rate we attained allows us to state our findings with sufficient precision. While we have no way of explicitly measuring nonrespondent bias, we think that nonrespondents would be even more likely to have been offered payments and gifts. Comments from the Public Health Service and Public Citizen Health Research Group support this position. We have made a more conclusive statement about this and other potential biases in the introduction to the report.

We agree with PMA that not all consulting arrangements or payments for research activity are necessarily inappropriate or even promotional in intent. Certain manufacturers must involve physicians in legitimate clinical research and other decisions and should compensate them for this time. Since, however, the potential exists for any type of financial offer to be used inappropriately to influence prescribing decisions, we felt it was important to profile all types of payments and gifts. We did not make any statement implying that all payments are inappropriate and certainly would not make that argument.

We agree with PMA's comments about our presentation of the values of the offers. We have changed our presentation of the value of offers to consistently reflect the median values, thus conservatively estimating the "average" value of the offers.

Accreditation Council for Continuing Medical Education

The ACCME made supportive comments.

Public Citizen Health Research Group

The Public Citizen Health Research Group (PCHRG) supported our findings. However, because they felt our findings demonstrated that the **AMA/PMA** guidelines have failed, they suggested that we recommend legislation banning gifts and payments extended for promotional purposes. They felt that our findings demonstrate that inappropriate offers have been made since the promulgation of the guidelines.

On the basis of the findings of this study, we cannot make definitive statements about the effectiveness of the AMA/PMA guidelines. We certainly agree that there is a possibility that inappropriate offers were extended after the promulgation of the guidelines, and in fact discuss the implications of that possibility in our conclusion. However, we must emphasize that our purpose in conducting this study was not to measure the effectiveness of the guidelines, but to estimate to what extent physicians are offered gifts and payments from pharmaceutical companies. That the guidelines were developed in the midst of the study period only serves to underscore the importance of these issues. Because we cannot draw conclusions about the effectiveness of the guidelines, we have not incorporated PCHRG's suggestion to recommend new legislation.

APPENDIX A

ETHICAL GUIDELINE#3 OF THE AMERICAN MEDICAL ASSOCIATION AND THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION

American Medical Association

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

Report: F
(X-90)

Subject: Opinion of the Council on Ethical and Judicial Affairs--Gifts to Physician6 from Industry

Presented by: Richard J. McMurray, MD, Chairman

Referred to: Reference Committee on Amendment6 to Constitution and Bylaw6
(David B. Carmichael, Jr., MD, Chairman)

1 The Council on Ethical and Judicial Affairs6 submits the
2 following opinion to the House of Delegate6 for its information and
3 recommends that **this** report be filed.
4

5 GIFTS TO PHYSICIANS FROM INDUSTRY. Many gifts given to
6 physicians by companies in the pharmaceutical, device and medical
7 equipment industries **serve** an important and socially beneficial
8 function. For example, companies have long provided funds for
9 educational seminars and conferences. **However**, there has been
10 growing concern about certain gifts from industry to physicians.
11 Some gifts that reflect customary practices of industry may not be
12 consistent with principles of medical ethics. To avoid the
13 acceptance of inappropriate gifts, physicians should **observe** the
14 following guidelines:
15

16 1. Any gift6 accepted by physicians individually should
17 primarily entail a benefit to patient6 and should not be of
18 substantial value. Accordingly, textbooks, modest meals and other
19 gift6 are appropriate if they **serve** a genuine educational
20 function. Cash payments should not be accepted.
21

22 2. Individual gifts of minimal value are permissible as long
23 as the gift6 are related to the physician's work (e.g., pen6 and
24 notepad6).
25

26 3. Subsidies to underwrite the costs of continuing medical
27 education conferences or professional meetings can contribute to
28 the improvement of patient care and therefore are **permissible**.
29 Since the giving of a subsidy directly to a physician by a
30 company's sales representative may create a relationship which
31 could influence the use of the company's products, any subsidy
32 should be accepted by the conference's sponsor who in turn can use
33 the money to reduce the conference's registration **fee**. Payment6 to
34 defray the costs of a conference should not be accepted directly
35 from the company by the physicians attending the conference.

1 4. **Subsidies** from **industry** **should** not be accepted to pay for
2 the **cost** of travel, **lodging** or other **personal expenses** of
3 **physicians** attending **conferences** or meetings, nor **should subsidies**
4 be accepted to compensate for the **physicians' time**. **Subsidies** for
5 hospitality **should** not be accepted outside of **modest meals** or
6 **social** events held as a part of a conference or meeting. It **is**
7 appropriate for faculty at conference or meeting to accept
8 reasonable honoraria and to accept reimbursement for reasonable
9 travel, lodging and **meal** expenses. It **is** also appropriate for
10 **consultants** who provide genuine services to receive reasonable
11 compensation and to accept reimbursement for **reasonable** travel,
12 lodging and meal expenses. Token **consulting** or advisory
13 arrangement cannot be used to justify **compensating** physicians for
14 their time or their travel, **lodging** and other out-of-pocket
15 expenses.

16
17 5. Scholarship or other special funds to permit medical
18 students, residents and **fellows** to attend carefully selected
19 educational conferences may be permissible as long as the selection
20 of students, residents or fellows who will receive the **funds is**
21 made by the academic or training institution.

22
23 6. No gifts **should** be accepted **if** there are **strings**
24 attached. For example, physician **should** not accept **gifts if they**
25 are given in relation to the physician's prescribing practices. **In**
26 addition, when **companies** underwrite medical conferences or **lectures**
27 other than their own, responsibility for and control over the
28 **selection** of content, faculty, educational methods and materials
29 **should** belong to the organizer of the conference or **lectures**.

APPENDIX B

METHODOLOGY

Sample selection

We surveyed a total of 997 physicians nationally. The physicians were identified from a data base of Medicare billing physicians (one percent BMAD file). This file identifies physicians not by name, but by Medicare provider number. The provider numbers must be linked to name and address by Medicare carriers. In order to limit the number of carriers we had to contact for names and addresses, we selected eight carriers and then drew a random sample of 125 physicians for each carrier. The carriers were selected with probability of selection equal to the number of provider numbers in the data base for the carrier divided by the total number of provider numbers in the data base nationally.

The carriers selected were:

- Equitable of North Carolina
- Aetna of Hawaii
- Florida Blue Shield
- Aetna of Oklahoma
- Aetna Georgia
- Michigan Blue Shield
- Texas Blue Shield
- Occidental California

We then randomly selected 125 provider numbers for each of the carriers. Each carrier was sent the provider numbers and asked to return the names and addresses of the physicians who used them. The carriers were able to identify all but three physicians, resulting in our surveying 997 physicians.

Survey methods

We sent each physician a survey and cover letter on September 25, 1991, asking them to return the survey by October 7, 1991. We mailed a **followup** letter and another copy of the survey to the physicians who had not returned it by October 15, 1991, asking them to return it by October 21, 1991. We cut off receipt of the surveys on November 29, 1991. Several surveys were received after this date and were not included in the analysis.

survey instrument

We asked physicians a total of 91 closed ended questions and then requested additional comments. Seven questions -- concerning whether the sampling provisions of the Prescription Drug Marketing Act of 1987 were being followed -- related to another study. See appendix D for a copy of the survey instrument.

Profile of respondents

We received usable responses from 617 or 62 percent of the physicians we sampled. Of the 38 percent who did not respond, 78, or 21 percent, were returned to us because they were undeliverable or the physician no longer practiced or was deceased. Table 2 details various characteristics of the physicians responding to the survey.

Table 2
Profile of Respondents

Average number of years in practice	22
Percent of respondents participating in research	14%
Average percent time working on research	10%
Average, percent of research funded by pharmaceutical companies	22%
Percent of respondents who see patients in a hospital	84%
Average percent time working in hospitals	37%
Percent most often working in an academic medical center	8%
Percent most often working in a community teaching hospital	30%
Percent most often working in a community nonteaching hospital	62%
Percent of respondents who see patients in private practice	92%
Percent in a group practice	42%
Percent of respondents who are salaried employees of an HMO	3%
Average number of patients seen per week	87
Average number of prescriptions written per week	79

Potential biases

There are three sources of potential bias in our sample: (1) The sample we drew could be biased, (2) the respondents could differ systematically from the nonrespondents, and (3) the respondents could have not answered questions truthfully or correctly.

Our sample was drawn as a random sample of physicians in the Medicare provider data base. This may not be representative of all physicians nationally. First, physicians in some specialties, such as pediatrics and obstetrics, rarely treat Medicare patients. Physicians who treat Medicare patients may be more or less likely than physicians who do not treat Medicare patients to have interactions with pharmaceutical companies. Second, our sample may not represent the Medicare population accurately. Our method of sampling could have drawn physicians more or less likely to have interactions with pharmaceutical companies. As an attempt to measure this potential bias, we compared the specialty mix in our sample with the specialty mix nationally and found no obvious problems. **Because we did not precisely analyze sample bias, we cannot make a judgement as to the direction or size of the bias.**

We looked at nonrespondent bias carefully. It seems that the potential for non-response was high with this survey. Some physicians who responded had very negative reactions to our survey. Physicians who had had interactions with pharmaceutical companies, particularly those who were unsure about the ethics and legality of those interactions, were probably less likely to respond to our voluntary survey. However, it is quite difficult to measure this potential bias. There is no information that we know about nonrespondents that obviously correlates with interactions with pharmaceutical companies. The only proxy we have is specialty of the physician. We compared the response rates for each specialty and found that overall, response rates are distributed across specialties as they are expected to be (see Table 2). A chi-square test was done to test whether the response rates were equal across specialties resulting in a statistic of 18.45 with 11 degrees of freedom (no significant difference at .05 level of significance).²³ **Although we cannot judge the strength of the bias, we expect non-respondent bias to cause our estimates of the level and size of offers to be low.**

We also looked at the potential bias of false, incomplete, or misunderstood answering of the questions in our survey. As noted above, some physicians were very negative about the survey and its implications, perceiving it as an attempt to elicit damaging information. In fact, prior to our survey being released, a lawyer was quoted in a national newsletter advising physicians to seek the advice of counsel before filling out the survey.²⁴ If, despite our best efforts to assure the physicians that all correspondence was strictly confidential, a respondent suspected that we were seeking to catch physicians involved in illegal activity, the person would be unlikely to inform us about an activity he or she considered marginally acceptable. There is, of course, no way to measure bias of this sort. But, given the relatively few very negative comments from physicians, we are inclined to believe this type of bias was minimal (see Table 3).

There is also the potential for underreporting because of recall bias. We asked physicians to recall events up to 12 months prior to the survey date. Physicians are probably more likely to recall their latest experiences than earlier ones. However, if a physician has been offered one or two payments or gifts that stood out as particularly interesting or inappropriate, they could recall them as having occurred within the past 12 months, even if they were extended more than 12 months prior. **We conclude that**

bias from avoidance of reporting inappropriate activities causes slight underreporting of offers. Bias caused by limited recall likely causes stronger underreporting, but this is balanced somewhat by bias caused by extended recall.

Overall, the effects of bias are not precisely known, but we believe they cause the information on number and value of offers to be underreported.

Data analysis

We analyzed the survey responses by inputting them into a dBASE III (Ashton-Tate Corporation) data base, converting that data base to a PC-SAS data base, and using a variety of PC-SAS procedures.²⁵

TABLE 2
Specialties of Physicians Selected for Inclusion

Specialty	Number in Selected Sample	Percent of Total Selected Sample	Number of Respondents	Percent of Total Respondents
Internal Medicine	175	17.5	85	14.1
Family Practice	112	11.2	82	13.6
General Practice	97	9.7	30	5.0
General Surgery	58	5.8	33	5.5
Radiology	52	5.2	26	4.3
Orthopedic Surgery	49	4.9	28	4.6
Cardiovascular Diseases	47	4.7	20	3.3
Ophthalmology	45	4.5	34	5.6
Anesthesiology	44	4.4	27	4.5
OB/GYN	35	3.5	23	3.8
Optometry	34	3.4	23	3.8
Podiatry	30	3.0	17	2.8
Other	222	22.2	175	28.4
<i>Urology</i>	27	2.7	18	3.0
<i>chiropractic</i>	25	2.5	12	2.0
<i>Psychiatry</i>	25	2.5	15	2.5
<i>Dermatology</i>	21	2.1	18	3.0
<i>Pathology</i>	19	1.9	12	2.0
<i>Neurology</i>	14	1.4	11	1.8
<i>Pulmonary Diseases</i>	13	1.3	8	1.3
<i>Gastroenterology</i>	12	1.2	9	1.5
<i>EENT</i>	11	1.1	8	1.3
<i>Thoracic Surgery</i>	11	1.1	4	0.7
<i>Neurological Surgery</i>	10	1.0	4	0.7
<i>Plastic Surgery</i>	7	0.7	5	0.8
<i>Nephrology</i>	6	0.6	3	0.5
<i>Allergy</i>	6	0.6	3	0.5
<i>oral Surgery</i>	4	0.4	2	0.3
<i>Geriatrics</i>	3	0.3	0	0
<i>Proctology</i>	3	0.3	0	0
<i>Physical Medicine</i>	2	0.2	2	0.3
<i>Pediatrics</i>	2	0.2	1	0.2

Specialty	Number in Selected Sample	Percent of Total Selected Sample	Number of Respondents	Percent of Total Respondents
<i>Osteopathic Ophthalmology</i>	1	0.1	0	0
<i>Oncology</i>	0	0	11	1.8
<i>Emergency Medicine</i>	0	0	8	1.3
<i>Rheumatology</i>	0	0	6	1.0
<i>Pain Management</i>	0	0	3	0.5
<i>Vascular Surgery</i>	0	0	3	0.5
<i>Dentist</i>	0	0	2	0.3
<i>Infectious Disease</i>	0	0	2	0.3
<i>EMT</i>	0	0	1	0.2
<i>Nuclear Medicine</i>	0	0	1	0.2
<i>Holter Monitoring</i>	0	0	1	0.2
<i>Hematology</i>	0	0	1	0.2
<i>Colon/Rectal Surgery</i>	0	0	1	0.2

Note: Specialties of physicians sampled were determined by the BMAD coding; specialties of physicians responding were self-reported by the physicians. It is possible a physician's specialty was more specific or general in the BMAD coding than in his or her own coding. It is also possible that the BMAD coding is several years old and the physician has shifted subspecialties.

Source: BMAD files and OIG Survey of Physicians' Interactions with Pharmaceutical Companies, Fall 1991.

TABLE 3

Comments of Responding Physicians

Paraphrased Comments	Number of Respondents Making Comment	Percent of Respondents Making Comment
All dealings with pharmaceutical companies have been ethical and positive/Nobody has bribed me/ This is not a problem here	49	8%
I have little or no contact with pharmaceutical companies	38	6%
I refuse all or most offers	17	3%
Offers have no influence	16	3%
This survey is a waste of time and/or money/The problem is blown out of proportion	15	2%
Drug companies do excessive things and/or should be controlled more	9	1%
Things have changed in the last few years/The industry polices itself	7	1%
This is a witch hunt	5	1%
Congress and other industries are just as much into this and should be investigated	5	1%
I wish I were offered these things	5	1%
Drugs cost too much money	5	1%

Source: Comments from respondents to OIG Survey of Physicians' Interactions with Pharmaceutical Companies, Fall 1991.

APPENDIX C

PHARMACEUTICAL COMPANIES OFFERS OF GIFTS AND PAYMENTS BY SPECIALTY

SPECIALTIES WITH TEN OR MORE RESPONDENTS		
Specialty	Number of physicians	Percent offered at least one gift or payment
Neurology	11	100%
Internal Medicine	85	99%
Family Practice	82	% %
Dermatology	18	94%
Urology	18	94%
Psychiatry	15	93%
Oncology	11	91%
Orthopedic Surgery	28	89%
Cardiovascular Disease	19	89%
General Surgery	33	88%
General Practice	30	87%
OB/GYN	16	87%
Podiatry	17	82%
Anesthesiology	27	78%
Ophthalmology	34	56%
Optometry	23	39%
Radiology	26	35%
Pathology	12	17%
Chiropractic	12	0%
SPECIALTIES WITH LESS THAN 10 RESPONDENTS		
Level of prescribing	Number of physicians	Percent offered at least one gift or payment
Low (Less than 10 prescriptions written per week)	14	71%
Medium (Between 10 and 49 prescriptions written per week)	29	93%
High (At least 50 prescriptions written per week)	43	95%

Source: OIG Survey of Physicians' Interactions with Pharmaceutical Companies, Fall 1991.

APPENDIX D

QUESTIONNAIRE

SURVEY OF PHYSICIANS REGARDING INTERACTIONS WITH PHARMACEUTICAL MANUFACTURERS

All of your answers are strictly confidential and will be used only for the purposes of this study.

We are interested in hearing about your responses to this survey. Please call 800-551-5154 to discuss specific promotions or to ask questions about the survey.

BACKGROUND

- B1.** What is your primary specialty? _____
- B2.** In what year did you receive your medical degree? _____
- B3.** Do you participate in research? Y N
- If YES,
- B3A.** What percentage of your working time do you do research? _____ %
- B3B.** What percentage of your research is funded by pharmaceutical companies? _____ %
- B4.** Do you see patients in a hospital? Y N
- If YES,
- B4A.** What percentage of your working time do you spend working in hospitals? _____ %
- B4B.** What kind of hospital do you most often work in? _____
1. Academic medical center
2. Community teaching hospital
3. Community non-teaching hospital
- B5.** Do you see patients in private practice? Y N
- B5A.** If YES, is it a group practice? Y N
- B6.** Are you a salaried employee of an HMO? Y N
- B7.** How many patients do you see per week? _____/week
- B8.** How many prescriptions for drugs do you write per week? _____/week

Promotion

Please indicate which of the following have been offered to you by pharmaceutical companies in the last 12 months and, if the offer has been extended, answer the questions in columns B and C.

OFFER	A. Was this offered to you in the last 12 months?	B. On how many occasions was this offered to you?	C. What was the total approximate value of these offers?	D. How many offers, as a condition for receiving them, required you to prescribe a manufacturer's drug?
P1. Small gifts (i.e. pens, prescription pads, etc.)	YES NO	_____	\$ _____	_____
P2. Meals or drinks	YES NO	_____	\$ _____	_____
P3. Entertainment or sporting event tickets	YES NO	_____	\$ _____	_____
P4. Medical texts	YES NO	_____	\$ _____	_____
P5. Medical equipment	YES NO	_____	\$ _____	_____
P6. Office equipment	YES NO	_____	\$ _____	_____
P7. Pharmaceutical samples for personal/family use	YES NO	_____	\$ _____	_____
P8. Other items for personal/family use (<i>specify</i>)	YES NO	_____	\$ _____	_____

P9. Gifts of money (<i>specify purposes</i>)	YES NO	_____	\$ _____	_____

Research and Information Gathering Activities

Please indicate which of the following have been offered to you by pharmaceutical companies in the last 12 months and, if the offer has been extended, answer the questions in columns B, C, and D.

OFFER	A. Was this offered to you in the last 12 months?	B. On how many occasions was this offered to you?	C. What is the approximate value of the offers?	D. For how many of these offers was your compensation dependent on the number of prescriptions you wrote?
R1. Compensation for supervising or conducting clinical trials on experimental drugs not yet approved by FDA	YES NO	_____	\$ _____	_____
STUDIES ON FDA-APPROVED DRUGS				
R2. Compensation for conducting studies which required recording demographic information, but did not require recording clinical information	YES N O	_____	\$ _____	_____
R3. Compensation for conducting studies which required recording clinical information	YES NO	_____	\$ _____	_____
R4. Compensation for conducting studies (including those in R2. and R3.) which required prescribing the drug being studied to people who were not previously taking it.	YES NO	_____	\$ _____	_____
R5. Compensation for participating in focus group sessions	YES NO	_____	\$ _____	_____

Educational Programs

Please indicate which of the following have been offered to you by pharmaceutical companies in the last 12 months and, if the offer has been extended, answer the questions in columns B, C, and D.

OFFER	A. Was this offered to you in the last 12 months?	B. On how many occasions was this offered to you?	C. What was the approximate value of the offers?	D. How many of these programs offered continuing medical education credits for those who attend?
E1. Travel and/or accommodation expenses for you to go to out of town programs at which you were not a presenter (<i>list sites</i>)	YES NO	_____	\$ _____	_____
E2. Travel and/or accommodation expenses for a spouse or companion to accompany you to educational programs at which you were not a presenter (<i>list sites</i>)	YES NO	_____	\$ _____	_____
E3. Cash honoraria for attending educational programs at which you were not a presenter (regardless of location)	YES NO	_____	\$ _____	_____
E4. Other gifts, tickets and hospitality for attending educational programs at which you were not a presenter (regardless of location)	YES NO	_____	\$ _____	_____
E5. Travel/accommodation expenses and/or honoraria for making presentations at educational programs	YES NO	_____	\$ _____	_____

Pharmaceutical Samples²⁶

Below we ask about pharmaceutical samples you have received in the last twelve months. Please indicate whether or not you have received samples. If you have, please indicate whether or not you have been required to request these samples in writing and confirm their receipt.

	A. Within the last 12 months, on how many occasions do you recall having received samples?	B. On how many of these occasions do you recall having signed <u>written</u> <u>requests/ written</u> <u>confirmations of receipt</u> for these samples?	
S1. Samples obtained at professional meetings	_____	_____	_____
S2. Samples delivered to your office by a company's representative	_____	_____	_____
S3. Samples delivered to your home or office by mail/common carrier	_____	_____ requests	_____ receipts

Additional Comments

Thank you for completing our survey. If you have any additional comments you would like to make or there were other offers that were not covered in our brief survey that you would like to inform **us** of, please do **so here. Remember: To tell us your feeling about offers from pharmaceutical manufacturers, to discuss specific offers, or to ask questions about the survey, please call (800) 551-5154.**

Comments:

APPENDIX E

DETAILED COMMENTS ON THE **DRAFT** REPORT

In this appendix, we present in full the comments on the draft report offered by the Assistant Secretary for Health, the American Medical Association, the Pharmaceutical Manufacturers Association, the Accreditation Council for Continuing Medical Education, and the Public Citizen Health Research Group.



Memorandum

JUN 9 1992

Date

from

Assistant Secretary for Health

Subject

Office of Inspector General (OIG) Draft Report "Promotion of Prescription Drugs Through Payments and Gifts: Physicians' Perspectives ," OEI-01-90-00481

To

Inspector General, OS

Attached are the PHS comments on the subject OIG draft report. We concur with the report's recommendation to PHS. Our comments outline the actions being taken to implement it.


James O. Mason, M.D., Dr.P.H.

Attachment

PUBLIC HEALTH SERVICE (PHS) COMMENTS ON THE OFFICE OF
INSPECTOR GENERAL (OIG) DRAFT REPORT "PROMOTION OF
PRESCRIPTION DRUGS THROUGH PAYMENTS AND GIFTS:
PHYSICIANS' PERSPECTIVES," OEI-01-90-00481

OIG Recommendation

The Public Health Service (PHS), through the Food and Drug Administration (FDA), should finalize guidelines defining what it considers promotional activity and what it considers scientific interchange.

PHS Comment

We concur. The PHS agrees that the FDA should provide guidance to pharmaceutical companies on the distinction drawn by the FDA between promotional activities and independent scientific exchange.

The FDA's Center for Drug Evaluation and Research's (CDER) Division of Drug Marketing, Advertising, and Communications, began this process in October 1991. At that **time, the** CDER issued in draft a paper entitled "Drug Company Supported Activities in Scientific or Educational Contexts: A **Draft** Concept Paper." The paper addresses the FDA's regulation of promotional activities that occur in scientific or educational settings.

The CDER requested and received comments on the draft paper from the pharmaceutical industry, medical community, other government agencies, and the general public. The comments have been evaluated and the concept paper has been presented to the Deputy Commissioner for Policy. The FDA's Deputy Commissioner for Policy is continuing the process of developing a policy guidance document in consultation with the Office of the Assistant Secretary for Health. We expect that the policy guidance will be finalized and published in Fiscal Year 1993.

Technical Comments

Page 3, Second Bullet, First Paragraph and Page 4, Table 1,
"Offers from Pharmaceutical Companies to Physicians"

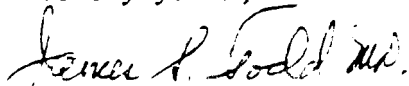
We noted the inconsistencies between the means and the median scores, on many of the measures reported on pages 3 and 4. In order to improve the clarity of the report, we suggest that the OIG address these inconsistencies and also **discuss the** potential significance of the positive skew in the distribution.

Letter to Richard P. Kusserow
Page 2

expenses to physician6 to attend speakers' training programs or to students, residents and fellows to attend educational conferences. In view of the frequency with which physicians were offered pharmaceutical samples for personal use, we will address the propriety of that gift as well.

We welcome the opportunity to continue working with you in addressing the concerns raised by gifts from industry to physicians.

Sincerely yours,

A handwritten signature in cursive script that reads "James S. Todd, MD". The signature is written in dark ink and is positioned above the typed name.

James S. Todd, MD

American Medical Association

Physicians dedicated to the health of America



James S. Todd, MD
Executive Vice President

515 North state street
Chicago, Illinois 60610

312 464-4810

June 4, 1992

Richard P. Kusserow
Inspector General
Department of Health & Human Services
330 Independence Avenue, SW, Room 5250
Washington, DC 20201

Re: Promotion of Prescription Drugs Through Payments and Gifts:
Physicians' Perspectives

Dear Mr. Kusserow:

Thank you for the opportunity to comment on the draft report of the Office of Inspector General.

The OIG study of gifts to physicians from the pharmaceutical industry is a very important one. There are still inadequate data on the gift-giving practices of industry.

Overall, we are encouraged by the survey results. For the most part, industry and the profession appear to be complying with the American Medical Association's guidelines on gifts from industry. For example, only 1% of physicians reported offers of gifts of money; only 6% of physicians reported offers of entertainment or sporting event tickets. In addition, the data reported would tend to underestimate the degree of compliance. The period covered by the study began before the guidelines were issued, and there was a transition period of several months before the guidelines were fully in effect. We believe that the joint efforts of the AMA and the Pharmaceutical Manufacturers Association provide an excellent model of self-regulation.

We agree that the guidelines do not always give specific enough guidance. Consequently, in October 1991, we issued a several-page document with clarifications of the guidelines. This interpretive document provides answers to more than thirty common questions about the guidelines. The interpretive process is on-going; we plan to issue clarifications on several other questions in the coming months, including the ones mentioned in your draft report. In particular, clarifications will be issued on when compensation is appropriate for participation in a market focus group or in clinical trials. We will also indicate more specifically when it is permissible to pay travel

Page 5, Bottom Paragraph, Appendix in Appendix C

The OIG draft report makes reference to the "gifts by specialty" breakouts. **Many** of the high **percentages appear** questionable because they are based on one or two individuals in each category. To mitigate this problem, the OIG should determine whether there are data that would allow the specialties to be combined as a function of frequency of prescribing. We believe a combined table would make a better presentation.

Page 9, First Paragraph, Second Sentence

We believe the phrase, "prior to the guidelines' development," should be changed to "prior to the guidelines' promulgation." This would clarify that the offers **under question took place**, before or after the issuance of **the guidelines and not during** the development of the guidelines.

Appendix B, Page B-2, Paragraph Under "Profile of Respondents"

The percentage reported as undeliverable (or ineligible) in the original sample is misleading. The sentence states "Of the 38 percent who did not respond . . . B percent, were returned **as**" In fact, the number represents **8 percent** of the total; 21 percent of the 380 non-responses.

Appendix B, Page B-2, Paragraph Under "Potential Biases"

We believe the OIG should address that **these data are** subject to a recall bias that would overemphasize the physicians' most recent experiences and underemphasize their experiences in the early part of the period covered. Accurate recall of events drops precipitously after 2 weeks. Therefore, **the physicians** were probably more likely to recall their latest experiences with pharmaceutical company offers, which took place subsequent to dissemination of the guidelines. This is a factor which would be likely to bias the data in favor of underreporting both the number and value of any offers **made.**

Appendix B, "Methodology"

Although there is a brief discussion of potentially biasing factors in the methodology appendix, we are concerned that most of the readers of these reports would not read **the appendices** and the discussion may **be lost.** We believe that it would be worthwhile to discuss **in the text of the report the likelihood** that offers were underreported because **those who received the most (and/or most valuable) offers were likely to be** overrepresented in the non-respondent category. The specialty breakout offered does not address this more general issue.

c. May contributions to a professional society's general fund be accepted from industry?

The guidelines are designed to deal with gifts from industry which affect, or could appear to affect, the judgment of individual practicing physicians. In general, a professional society **should** make its own judgment about gifts from industry to the society itself.

d. When companies invite physicians to a dinner with a **speaker**, what are the relevant guidelines?

First, the dinner must be a **modest** meal. Second, the guideline does allow gifts that primarily benefit patients and that are not of substantial value. Accordingly, textbooks and other gifts that primarily benefit patient care and that have a value to the physician in the general range of \$100 are permissible.

e. May physicians accept vouchers that reimburse them for uncompensated care they have provided?

No. Such a voucher would result directly in increased income for the physician.

f. May physicians accumulate "points" by attending several educational or promotional meetings and then choose a gift from a catalogue of educational options?

This guideline permits gifts only if they are not of **substantial** value. If accumulation of points would result in physicians receiving a substantial gift by combining insubstantial gifts over a relatively short period of time, it would be inappropriate.

g. May physicians accept gift certificates for educational materials when attending promotional or educational events?

The Council views gift certificates as a grey area which is not **per se** prohibited by the guidelines. Medical textbooks are explicitly approved as gifts under the guidelines. A gift certificate for educational materials, i.e., for the selection by the physician from an exclusively medical textbook catalogue, would not seem to be materially different. The issue is whether the gift certificate gives the recipient such control as to make the **certificate** similar to cash. As with charitable donations, pre-selection by the sponsor removes any question. It is up to the individual physician to make the final judgment.

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

Guideline 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

American Medical Association

Physicians dedicated to the health of America



Annotated Guidelines on Gifts to Physicians from Industry

Council on Ethical and Judicial Affairs
American Medical Association
Chicago, Illinois

Final Version
Issued October 9, 1991

k. May continuing medical education conference⁶ be held in the Bahamas, Europe or South America?

There are no restrictions on the location of conferences as long as the attendee⁶ are paying their own travel **expenses**.

l. May travel expenses be accepted by physicians who are being trained as **speakers** or faculty for educational conference⁶ and meetings?

In general, no. If a physician is presenting as an independent expert at a **CME event** both the training and its reimbursement raise questions about independence. In addition, the training is a gift because the **physician's** role is generally more analogous to that of an attendee than a participant. Speaker training **sessions** can be distinguished from meetings (**See 4b**) with leading researchers, sponsored by a company, designed primarily for an exchange of information about important development⁶ or treatments, including the **sponsor's** own research, for which reimbursement for travel may be appropriate.

m. What kinds of social event⁶ during conference⁶ and meetings may be subsidized by industry?

Social events should satisfy three criteria. First, the value of the event to the physician should be **modest**. Second, the event should facilitate discussion among attendee⁶ and/or discussion between attendees and faculty. Third, the educational part of the conference should account for a substantial majority of the total time accounted for by the educational activities and social event⁶ together. Events that would be viewed (as in the succeeding question) as lavish or expensive should be avoided. But modest social activities that are not elaborate or unusual are permissible, e.g., inexpensive boat rides, barbecues, entertainment that draw⁶ on the local performers. In general, any such events which are a part of the conference program should be open to all registrants.

n. May a company rent an 'expensive entertainment complex for an evening during a medical conference and invite the physicians attending the conference?

NO. The guidelines permit only modest hospitality.

o. If physicians attending a conference engage in interactive exchange, may their travel expenses be paid by industry?

NO. Mere interactive exchange would not constitute genuine consulting **services**.

p. If a company schedules a conference and provides meals for the attendees that fall within the guidelines, may the company also pay the costs of the **meals** for spouses?

If a meal falls within the guidelines, then the physician's spouse **may** be included.

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.

a. Are conference subsidies from the educational division of a company covered by the guidelines?

Yes. When the Council says "any subsidy," it would not matter whether the subsidy comes from the sales division, the educational division or some other section of the company.

b. May a company or its intermediary send physicians a check or voucher to offset the registration fee at a specific conference or a conference of the physician's choice?

Physicians should not directly accept checks or certificates which would be used to offset registration fees. The gift of a reduced registration should be made across the board and through the accredited sponsor.

Guideline 4. Subsidies from industry should not be accepted directly or indirectly 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.

a. If a company invites physicians to visit its facilities for a tour or to become educated about one of its products, may the company pay travel expenses and honoraria? This question has come up in the context of a rehabilitation facility that wants physicians to know of its existence so that they may refer their patients to the facility. It has also come up in the context of surgical device or equipment manufacturers who want physicians to become familiar with their products.

In general, travel expenses should not be reimbursed, nor should honoraria be paid for the visiting physician's time since the presentations are analogous to a pharmaceutical company's educational or promotional meetings. The Council recognizes that medical device-c, equipment and other technologies may require, in some circumstances, special evaluation or training in proper usage which can not

f. May a company compensate physicians for their time and travel expenses when they participate in focus groups?

Yes. As long as the focus groups serve a genuine and exclusive research purpose and are not used for promotional purposes, physicians may be compensated for time and travel expenses. The number of physicians used in a particular focus group or in multiple focus groups should be an appropriate size to accomplish the research purpose, but no larger.

g. Do the restrictions on travel, lodging and meals apply to educational programs run by medical schools, professional societies or other accredited organizations which are funded by industry, or do they apply only to programs developed and run by industry?

The restrictions apply to all conferences or meetings which are funded by industry. The Council drew no distinction on the basis of the organizer of the conference or meeting. The Council felt that the gift of travel expenses is too substantial even when the conference is run by a non-industry sponsor. (Industry includes all "proprietary health-related entities that might create a conflict of interest" as recommended by the American Academy of Family Physicians.)

h. May company funds be used for travel expenses and honoraria of bona fide faculty at educational meetings?

This guideline draws a distinction between attendees and faculty. As was stated, "[i]t is appropriate for faculty at conferences or meetings to accept reasonable honoraria and to accept reimbursement for reasonable travel, lodging, and meal expenses."

Companies need to be mindful of the guidelines of the Accreditation Council on Continuing Medical Education. According to those guidelines, "[f]unds from a commercial source should be in the form of an educational grant made payable to the CME sponsor for the support of programming."

i. May travel expenses be reimbursed for physicians presenting a poster or a "free paper" at a scientific conference?

Reimbursement may be accepted only by bona fide faculty. The presentation of a poster or a free paper does not by itself qualify a person as a member of the conference faculty for purposes of these guidelines.

j. When a professional association schedules a long-range planning meeting, is it appropriate for industry to subsidize the travel expenses of the meeting participants?

The guidelines are designed to deal with gifts from industry which affect, or could appear to affect, the judgment of individual practicing physicians. In general, a professional society should make its own judgment about gifts from industry to the society itself.

practicably be provided except on site. Medical specialties are in a better position to advise physicians regarding the appropriateness of reimbursement with regard to these trips. In cases where the company insists on such visits as a means of protection from liability for improper **usage**, physicians and their specialties should make the judgment. In no case would honoraria be appropriate and any travel expenses should be only those strictly necessary.

- b. If the company invites physicians to visit its facilities for review and comment on a product, to discuss their independent research projects or to explore the potential for collaborative research, may the company pay travel expenses and an honorarium?

If the physician is providing genuine services, reasonable compensation for time and travel expenses can be given. However, token advisory or consulting arrangements cannot be used to justify compensation.

- c. May a company hold a sweepstakes for physicians in which five entrants receive a trip to **the** Virgin Islands or airfare to the medical meeting of their choice?

No. The use of a sweepstakes or raffle to deliver a gift does not affect **the** permissibility of **the** gift. Since the sweepstakes is not open to the public, the guidelines apply in full force. .

- d. If a company convenes a group of physicians to recruit clinical investigators or convenes a group of clinical investigators for a meeting to discuss their results, may the company pay for their travel expenses?

Expenses may be paid if the meetings serve a genuine research purpose. One guide to their propriety would be whether the NIH conducts similar meetings when it sponsors multi-center clinical trials. When travel subsidies are acceptable, the guidelines emphasize that they be used to pay only for "reasonable" expenses. The reasonableness of expenses would depend on a number of considerations. For example, meetings are likely to be problematic if overseas locations are used for exclusively domestic **investigators**. It would be inappropriate to pay for recreation or entertainment beyond the kind of modest hospitality described in this guideline.

- e. How can' a physician tell whether there is a "genuine research purpose?"

A number of factors can be considered. Signs **that** a genuine **research** purpose exists include the facts that there are (1) a valid study protocol, (2) recruitment of physicians with appropriate qualifications or expertise, and (3) recruitment of an appropriate number of physicians in light of the number of study participants needed for **statistic**21 evaluation.

9* May companies donate funds to sponsor a professional society's charity golf tournament?

Yes. But it is sensible if physicians who play in the tournament make **some** contribution themselves to the event.

r. If a company invites a group of consultants to a meeting and a consultant brings a spouse, **may** the company pay the costs of lodging or meals of the spouse? Does it **matter** if the meal is part of the program for the consultants?

Since the costs of having a spouse share a hotel room or join a modest meal are nominal, it is permissible for the company to subsidize those **cos** ts. However, if the total subsidies become substantial, **then they** become unacceptable.

Guideline 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.

a. When a company subsidizes the travel expenses of residents to an appropriately selected conference, **may** the residents receive the subsidy directly from the company?

Funds for **scholarships** or other special funds should be given to the academic department⁶ or the accredited sponsor **of** the conference. The disbursement of funds can then be made by the departments or the conference sponsor.

Guideline 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.

a. May companies send their top prescribers, purchasers, or referrers on cruises?

No. There can be no link between prescribing or referring patterns and gifts. In addition, travel expenses, including cruises, are not permissible.

b. May **the** funding company itself develop the complete educational program that is sponsored by an accredited continuing **medical** education sponsor?

No. The funding company **may** finance **the** development of the program through its grant to **the** sponsor, but **the** accredited sponsor must have responsibility and control over the content and faculty of

conferences, meetings, or lectures. Neither the funding company nor an independent consulting firm should develop the complete educational program for approval by the accredited sponsor.

c. How much input may a funding company have in the development of a conference, meeting, or lectures?

The guidelines of the Accreditation Council on Continuing Medical Education on commercial support of continuing medical education address this question.

Any questions regarding the guidelines should be directed to the Council in care of:

Kirk B. Johnson, JD
General Counsel
American Medical Association
515 N. State Street
Chicago, Illinois 60610
FAX: 312-464-5846

Gerald J. Mossinghoff
PRESIDENT

Pharmaceutical
Manufacturers
Association

April 17, 1992

The Honorable Richard P. Kusserow
Inspector **General**
Department of Health and Human Services
Washington, D.C. 20201

Dear Richard:

I appreciate the opportunity to provide the comments of the Pharmaceutical Manufacturers Association (PMA) on the draft report "Promotion of Prescription Drugs Through Payments and Gifts: Physicians' Perspectives." Because we have many concerns regarding this report, we were disappointed to see that this draft has been quoted in the press. Because the survey is flawed methodologically, reporting of the results and conclusions, even tentative or speculative ones, **are** misleading and inappropriate. **PMA** recommends that the report not be published. However, if the Inspector General's Office is under obligation to publish this report, **PMA** strongly recommends that the report clearly state that the data do not support any firm conclusions regarding the status of pharmaceutical marketing **and** promotion activities. I am enclosing more detailed comments on the draft report, but **PMA's** major concerns are summarized below.

Briefly, **PMA's** primary concerns relate to the methodology employed for the survey. As noted in the report, the time period selected for the survey began before industry and AMA adoption of new guidelines regarding gifts to physicians from industry. *Even* after adoption of the guidelines, there was an acknowledged transition period and continuing interpretation of the new guidelines. These additional factors are not recognized in the conclusions drawn in the draft report. The response rate to the survey, **only 62** percent, raises significantly the possibility of bias in the results. This potential for bias, and the inability to measure this bias reinforce our recommendation that conclusions not be drawn from the survey results.

We are also concerned about the way in which results are described and interpreted in the report. Research funding, legitimate reimbursement for consulting services, and appropriate payment of travel expenses to educational events for consultant physicians are all described as gifts and payments--interpreted as promotional activities and combined with usual and appropriate gifts to physicians of pens, notepads and other reminder items. Moreover, the average value of \$727 for **gifts** and payments reported is based on a highly skewed range of physician estimates of questionable accuracy. Most items provided to physicians fall

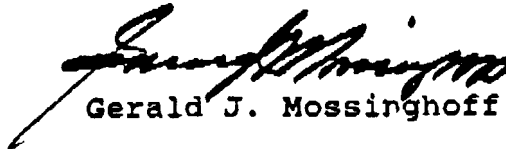
America's Pharmaceutical Research Companies

well below the **AMA's** criterion of \$100 for "minimal value" and are of utility in the physician's daily practice.

We believe, and we think **AMA** would agree, that the guidelines adopted by industry **are working** well. **PMA** and **AMA** continue to work closely together to foster better understanding of and adherence to these guidelines. We are also working closely with FDA to ensure that their guidelines on **industry-funded** continuing medical education programs are reasonable and appropriate. Representatives from both **AMA** and FDA spoke on these topics at a PMA meeting last week attended by more than 100 senior marketing executives.

PMA feels that dissemination of this survey report would not be productive because of the flaws in the methodology and the lack of any basis for drawing conclusions from the survey results. These results do not accurately reflect the current state of practice in pharmaceutical marketing and promotion and could only serve to reinforce old and invalid perceptions regarding these very necessary and useful activities.

Sincerely,



Gerald J. Mossinghoff

Enclosure

cc: Kirk Johnson, American Medical Association

Detailed Comments on the Office of the Inspector General's
Draft Report on Promotion of Prescription Drugs
Through Payments and Gifts

The **draft** report from the Office of the Inspector General on pharmaceutical promotion through gifts and payments describes the results of a mail survey of physicians. In this survey physicians reported on instances in which gifts and payments were offered by pharmaceutical firms during the 12 months beginning in the fall of 1990. The responding physicians attempted to estimate the value of each gift or offer.

PMA finds serious flaws in the methodology for this survey that cast doubt on the validity and utility of the results obtained. We also believe that the way in which the results are summarized and interpreted in the draft report lead to highly speculative and erroneous conclusions. PMA recommends that the study not be released. However, if the report is released in final form, the report should not offer any conclusions, even speculative ones. PMA's comments are detailed below.

Methodology

The report acknowledges that the time period focused on in the survey began before AMA and industry adoption of new guidelines on industry gifts to physicians. Consequently, it is impossible from the survey results to assess the degree of compliance with the guidelines. This is further complicated by the fact that AMA acknowledged the need for a transition period after adoption of the guidelines because many firms and physicians already had contractual and financial commitments for activities that would occur within a few months after the guidelines were adopted. In addition, during the first several months, AMA was in the process of developing more specific interpretations of the guidelines and subsequently provided these interpretations to the industry in July 1991.

Mail surveys typically suffer from the problem of gaining an acceptable response rate. This survey is no exception. Only 62 percent of surveyed physicians responded, thus exposing the results to the potential for substantial bias. It is not possible to assess adequately the degree of bias, because as the report states "there is no information that we know about nonrespondents that obviously correlates with interactions with pharmaceutical companies." Any speculations regarding the direction of the bias are just that, speculation.

The survey questionnaire asked physicians to estimate the value of offers and gifts that were received from pharmaceutical companies. These valuations are unreliable, yet are reported and analyzed in the survey report with unwarranted precision. The figures provided by physicians represent a highly skewed set of data, and yet the focus of the analysis is on arithmetic averages

that are **significantly** affected by a **few** large estimates from physicians, **some** of which represented payments for conducting clinical studies unrelated to marketing and promotion. **For** example while the average value **for** gifts or payments is reported as \$727, the median value is only \$125, just above the **AMA's** established criteria for "minimal **value.**" Placing **confidence** intervals around such questionable averages is without any statistical validity.

Interpretation of Results

Marketing and promotion activities directed to physicians are legitimate and necessary ways of bringing products to physicians' attention and facilitating the use of those products. **Reminder** items such as **pens, notepads, and other small gifts** serve to remind physicians of certain products, but **physicians** still are responsible for understanding how to use products appropriately. In addition, there are educational activities that pharmaceutical firms undertake to increase physicians' understanding **regarding the use of products.** Physicians **are** also sometimes asked to participate as consultant⁶ in marketing research activities or in clinical studies that **fall** outside the realm of marketing and promotion. All of these items **and** activities **are** combined in the analysis **of** the survey **results** and implicitly interpreted as gifts and payments provided by **companies in an effort to influence physician prescribing.** The data are **presented and interpreted in a way that infers** inappropriate activities by pharmaceutical companies.

Compensation to physicians for participation in clinical studies should not be aggregated with other results from the **survey.** As noted above, these amounts **are** largely the reason for the degree to which the combined results are unrepresentative of the skewed nature of the data **collected.** Similarly, physicians are asked to and do participate in marketing research **activities such as** focus groups and are often compensated for their services. **Inclusion** of these figures **in** overall **averages** also tends to skew the aggregate results from the survey.

All of the interpretations **in** the report are tentative and qualified in some way. **In** fact, the survey results provide no clear evidence that any guidelines or regulations were exceeded by any **of** the activities reported by physicians. The report **unfortunately speculates that such excesses** may have **occurred** without any basis **for** such speculation. PMA recommends that all such speculations be eliminated and believes that the only firm conclusion that may be drawn from this study is that the data are **not** conclusive in any way.



Accreditation Council for Continuing Medical Education

P. O. Box 245 51-B Sherwood Terrace Lake Bluff, IL 60044 (708) 295-1490 FAX# (708) 295-3759

7 April 1992

Richard R. Kusserow
Inspector General
Department of Health & Human Services
Washington, DC 20201

Dear Mr. Kusserow:

Thank you for forwarding the draft inspection report, "Promotion of Prescription Drugs Through Payments and Gifts: Physicians' Perspectives".

The HHS draft report serves to highlight some of the problems that interested organizations, including the Food and Drug Administration, have been attempting to address, by a variety of methods. The Accreditation Council for Continuing Medical Education has been working closely with the FDA during the revision of the ACCME "Guidelines for Commercial Support of Continuing Medical Education". These Guidelines address the behavior of *institutions and organizations* sponsoring continuing medical education activities, unlike the AMA Guidelines that address the behavior of *individual physicians* accepting gifts and gratuities. It is the hope of the ACCME that all of these efforts to control pharmaceutical and device industry "freebies" will work together to minimize and restrict what has been an increasingly egregious problem.

We appreciate the opportunity to comment.

Sincerely,

Frances M. Maitland
Acting Secretary

FMM:jh

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Accreditation Council for Continuing Medical Education

**STANDARDS FOR COMMERCIAL SUPPORT OF
CONTINUING MEDICAL EDUCATION****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 Standards is to describe appropriate behavior of accredited sponsors in planning, designing, implementing, and evaluating certified CME activities for which commercial support is received.

STANDARDS**1. *General Responsibilities of Accredited Sponsors***

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.

a. *Basic Design Requirements for CME Activities*

In designing educational activities, the accredited sponsor must assure that the activities have the following characteristics: They must be free of commercial bias for or against any product; If the activities are concerned with commercial products, they must present objective information about those products, based on scientific methods generally accepted in the medical community.

b. *Independence of Accredited Sponsors*

The design and production of educational activities shall be the ultimate responsibility of the accredited sponsor. Commercial support-

2. Enduring Materials

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

3. Identifying Products, Reporting on Research, and Discussing Unlabeled Uses of Products

a. Generic and Trade Names

Presentations must give a balanced view of therapeutic options. Faculty 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 supporting company.

b. Reporting Scientific Research

Objective rigorous, scientific research conducted by commercial companies is an essential part of the process of developing new pharmaceutical or other medical products or devices. It is desirable that direct reports of such research be communicated to the medical community. An offer by a commercial entity to provide a presentation reporting the results of scientific research shall be accompanied by a detailed outline of the presentation which shall be used by the accredited sponsor to confirm the scientific objectivity of the presentation. Such information must conform to the generally accepted standards of experimental design, data collection and analysis.

c. Unlabeled Uses of Products

When an unlabeled use of a commercial product, or an investigational use not yet approved for any purpose is discussed during an educational activity, the accredited sponsor shall require the speaker to disclose that the product is not labeled for the use under discussion or that the product is still investigational.

4. Exhibits and Other Commercial Activities

a. Exhibits

When commercial exhibits are part of the overall program, arrangements for these should not influence planning or interfere with the presentation of CME activities. Exhibit placement should not be a condition of support for a CME activity.

b. Commercial Activities During Educational Activities

No commercial promotional materials shall be displayed or distributed in the same room immediately before, during, or immediately after

an educational activity certified for credit.

c. Commercial Supporters at Educational Activities

Representatives of commercial supporters may attend an educational activity, but may not engage in sales activities while in the room where the activity takes place.

5. Management of Funds from Commercial Sources

a Independence of the Accredited Sponsor in the Use of Contributed Funds

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. The terms, conditions and purposes of such grants must be documented by a signed agreement between the commercial supporter and the accredited sponsor. All support associated with a CME activity, whether in the form of an educational grant or not, must be given with the full knowledge and approval of the accredited sponsor. No other funds from a commercial source shall be paid to the director of the activity, faculty, or others involved with the supported activity.

b. Payments to Faculty

Payment of reasonable honoraria and reimbursement of out-of-pocket expenses for faculty is customary and proper.

c Acknowledgement of Commercial Support

Commercial support must be acknowledged in printed announcements and brochures, however, reference must not be made to specific products.

d. Accountability for Commercial Support

Following the CME activity, upon request, the accredited sponsor should be prepared to report to each commercial supporter, and other relevant parties, information concerning the expenditure of funds each has provided. Likewise, each commercial supporter should report to the accredited sponsor information concerning their expenditures in support of the activity.

6. Commercially Supported Social Events

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

7. Policy on Disclosure of Faculty and Sponsor Relationships

*a. Disclosure Policy for All **CME** Activities*

An accredited sponsor shall have a policy requiring disclosure of the existence of any significant financial interest or other relationship a faculty member or the sponsor has with the manufacturer(s) of any commercial product(s) discussed in an educational presentation. All certified CME activities shall conform to this policy.

b. Disclosure in Conference Materials

CME faculty or sponsor relationships with commercial supporters shall be disclosed to participants **prior** to educational activities in brief statements in conference materials such as brochures, syllabi, exhibits, poster sessions, and also in post-meeting publications.

c. Disclosure for Regularly Scheduled Activities

In the case of regularly scheduled events, such as grand rounds, disclosure shall be made by the moderator of the activity after consultation with the faculty member or a representative of the supporter. Written documentation that disclosure information was given to participants shall be entered in the file for that activity.

8. Financial Support for Participants in Educational Activities

a. Expenses of Non-Faculty Attendees

In connection with an educational activity offered by an accredited sponsor, the sponsor may not use funds originating from a commercial source to pay travel, lodging, registration fees, honoraria, or personal expenses for non-faculty attendees. Subsidies for hospitality should not be provided outside of modest meals or social events that are held as part of the activity.

b. Scholarships for Medical Students, Residents and Fellows

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.

3/20/92



Buyers Up • Congress Watch • Critical Mass • Health Research Group • Litigation Group

Ralph Nader, Founder

May 15, 1992

Richard P. Kusserow
Inspector General
330 Independence Ave. SW
Room 5246
Washington, DC 20201

Dear Mr. Kusserow:

Public Citizen is not surprised by the massive scope of doctor bribing described in your report, "Promotion of Prescription Drugs Through Payments and Gifts: Physicians' Perspectives," but we are disappointed by the timidity of the report's conclusions.

In detailing the brazen efforts of pharmaceutical companies to influence prescribing decisions of physicians, you have done American health consumers a great service. Consumers now know how often drug companies try to bribe their doctors and what form these bribes take. An astounding 82 percent of surveyed physicians reported being offered gifts and payments by the pharmaceutical industry between fall 1990 and fall 1991.

Your study also highlights the failure of the **AMA/PMA** ethical guidelines to stop the most outrageous types of bribes. Despite the fact that the guidelines were in effect for 10 of the 12 months of the survey period, 27 percent of physicians surveyed still received blantly unethical offers of gifts from pharmaceutical companies. Only someone with a wild imagination could believe that all of these abuses took place in the two months of the survey before the guidelines were adopted. Even if half took place in this period, another half represent violations of the ethical code. In addition, the total number of violations is likely an underestimate, as doctors who accepted these offers might have been ashamed to report them.

The results confirm what we have long suspected: In the absence of a reliable enforcement mechanism, no voluntary ethical code or set of guidelines will stop the pharmaceutical industry from attempting to buy off doctors. At Public Citizen, we continue

to receive reports of unethical gift offers -- offers that blatantly violate the AMA/PMA guidelines -- now 16 months after the voluntary code was adopted.

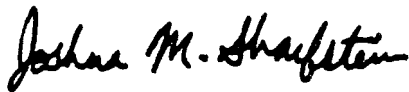
Unfortunately, your report draws only two weak conclusions from its landmark survey: (1) The Food and Drug Administration should "finalize guidelines defining what it considers promotional activity and what it considers scientific interchange" and (2) "The Pharmaceutical Manufacturers Association should work with the American Medical Association to more specifically define lines of propriety in the remaining gray areas of their guidelines."

Neither recommendation addresses the heart of the issue -- what will finally stop the pharmaceutical industry from bribing doctors and sticking U.S. consumers with the bill. Even the clearest voluntary guidelines are being flaunted today. We believe the evidence of this failure is compelling enough to justify a role for the federal government in protecting consumers and defending the integrity of medicine.

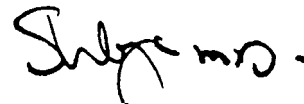
Accordingly, you should recommend legislation modeled on Senator Edward Kennedy's 1977 proposal to outlaw "the transfer . . . of any gift, product, premium, prize or other things of value" to a doctor or pharmacist from the drug industry "if the purpose of such transfer is to influence the prescribing, administering or dispensing of any such drug."

Mr. Kusserow, you have taken the lead in exposing the corrupting influence of pharmaceutical companies in medicine. We hope that you will not shy away from the fight to eradicate it.

Sincerely,



Joshua M. Sharfstein
Researcher, Public Citizen
Health Research Group



Sidney M. Wolfe, M.D.
Director, Public Citizen
Health Research Group

APPENDIX F

NOTES

1. The AMA and PMA allowed a transition period of a few months to allow already committed obligations to be carried out.
2. U.S. Department of Health and Human Services, Office of Inspector General, "Promotion of Prescription Drugs through Payments and Gifts," August 1991, OEI-01-90-00480.
3. One observer of relationships between physicians and pharmaceutical companies noted the following: "Whenever a physician accepts a gift from a drug company, an implicit relationship is established between a 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 decision with regard to patient care." M. Chren, C.S. Landefield, and T. Murray, "Doctors, Drug Companies and Gifts," *Journal of the American Medical Association* **262**, no. 24 (1989): 3448-3451. Further, the American Medical Association Council on Ethical and Judicial Affairs acknowledged the subtle effects of gifts: "There is no evidence that physicians knowingly or intentionally compromise their patients' care as a result of gifts from industry. Nevertheless, the practice of gift-giving may mobilize subtle influences that can result in practice patterns based on considerations that go beyond scientific knowledge and patient needs." Gifts to Physicians from Industry, American Medical Association, Council on Ethical and Judicial Affairs, Report G, Adopted 12/4/90.
4. The American Medical Association guidelines on gifts from industry, which were fully adopted by the Pharmaceutical Manufacturers Association state that "Some gifts that reflect customary practices of industry may not be consistent with principles of medical ethics" (see appendix A for the complete text).
5. Observers such as the AMA's general counsel note dramatic effects of the guidelines in positive respects: "As a general rule, today, unlike this time last year, physicians are not receiving substantial inducements -- in forms of travel, lodging, and cash -- to attend either educational or promotional events which are funded by drug companies." C. Culhane, "... But AMA, PMA Say Guidelines Working," *American Medical News* (September 2, 1991): 3. In contrast, *Consumer Reports* cited efforts by the pharmaceutical industry to comply with the letter but not the spirit of the guidelines: "Consulting firms who design and run campaigns for drug companies are even placing ads in trade publications bragging of their ability to put on sales-boosting dinner meetings that comply with the AMA rules." "Pushing Drugs to Doctors," *Consumer Reports*, February 1992, 89.

6. As of December 27, 1991, 55 of the calls to the hotline have generated information deemed as “possible investigative leads” into inappropriate or illegal advertising or promotional practices. “Snitchline Proves Professionals Want to Talk to FDA & Not Just about Ads,” *PMA Newsletter*, January 13, 1992, 4-5.
7. The 95 percent confidence interval around these estimates are 79 percent to 85 percent and 75 percent to 83 percent.
8. Based on 460 physicians who answered the question. The 95 percent confidence interval around this estimate is 24 to 32 occasions.
9. The 95 percent confidence interval around the percent offered gifts and payments other than small gifts is 67 percent to 75 percent; the 95 percent confidence interval around the number of occasions is 10 to 16.
10. Based on 460 physicians who answered the question. The mean value was \$727, but this was clearly skewed by some very high values. Accordingly, the 95 percent confidence interval around the mean is \$457 to \$1,013. We feel the median more accurately describes the central value of the offers.
11. Again the mean was skewed by some high values. The 95 percent confidence interval around the mean is \$24 to \$66.
12. We tested the hypothesis that physicians who write 50 or more prescriptions per week were as likely as physician who write less than 50 prescriptions per week to be offered a payment or gift on at least one occasion. We rejected this hypothesis because the chi-square value was 50 at 1 degree of freedom.
13. Council on Ethical and Judicial Affairs, “Gifts to Physicians from Industry,” *Journal of the American Medical Association* **265**, no. 4 (1991): 501.
14. Focus group sessions pose this issue particularly pointedly. Pharmaceutical manufacturers often hire marketing consultants to organize and gather focus groups to discuss the marketing plans for a new or existing drug. These focus groups consist of several physicians who are paid for their time. The physicians are asked to judge the relative effectiveness of various sets of marketing material. Meanwhile, they are being given a variety of messages about the effectiveness and power of the drug in the material. It is not clear whether this type of consulting arrangement is token or not, probably not even to the physician involved. It could very well be that these sessions have dual purposes: (1) to provide direct marketing to the physician and (2) to get some advice on marketing plans.
15. We asked physicians whether they had been offered entertainment or sporting event tickets, pharmaceutical samples for personal/family use, and other items for personal/family use. We question whether the pharmaceutical samples for

personal/family use fall within the **AMA/PMA** guidelines and for that reason did not include them in this analysis.

16. The 95 percent confidence interval on the overall proportion of physician extended at least one offer defined by the guidelines as inappropriate is 23 percent to 31 percent.
17. The rate of offers was significantly lower for physicians who prescribe less frequently. For example, the chi-square comparing rates for physicians who write less than 5 prescriptions a week to physicians who write at least 5 was 10 with 1 degree of freedom; at 10 or more prescriptions per week vs. less than 10 per week it was 15.5 (1 degree of freedom), and at 50 or more prescriptions per week vs. less than 50 per week it was 22 (1 degree of freedom).
18. It may be that physicians did not answer this question entirely correctly, and that pharmaceutical companies are not offering samples for this use, but physicians are requesting them for this use.
19. See Office of Inspector General, op. cit., pp. 13-14. Other medical organizations are more clear about defining research funding that constitutes unethical behavior by their members. The American College of Obstetricians and Gynecologists' guidelines do not allow pharmaceutical companies to control the design of studies or the publishing of data. The Infectious Diseases Society of America disapproves of accepting research funding directly from a pharmaceutical company, and instead advises that funding flow through an institution.
20. See our earlier report on this issue for a description of FDA's roles and activity in this area.
21. Food and Drug Administration, "Drug Company Supported Activities in Scientific or Educational Contexts: Draft Concept Paper", October 26, 1991.
22. 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." T. Randall, "AMA, Pharmaceutical Association for 'Solid Front' on Gift-Giving Guidelines," *Journal of the American Medical Association* **265**, no. 18 (May 8, 1991): 2304.
23. All specialties with less than 30 sampled were grouped into an Other category.
24. "IG to Survey MDs on Gifts from Pharmaceutical Firms," Medicare Compliance Alert, V.3, N.9, April 29, 1991, p. 2.
25. SAS Institute Inc., *SAS Language Guide for Personal Computers, Version 6 Edition*. Cary, NC: SAS Institute Inc.. 1985

26. This section of the survey relates to another inspection on adherence to the Prescription Drug Marketing Act of 1987.

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