



A Message from

Michel Pettigrew, President and CEO

At Ferring, we are committed to meeting the needs of patients through research and development of safe and effective medicines. But all our effort will be ignored if the ethics of our sales and marketing practices do not measure up to public expectations. That is as it should be, for how can patients trust the integrity of our products if the integrity of our business practices is not trustworthy?

In order to maintain the highest ethics in everything we do, we have undertaken a renewed effort focusing on compliance. This effort is companywide and it began with the adoption of the Global Business Ethics and Conflict of Interest Policy. Our focus in the Sales Force will be on the Ethical Promotion of Pharmaceutical Products.

This Field Guide will provide you with the information you need to know to make sure that your activities meet the high ethical standards that Ferring maintains. Please review this material thoroughly. Your knowledge of these rules is as important to the proper exercise of your duties as is your product knowledge.

Ethics is all about motives. There are many activities in our professional and personal lives that are completely appropriate. However, when we try to accomplish things that we know are not appropriate by making them appear to be something they are not, we have violated the trust that Ferring puts in us and the trust that patients put in Ferring. An easy test to see if a course of action meets general ethical standards is to ask yourself how it would look if it were written up in the *New York Times*.

Our patients will be best served if we maintain our high ethical standards in everything we do.

A handwritten signature in black ink, appearing to read "Michel Pettigrew", with a large, sweeping flourish at the end.

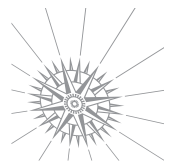
Ethical Promotion of Pharmaceutical Products

Ethical promotion of our products is critical to our mission of providing products and information for the benefit of patients. Our promotional efforts are focused on informing healthcare providers about the benefits and proper use of our products, providing scientific and educational information, and supporting medical research and education. As the principal point of contact between Ferring and the providers who prescribe and use our products, the burden is on you to maintain the highest ethical standards at all times.

The rules set forth in this Field Guide are consistent with our Global Business Ethics and Conflict of Interest Policy; and they meet the requirements of the Compliance Program Guidance for Pharmaceutical Manufacturers issued by the Office of the Inspector General of the United States Department of Health and Human Services, the Code on Interactions with Healthcare Professionals issued by the Pharmaceutical Research and Manufacturers Association, and the American Medical Association Ethical Guidelines for Gifts to Physicians from Industry.

Of course, these rules are also in conformance with the many laws that affect the marketing, sale, and distribution of prescription medicines. Key laws in this area are the Federal Anti-Kickback Statute, the Federal Civil False Claims Act, and the Food, Drug and Cosmetic Act. However, in many cases our policies may be stricter than these outside sources might require. Ferring employees must comply with our policies and procedures at all times, even if other activities might be legal and ethical.

This Field Guide is divided into two parts. The first part deals with the rules that pertain to the promotion of our products and therefore deals directly with the job of the sales representative. The second part deals with other interactions with physicians



Ethical Promotion of Pharmaceutical Products

such as consulting arrangements. In order to avoid the appearance of impropriety, these interactions are carried out by persons other than the field sales representatives. They are included in this Field Guide to acquaint the field sales representative with the policies and processes for those activities so that the representative can direct any inquiries from a provider to the appropriate person.

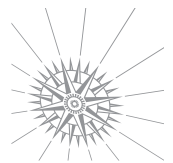
The failure to adhere to all of the rules set forth herein is a serious matter, and could be grounds for disciplinary action up to and including termination of employment. If you have any questions about the meaning or intent of these rules, please contact your manager or the U.S. Compliance Officer, Ms Jean Frydman (973-796-1702).

To report any suspected infraction of these rules you may contact the U.S. Compliance Officer, either directly or by using the Ferring Alert Line (800-446-1494). By using the Ferring Alert Line, you may report a suspected infraction anonymously.

PART 1

Promotional Rules

- Record Keeping
- Product Marketing and Promotional Materials
- Payments or Gifts to Physicians and Other Healthcare Providers
 - Service Agreements
 - Meals in Association With a Sales Presentation
 - Gifts and Courtesies to Providers
 - Grants for Educational and Community Activities
- Group Selling Events
- Physician-Assisted Training
- Samples
- Q&A



Promotional Rules

Record Keeping

No company's ethics are credible if the records it keeps in the ordinary course of business cannot be relied upon as complete and accurate. Additionally, several states require Ferring to file regular reports with respect to interactions with physicians. Failure to file accurate reports in a timely manner could have serious legal repercussions for Ferring. It is the responsibility of all Ferring employees to completely and accurately record all aspects of their interactions with physicians and other healthcare providers.

In order to facilitate accurate and complete record keeping, Ferring employees maintain a centralized sales information system, Target SFA. Information required to be entered into the system is stated in the Ferring Expense Guidelines from Sales Operations. Information required for entry into the system is built into the software system. Such entries are monitored by the district managers. The failure to enter information per instructions will lead to disciplinary action up to and including termination.

There are also other specific record-keeping requirements that are in addition to the information in the Target SFA. These include the tracking of expenses for gifts, meals, and other payments to physicians and other healthcare providers required by various governmental agencies, and the tracking of samples distributed directly by sales representatives. These records are discussed in the relevant sections below.

Product Promotion

The Food and Drug Administration strictly controls what a Ferring representative can say about its products in a promotional context. We may only make statements about our products that are consistent with the information in the approved prescribing information. In order to ensure compliance with this rule, the Legal, Medical, Regulatory Promotional Review Committee ("LMR Committee") determines what information may be given to providers either orally or in writing. Promotional, Sales Training, and Public Relations materials and activities developed

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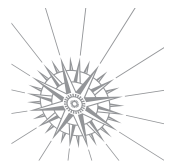
and implemented by Ferring must be consistent with applicable US laws, regulations and guidelines including the Pharmaceutical Research and Manufacturers of America (PhRMA) and AvaMed applicable guidelines. All promotional, sales training, and public relations materials and activities must be consistent with the approved product labeling and source documents (FDA Submission Application, study reports, scientific literature, textbooks, etc.).

Only materials which have been approved by the Promotional Review Board Committee will be used in the marketing and promotion of our products. Ferring Sales Representatives are prohibited from making, using, or referring to any other materials, and from making any verbal statements about the products that are inconsistent with the approved materials and the FDA-approved labeling.

The rules for product promotion apply to all promotional events including office or hospital calls on physicians or other providers, group-selling events, and Company booths at medical conferences and educational events.

All Ferring Sales Representatives will be fully trained on the product labeling and the proper use of promotional materials. As mentioned above, sales training materials must also be approved by the LMR Committee.

From time to time, information may become available as a result of research that relates to uses of our products that are not within the scope of the approved labeling for the product. This frequently happens when the results of research are published in medical journals. This information may be provided to Sales Representatives for distribution to medical professionals, provided that the article has been approved by the LMR Committee, with the required disclaimers. In 2009, the FDA approved the distribution of reprints of journal articles discussing off-label product use so long as (a) a statement disclosing the off-label use is affixed and clearly visible; (b) the article is kept separate from any promotional information presented by the



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Sales Representative; and (c) is not part of any promotional discussion by the Sales Representative. In addition, the disclosure statement must include the relationship or affiliation of the article's authors with the product's manufacturer or distributor (such as a consultant or a member of an Advisory Board or Speakers Bureau). Healthcare providers may occasionally ask Sales Representatives about information which they may have read in medical or scientific journals. Frequently, that information involves uses of the products that are not in the approved labeling. Under no circumstances may the Sales Representative engage in any discussion about this material, unless the article has been approved for discussion by the LMR Committee (as previously discussed). Any further questions must be referred to Medical Affairs for a response. (See the discussion of Medical Information in Part 2.)

From time to time articles may appear in the lay press about our products. Those articles may also contain information that is not within the scope of the approved labeling. Additionally, articles in the lay press generally do not have the level of scientific data to be of value to the physician. Even though the article is widely available, Ferring Sales Representatives are prohibited from discussing it. Under no circumstances may you purchase a copy of the magazine or photocopy the article to give to physicians.

Payments to Physicians and Other Healthcare Providers

No Ferring employee may provide anything of value to a healthcare provider for the purpose of inducing the provision of services or the sale or prescribing of our products. This rule is basic to the sales function in any industry, but it is more important in pharmaceuticals. Our customers, physicians, and other providers have a duty to do only what is best for the patient. Offering gifts, meals, travel, or consideration of any kind to a provider to induce him/her to use Ferring products interferes with that duty. This is an area in which it is important to avoid even the appearance of any improper conduct.

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Certain transactions with healthcare providers that are not done for the purpose of inducing the use or prescribing of Ferring products are permitted. Strict compliance with the rules set forth in these pages is necessary to avoid any appearance of impropriety.

SERVICE AGREEMENTS:

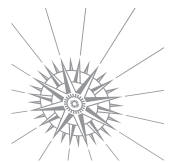
Ferring relies on physicians, especially those who are thought leaders in the diseases our products are indicated for, to expand our knowledge of the diseases, the use of our products, the needs of physicians in the field, and the competition. Physicians can also be helpful in educating other physicians about the disease and the proper use of our products. Ferring also employs physicians to carry out clinical trials to assess the value of using our products in new indications or different dosing regimens. Permitted transactions with physicians and other healthcare providers fall into the following categories; however, **NO SERVICE AGREEMENT MAY BE ENTERED INTO FOR THE PURPOSE OF INDUCING THE PRESCRIBING OF FERRING PRODUCTS.**

CONSULTING AGREEMENTS AND SCIENTIFIC ADVISORY BOARDS:

Ferring frequently engages physicians as consultants to answer a variety of questions about diseases, treatment options, the marketplace, and the competition. We might also seek advice on an area for new products or research. As long as the compensation is reasonable for the work performed, and based on fair market value, it is permissible to pay physicians for that type of work. However, in order to avoid any impression that the consulting agreement is for the purpose of inducing the use of our products, Sales Representatives are prohibited from engaging any healthcare provider as a consultant. For more information on consulting arrangements, please see Part 2 of this Field Guide.

SPEAKERS:

Having physicians speak to other physicians about our products can be an effective promotional method, particularly in the group selling situation. Their knowledge of the disease and treatment options and the respect they have from other physicians can be



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compelling. However, it is necessary to avoid any appearance of impropriety. Therefore, the selection of physicians for the Speakers Bureau has been assigned to Medical Affairs, Marketing, and outside vendors. It is the responsibility of Medical Affairs and Marketing to ensure the speakers are properly trained on the limitations on discussion and that the agreed compensation is appropriate. For more information on the Speakers Bureau, please see Part 2 of this Field Guide. For more information on Group Selling Events, see page 9 of Part 1 of this Field Guide.

PHYSICIAN-ASSISTED TRAINING PROGRAMS:

Gaining a clear understanding of the physician-patient relationship is an important part of the training of pharmaceutical sales representatives. Ferring allows sales representatives who have been employed for greater than one year to participate in two training programs per year, per specialty. Ferring home office employees are entitled to participate in one training program per year, per specialty. For more information on Physician-Assisted Training Programs, please see page 10 of Part 1 of this Field Guide.

CLINICAL RESEARCH:

Arguably the most important work that a pharmaceutical company undertakes is clinical research to identify the benefits and risks of its products. To do this work, Ferring contracts with physicians to be investigators, and with institutions where the trial will be performed. For more information on clinical trials, see Part 2 of this Field Guide.

INVESTIGATOR-INITIATED TRIALS:

Ferring may provide support for clinical trials that are independently initiated, developed, and conducted by external investigators. Sales Representatives may not engage in any discussion or solicit providers to apply for an Investigator-Initiated Trial. Medical Affairs is the only department that may engage in discussions with investigators or institution study personnel. If a provider asks a Sales Representative about conducting an Investigator-Initiated Trial, the Sales Representative should refer the provider to Ferring's Medical Affairs Department.

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MEALS IN ASSOCIATION WITH A SALES PRESENTATION:

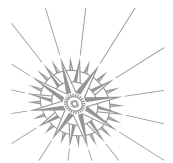
A Sales Representative or his/her immediate manager may, in connection with an informational, scientific, educational presentation, offer to healthcare professionals and members of staff in attendance at the presentation, a modest meal that is provided in a manner that is conducive to informational communication. Such meals that are offered should be limited to in-office or in-hospital settings and should be occasional.

“Modest” is defined according to the standards of the area, but in no event (not even in New York City) is a meal costing in excess of \$175 per person to be considered modest.

GIFTS AND COURTESIES TO PROVIDERS:

Because a healthcare provider’s primary responsibility is to his/her patients, Ferring Pharmaceuticals has adopted the PhRMA Code concerning gifts so that it is clear there is no intent to interfere with that responsibility or unduly influence the provider’s choice of products. The PhRMA Code states that companies should not provide healthcare professionals with non-educational items even if they are accompanied by patient or physician educational materials. Items intended for personal benefit of a healthcare professional such as floral arrangements, artwork, music CDs, or tickets to a sporting event should not be offered. Despite the restrictions noted above, it is acceptable to offer items primarily for the education of patients or healthcare professionals not greater than \$100, so long as the item doesn’t have a value outside of his/her professional responsibility. Such items include medical textbooks, anatomical models, and patient self-assessment and tracking tools. In all cases, these items must be selected by the appropriate designee of the Vice President of Sales and Marketing, and be approved for distribution to providers by the LMR Committee. In no case may the value of the item (defined as the cost of the item if the provider were to purchase it) be in excess of \$100. Gifts of this nature may only be given to a provider on an occasional basis, roughly once a year.

Practice-related items of minimum value such as pens, note pads, mugs, and similar reminder items should not be distributed.



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Several states have enacted or are considering legislation that restricts the items that may be given to physicians, or requires Ferring to file reports with the state as to the value of all transactions with providers. If you call on providers in these states, your district manager will instruct you on the limitations and reporting requirements. All reports will be compiled and filed with the states under the direction of the Chief Compliance Officer. It is critical for compliance that your reports be complete, accurate, and timely.

ENTERTAINMENT:

Ferring Pharmaceuticals has adopted the PhRMA Code concerning prohibition of entertainment so that it is clear that the education and informational exchange is the focus of interactions between Sales Representatives and healthcare professionals. The PhRMA Code prohibits the provision of any entertainment or recreational items, such as tickets to the theater or sporting events, sporting equipment, or leisure or vacation trips to any healthcare professional who is not a salaried employee of the company. Such entertainment or recreational benefit should not be offered (a) regardless of the value of the item; (b) whether the company engages the healthcare professional as a speaker or consultant; or (c) whether the entertainment or recreation is secondary to an educational purpose.

GRANTS IN SUPPORT OF EDUCATIONAL AND COMMUNITY ACTIVITIES:

Ferring makes funding available to support various activities. These include providing Continuing Medical Education (CME), patient or community education, and community-based disease screening programs. However, to ensure that these grants do not appear to be improper payment to providers, Sales Representatives may not offer grants to providers, nor solicit providers to apply for a grant.

From time to time, a provider may ask a Sales Representative about the availability of a grant for a particular purpose. The Sales Representative should refer the provider to Ferring's Medical Affairs Department. For more information on Grants for

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Educational and Community Activities, please see Part 2 of this Field Guide.

Group Selling Events

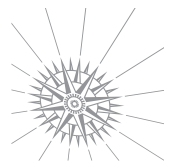
Convening small gatherings of physicians for the purpose of presenting scientific information about our products has been shown to be an effective educational method. Typically, five to twenty providers will be invited to hear a presentation by a physician in the community who has been trained by Ferring to discuss scientific data supporting the use of our products. Following the presentation, attendees are invited to ask questions and discuss the information that has been presented. There are several rules for these events that must be strictly complied with.

Only physicians who are listed in the Speakers Bureau may be engaged for Group Selling Events. These are sales presentations. As such, the information presented must be limited to the approved uses of our products. To ensure that this rule is followed, Ferring trains a limited number of physicians in how to make the presentation and how to keep the ensuing discussion within the bounds of the approved indications. These physicians constitute the Speakers Bureau for the product.

Any materials used in presentations must be approved by the LMR Committee. This rule is designed to ensure that the presentation stays within the approved uses.

Attendees may not be compensated for their time or any travel expenses incurred in attending the Event, nor may spouses or guests of healthcare providers be invited to attend.

The venue for such presentations must be conducive to providing educational information. The location selected must be such that all attendees can easily hear the presenter and other attendees. There must be minimal distractions from other persons in the area; venues with entertainment must be avoided. Any materials used in presentations must be approved by LMR. This rule



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is designed to ensure that the presentation stays within the approved uses.

Speakers at such meetings may be paid a reasonable fee based on fair market value for presentation of scientific information. As part of becoming a member of the Speakers Bureau, a provider will be required to commit to make a certain number of presentations and the fee for each presentation will be established. All other terms of the arrangement between the provider and Ferring will be determined as well. Sales Representatives may attend a Group Selling Event only to observe.

Physician-Assisted Training Program

A Physician-Assisted Training Program is an educational opportunity in which a Sales Representative or home office employee spends a half day to a full day with a physician as he/she sees patients. There are a number of ethical and legal issues presented by Training Programs, so strict compliance with the rules in this section is a must. Any failure to follow these rules can have serious consequences for Ferring and the Sales Representative or home office employee. See SOP COMP-003.01.

The Sales Representative may select a physician to be a Trainer. The Trainer should be chosen based on the following criteria:

1. The Trainer should specialize in or devote a significant part of his/her practice to treatment of diseases for which our products are approved for use.
2. The Trainer should be recognized as a leader in the field within his/her community.
3. The Trainer should have experience in providing education to pharmaceutical sales representatives and be knowledgeable about the issues of patient privacy associated with this type of training.

Once the Trainer has been identified, the Trainer should sign the Physician-Assisted Training Contract, be routed to the Sales

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Representative's District Manager for review, and to an employee one level higher than the District Manager for review.

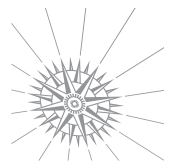
If the Physician-Assisted Training Program is approved, an engagement letter will be sent to the Trainer. The letter shall specify the terms of the agreement and the amount of compensation. Terms of the agreement will also provide that:

1. The Trainer will agree to inform each patient that the Sales Representative and home office employee are employees of Ferring Pharmaceuticals who are present to learn more about the physician-patient relationship, the disease, and the effects of the disease on the lives of patients.
2. The Trainer will agree to obtain each patient's consent that the Sales Representative and home office employee may be present during the examination, treatment, or consultation and that the Sales Representative and home office employee may be informed of medical information about the patient.
3. The Agreement should also describe established goals to be achieved during the Training program.

It is of the utmost importance that the patient's privacy be respected at all times. A variety of state and federal laws are in place to protect that privacy, most notably the Health Insurance Portability and Accountability Act. Although these laws generally apply to the provider and not to Ferring, it is our intent to comply with the spirit of these laws.

Therefore you must not:

1. Be present at any examination, treatment, or consultation unless you have been assured by the physician that the patient has consented to your presence.
2. Make any notes, reports, or other written documents concerning what you see or hear or obtain any copies of any medical records from the physician.
3. Discuss with anyone the information you receive during the Physician-Assisted Training Program in any way that would



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allow another person to learn medical information about a specific person.

Samples

Samples of our products are an important aid to patients. By giving patients a free supply of the product, a physician is able to evaluate whether it will be effective and whether the patient will have any adverse effect. Additionally, samples allow a patient to begin treatment immediately without waiting for his/her insurance company to approve a prescription.

However, samples have created ethical and legal problems in the past. As a result, the distribution of samples of prescription drugs is strictly regulated by the Prescription Drug Marketing Act (PDMA) and regulations which, among other things, prohibit the sale or other transfer of samples and set rigorous standards for pharmaceutical companies to keep records of distribution of samples. Violations of the PDMA can result in civil and criminal penalties for Ferring and any employee who commits this violation.

No Ferring employee shall sell drug samples or distribute samples except in strict compliance with this policy.

The PDMA requires that all samples be requested by a person authorized to prescribe under state law. Ferring must retain a copy of the request. When samples are delivered, the recipient must sign a receipt and return it to Ferring. Finally, Ferring must be able to account for each unit of samples it ships out. Any failure of an individual Sales Representative or Ferring to have complete records or any discrepancy between the records and the actual audited count of samples in a Sales Representative's possession can result in significant fines or criminal prosecution.

Promotional Rules

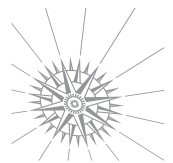
Ferring distributes samples in two ways.

Most frequently we use an outside vendor to ship samples. The procedure for this method is:

1. The Sales Representative obtains the prescriber's signature on a sample request form.
2. The signed form is sent to the Associate Manager of Sales Operations for physician identification verification. Upon verification, the sample request is forwarded to a fulfillment house for processing.
3. Samples are sent to the physician from the fulfillment house with a receipt form for signature.
4. The signed receipt form is sent to the Associate Manager of Sales Operations for reconciliation.
5. If the signed receipt form is not received within 60 days of receipt of samples, no further samples will be shipped to the physician. If the signed receipt form is not received within 90 days of receipt of samples, the sales representative may not present any further sample request forms to physicians until reconciliation.

For some products, samples are delivered directly by Ferring Sales Representatives. The procedure for those samples is:

1. Ferring will ship samples to the Ferring Sales Representative.
2. Ferring Sales Representatives will be able to sample prescribers based on eligibility within the Target SFA system.
3. If the prescriber is eligible to receive samples, the prescriber will be required to sign the PDA as proof of receipt of those samples. If the PDA is not functional, a paper form will be used and accounted for accordingly.
4. The Ferring Sales Representatives will conduct a monthly audit to verify that the number of samples in the possession of its representatives is consistent with the shipments, requests, and receipts.
5. The Ferring Sales Representatives will immediately report any discrepancies to Sales Operations.



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Q & A

Q. While getting lunch a Sales Representative sees a small trinket similar to those in a collection displayed by a physician she will call on later that day. The trinket costs \$2. Can the Sales Representative purchase it to give to the physician?

A. NO. Pursuant to change in the PhRMA Code, gifts to healthcare providers are no longer permitted.

Q. During a sales presentation, a physician makes a comment that would suggest that he is billing patients' insurers for products used in his office, which he received as samples. What should the representative do?

A. CONTACT THE COMPLIANCE OFFICER IMMEDIATELY. This is a very serious matter. If the insurer is any governmental agency such as Medicare or Medicaid, then billing for a product that was received as a free sample could be a violation of the False Claims Act. Additionally, if the Company is aware of the practice, it could be in violation of the Anti-Kickback Statute.

Q. During a sales call, a physician indicates to a Sales Representative that he would like to be considered for the Ferring Speakers Bureau. He further indicates that he would be more likely to prescribe Ferring products if he were in the Speakers Bureau. What should the Sales Representative do?

A. NOTIFY THE COMPLIANCE OFFICER IMMEDIATELY. Including the physician in the Speakers Bureau would be a violation of the Anti-Kickback Statute because the remuneration paid for being a speaker would clearly be consideration for additional use of Ferring products. Notifying the Medical Department of the physician's interest without including the information about the offer of increased prescribing would be a clear violation of these rules.

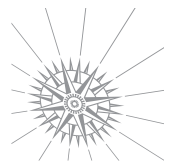
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Q. May a Sales Representative purchase a slot in a charity golf event and invite 3 physicians to join him in the group?

A. NO. A Sales Representative must never provide entertainment or recreational activities to healthcare providers.

Q. A physician tells a Sales Representative that he has recently heard of a journal article about a new use for the product. The Sales Representative has a copy of the journal with him. Can he leave the journal with the physician?

A. NO. Although the journal is publicly available, all interactions between a Sales Representative and a healthcare provider must be deemed to be promotional in nature. Leaving a copy of the journal would be off-label promotion of the product. A reprint of a publication in a journal, which has been approved through the LMR Committee for distribution with the required disclaimer attached, is the only exception.

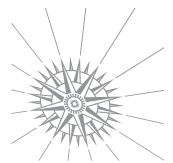




PART 2

Non-Promotional Transactions with Physicians

- Consulting Agreements/Scientific Advisory Boards
- Speakers Bureaus
- Clinical Research
- Grants for Educational and Community Activities
- Medical Information
- Q&A



Non-promotional Transactions with Physicians

Consultants

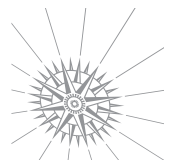
Our customers are perhaps our best source of information about their needs and the needs of their patients. In order to take advantage of this resource, Ferring may from time to time retain the services of healthcare providers as consultants. Because these consulting arrangements include payments to providers, it is of critical importance that the relationship not be promotional in nature. Put in its simplest terms, if the purpose of the consulting arrangement is for Ferring to get information from the consultant, it is probably a valid arrangement. On the other hand, if the goal of the consulting arrangement is for Ferring to educate the consultant, it would probably be found to be promotional in nature and subject to all the restrictions in Part 1.

In order to avoid entering into improper arrangements with healthcare providers, the following rules must be followed before entering into a consulting agreement.

1. The need for consulting services to be rendered by the healthcare provider must be clearly documented. The documentation must include a justification for the number and qualifications of consultants. For example, if the purpose of the consulting is to conduct a marketing focus group, the documentation should include information on the size of the market (in terms of number of customers) and an analysis of how many subjects are required to obtain reasonable results.
2. The person selecting the consultant must have the training and experience necessary to determine whether the healthcare provider has the necessary qualifications. If the purpose of the consultancy is to obtain information on medical issues, it should be conducted by the Medical Affairs Department. Under no circumstances should Sales Representatives select consultants, although Sales Representatives may suggest candidates who they believe may have the necessary qualifications.

Non-promotional Transactions with Physicians

3. Ferring must enter into a written contract with the consultant which clearly specifies the services to be rendered and the compensation to be paid for the services.
4. Compensation for the consultant should be reasonable and based on fair market value. Fair market value can be calculated by considering the consultant's area of expertise and years of schooling, specific areas of sub-specialty or training, as well as compensation for missed revenue while away from their practice.
5. In addition to consulting fees, Ferring may pay travel expenses for consultants to attend meetings. Any meeting with consultants must be held in a time and manner consistent with the services to be rendered. Although the rules against providing entertainment do not apply to consultant meetings, any social events connected with the meeting must be modest in scope and clearly subordinate to the consulting services to be rendered. In any event, meeting arrangements should not be lavish. In other words, a weeklong meeting in Hawaii in January at which the agenda calls for only a half hour of actual consulting services is not in compliance with Company policy.
6. Consulting Agreements may include participation in an Advisory Board that regularly consults with Ferring on scientific and marketing issues. The number of providers on an Advisory Board may be only as many as are needed to provide the information sought.
7. The information, recommendations, and advice received from consultants must be accurately recorded, and the actions taken by Ferring in response to such information, recommendations, and advice must be documented. This is another test of whether the consultancy was needed to begin with. Ignoring the results invites the conclusion that the payment of the fee was for something other than the consulting services.



Non-promotional Transactions with Physicians

Speakers Bureaus

Having physicians speak to other physicians about our products can be an effective selling method, particularly in the group selling situation. Ferring therefore recruits and trains a limited number of physicians to speak on our behalf of our products. Marketing and Medical Affairs have joint responsibility for establishing and maintaining Speakers Bureaus.

It is important that the number of speakers trained with respect to any product be reasonable. Factors that should be considered in determining the number of speakers include the number of physicians that will be the target of the speakers' presentations, the number of events anticipated in a year, and the number of qualified speakers in the field. Speakers are selected based on their expertise in the clinical area for discussion by an outside vendor and Ferring. Such expertise is based on the speaker's credentials and years in practice. In no event is a healthcare provider to be recruited to be a speaker based on his/her use or prescribing of our products.

In order to ensure that speakers are adequately trained with respect to Ferring's products and the regulations pertaining to proper promotional practices, Ferring will conduct Speaker Training Sessions from time to time. Attendees at such training sessions may be compensated a reasonable amount for the time spent attending the sessions and any travel, lodging, and meal expenses may be paid by Ferring.

Presentations made by speakers on behalf of Ferring are promotional events and are therefore subject to all of the rules regarding promotion covered in Part 1. Speakers may only discuss approved uses of the products. Presentation materials used by speakers must be reviewed and approved by the LMR Committee. Speakers are trained to speak about Ferring products in a fair and balanced manner by Medical Affairs and Marketing. Speakers must avoid responding to any questions about unapproved uses, even if those questions are raised spontaneously by one of the attendees. Such questions should be referred to Medical Affairs for response in accordance with the rules set forth in this document.

Non-promotional Transactions with Physicians

Clinical Research

Arguably the most important work that a pharmaceutical company undertakes is clinical research to identify the benefits and risks of its products. However, we have a high ethical standard that we will not conduct clinical research unless the information we expect to gain is significant, and that information will be useful in the treatment of patients. All clinical trials involve some degree of risk to the participants, and no level of risk is acceptable if the expected results are insignificant.

All clinical trials funded by Ferring will be under the direction of Research and Development. The lead investigator shall be selected solely on the basis of his/her knowledge of the disease to be studied and experience in conducting clinical trials. Ferring will observe all FDA regulations pertaining to the conduct of human clinical trials. Ferring will make public disclosure of the trial and publish the results of all trials.

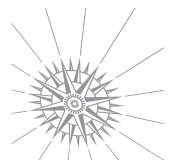
Ferring will maintain the confidentiality of all personally identifiable medical information.

Grants for Educational or Community Activities

Ferring may provide educational grants to third parties in support of continuing medical education (CME) or other scientific and educational conferences or professional meetings. Ferring may also provide funding for patient or community education. These programs must be sponsored by an appropriate organization, and all funding must be given to the sponsor of the event and not to any individual practitioner, participant, or attendee.

All requests for a grant or honorarium for educational events or community activities are submitted by the sponsor of the event to the Grant Committee in Medical Affairs for review.

Medical educational grants may be made only to an organization, such as a hospital, medical professional society, conference sponsor, or continuing medical education organization for the



Non-promotional Transactions with Physicians

purpose of fostering increased understanding of scientific, clinical, or healthcare issues that contribute to the improvement of patient care.

The Grant Committee must first determine whether the sponsor is an appropriate group to receive funding.

Medical Educational grants may not be provided to individual physicians or group practices. Grants of this type have the appearance of promoting the practice of the recipient and could be construed as an illegal payment.

With respect to grants for educational conferences, the use of funds provided by Ferring is limited to legitimate expenses related to the education or training of healthcare professionals or patients in connection with the improvement of patient care. These can include (a) general expenses of the conference (e.g., costs of travel, lodging and meals of the faculty); (b) sponsorship of meals or receptions; and/or (c) financial assistance for medical students, residents, fellows, or other healthcare professionals in training (selected by the sponsor of the conference or academic/training institution) to attend major educational conferences. Ferring shall have no control or influence over the selection of the content, faculty, location, audience, or agenda for the conference.

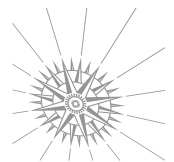
In order to ensure that medical educational grants do not appear to be improper payment to providers, Sales Representatives may not offer grants or solicit providers to apply for grants. If a Sales Representative is approached by a provider regarding a medical educational grant, they should refer the provider to the Medical Affairs Department.

All expenditures for approved grants are provided to the appropriate individual within Ferring for payment and state tracking purposes.

Non-promotional Transactions with Physicians

Medical Information

Under certain circumstances Ferring may discuss unapproved uses of our products with physicians; however, these interactions must comply with FDA regulations for providing off-label information and may not be done in a way to promote the use of the product outside of the approved labeling. The discussion must result from an unsolicited inquiry by the physician. The Ferring employee involved in the discussion must be a medical professional specifically authorized to discuss the topic. Information provided must be fair and balanced and provide complete details of any adverse events or limitations of the scientific data. It must be clearly stated that the use, if not included in the approved labeling for the product, is off label.



Non-promotional Transactions with Physicians

Q & A

Q. May Ferring provide a copy of a journal article pertaining to an off-label use of a product?

- A. Yes, but only under very limited conditions (see Part 1, page 3). Under no circumstances may any Ferring employee other than an authorized Medical Information specialist discuss off-label use of a product with a healthcare provider.

Q. In order to promote his practice, a physician wants to make a presentation to a local organization in his/her community about a disease in which he specializes. The physician has asked you for funding in order to advertise his/her presentation and for assistance in preparing slides. Can Ferring provide funding for this event?

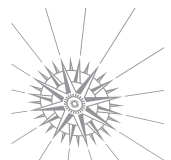
- A. NO. While we cannot know the physician's motives, it appears that one reason for the presentation could be to bring more patients to the physician's practice. Therefore, this funding would have the appearance of providing a monetary benefit to the physician.

Q. A consultant has proposed that Ferring perform a clinical trial on a recently approved product in order to gain information about its actual use in the practicing physician's daily treatment of patients. The trial would involve 300 physicians, each enrolling 5 to 10 patients. Participating physicians will be paid \$1000 for each completed patient report form. The results to be tabulated would include whether the patient's symptoms improved and whether there were any adverse reactions. Should Ferring undertake this trial?

- A. NO. Although the FDA occasionally requests clinical experience trials, the type of trial described is generally thought of by FDA and others as a seeding trial, designed simply to pay large numbers of physicians to try the drug in their practice.

Non-promotional Transactions with Physicians

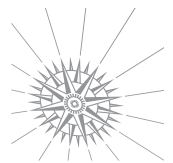
- Q. Ferring has been approached by an accredited CME provider. The provider has proposed holding a seminar about a disease for which one of Ferring's products is the leading treatment. All of the faculty of the seminar have been involved in clinical trials of the product and are highly enthusiastic about its success. The CME provider has offered Ferring the opportunity to be the sole corporate sponsor of the seminar. Ferring's support would pay for meals and receptions as well as the cost of remuneration to the faculty for their time and travel expense. The seminar would be held at a high-end resort that has agreed to give attendees a significant discount on lodgings. The CME provider has also negotiated a discount on air fares for attendees. Can Ferring support the seminar?**
- A. No. Each individual element of the proposal meets the rules for educational grants. The CME provider is accredited and has selected the faculty without input from Ferring. Ferring has had no control on the topics to be discussed. The provider has asked that Ferring pay only for group meals and receptions, which are open to all attendees, and for the expenses of the faculty. However, to a third-party observer, the seminar would appear to be a junket for physicians paid for in large part by Ferring. To avoid the appearance of impropriety, Ferring should not participate in the funding of the seminar.





Appendix

- Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals
- Summaries of Relevant Laws



Pharmaceutical Research and Manufacturers Code on Interactions with Healthcare Professionals

Preamble

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

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

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

- *Inform healthcare professionals about the benefits and risks of our products;*
- *Provide scientific and educational information;*
- *Support medical research and education; and*
- *Obtain feedback and advice about our products through consultation with medical experts.*

This Code is to reinforce our intention that our interactions with healthcare professionals are professional exchanges designed to benefit patients and to enhance the practice of medicine. This Code is based on the principle that a healthcare professional's care of a patient should be based, and should be perceived as being based, on each patient's medical needs and the healthcare professional's medical knowledge and experience.

Therefore PhRMA adopts this updated and enhanced voluntary Code on relationships with U.S. healthcare professionals. This Code reflects and builds upon the standards and principles set forth in its predecessor, the PhRMA Code on Interactions with Healthcare Professionals that took effect on July 1, 2002. Like the 2002 edition, this Code addresses interactions with respect to marketed products and related pre-launch activities. PhRMA member companies' relationships with clinical investigators and other individuals and entities as they

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relate to the clinical research process are addressed in the PhRMA Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results.

This updated Code took effect in January 2009.

PhRMA Code on Interactions with Healthcare Professionals

1. BASIS OF INTERACTIONS

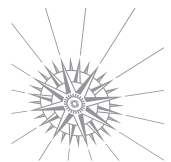
Our relationships with healthcare professionals are regulated by multiple entities and are intended to benefit patients and enhance the practice of medicine. Interactions should be focused on informing healthcare professionals about products and providing scientific and educational information, and supporting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

Promotional material provided to healthcare professionals by and on behalf of a company should: (a) be accurate and not misleading; (b) make claims about a product only when properly substantiated; (c) reflect the balance between risks and benefits; and (d) be consistent with all other Food and Drug Administration (FDA) requirements governing such communications.

2. INFORMATIONAL PRESENTATIONS BY PHARMACEUTICAL COMPANY REPRESENTATIVES AND ACCOMPANYING MEALS

Informational presentations and discussions by industry representatives and others speaking on behalf of a company provide healthcare providers with valuable scientific and clinical information about medicines that may lead to improved patient care.

In order to provide important scientific information and to respect healthcare professionals' abilities to manage their schedules and provide patient care, company representatives may take the opportunity to present information during healthcare professionals' working day, including mealtimes. In connection with such presentations or discussions, it is appropriate for occasional meals to be offered as a business courtesy to the healthcare professionals as well as members



of their staff attending presentations, so long as the presentations provide scientific or educational value and the meals are (a) modest by local standards; (b) are not part of an entertainment or recreational event; and (c) are provided in a manner conducive to informational communication.

Any such meals offered in connection with informational presentations made by field representatives or their immediate managers should also be limited to in-office or in-hospital settings.

Inclusion of a healthcare professional's spouse or other guest in a meal accompanying an informational presentation made by or on behalf of a company is not appropriate. Offering "take-out" meals or meals to be eaten without a company representative being present (such as "dine & dash" programs) is not appropriate.

3. PROHIBITION ON ENTERTAINMENT AND RECREATION

Company interactions with healthcare professionals are professional in nature and are intended to facilitate the exchange of medical or scientific information that will benefit patient care. To ensure the appropriate focus on education and informational exchange and try to avoid the appearance of impropriety, companies should not provide any entertainment or recreational items, such as tickets to theater or sporting events, sporting equipment, or leisure or vacation trips, to any healthcare professional who is not a salaried employee of the company. Such entertainment or recreational benefits should be not offered, regardless of (a) the value of the items; (b) whether the company engages the healthcare professional as a speaker or consultant; or (c) whether the entertainment or recreation is secondary to an educational purpose.

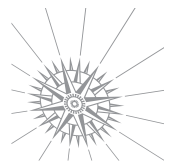
Modest, occasional meals are permitted as long as they are offered in the appropriate circumstances and venues are described in relevant sections of this Code.

4. PHARMACEUTICAL COMPANY SUPPORT FOR CONTINUING MEDICAL EDUCATION

Continuing medical education (CME), also known as independent medical education (IME), helps physicians and other medical professionals to obtain information and insights that can contribute to the improvement of patient care, and therefore, financial support from companies is appropriate. Such financial support for CME is intended to support education on a full range of treatment options and not to promote a particular medicine. Accordingly, a company should separate its CME grant-making functions from its sales and marketing departments. In addition, a company should develop objective criteria for making CME grant decisions to ensure that the financial support is not an inducement to prescribe or recommend a particular medicine or course of treatment.

Since the giving of any subsidy directly to a healthcare professional by a company may be viewed as an inappropriate cash gift, any financial support should be given to the CME provider, which, in turn, can use the money to reduce the overall CME registration fee for all participants. The company should respect the independent judgment of the CME provider and should follow standards for commercial support established by the Accreditation Council for Continuing Medical Education (ACCME) or other entity that may accredit CME. When companies underwrite CME, responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the organizers of the conferences or meetings in accordance with their guidelines. The company should not provide any advice or guidance to the CME provider, even if asked by the provider, regarding the content or faculty for a particular CME program funded by the company.

Financial support should not be offered for the costs of travel, lodging, or other personal expenses of non-faculty healthcare professionals attending CME, either directly to the individuals participating in the event or indirectly to the event's sponsor



(except as set out in Section 9 below). Similarly, funding should not be offered to compensate for the time spent by healthcare professionals participating in the CME event.

A company should not provide meals directly at CME events, except that a CME provider at its own discretion may use the financial support provided by a company for a CME event to provide meals for all participants at sponsored meetings, including attendees who participate in interactive sessions.

5. PHARMACEUTICAL COMPANY SUPPORT FOR THIRD-PARTY EDUCATIONAL OR PROFESSIONAL MEETINGS

Third-party scientific and educational conferences or professional meetings can contribute to the improvement of patient care, and therefore, financial support from companies is appropriate. A conference or meeting is any activity held at an appropriate location, where (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering); and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented.

Since the giving of any subsidy directly to a healthcare professional by a company may be viewed as an inappropriate cash gift, any financial support should be given to the conference's sponsor, which, in turn, can use the money to reduce the overall conference registration fee for all attendees. When companies underwrite medical conferences or meetings other than their own, responsibility for and control over the selection of content, faculty educational methods, materials, and venue belongs to the organizers of the conferences or meetings in accordance with their guidelines.

Financial support should not be offered for the costs of travel, lodging, or other personal expenses of non-faculty healthcare professionals attending third-party scientific or educational conferences or professional meetings, either directly to the individuals attending the conference or indirectly to the

conference's sponsor (except as set out in Section 9 below). Similarly, funding should not be offered to compensate for the time spent by healthcare professionals attending the conference or meeting.

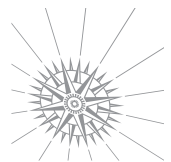
6. CONSULTANTS

Consulting arrangements with healthcare professionals allow companies to obtain information or advice from medical experts on such topics as the marketplace, products, therapeutic areas, and the needs of patients. Decisions regarding the selection and retention of healthcare professionals as consultants should be made based on defined criteria such as general medical expertise and reputation, or knowledge and experience regarding a particular therapeutic area. Companies should continue to ensure that consulting arrangements are neither inducements nor rewards for prescribing or recommending a particular medicine or course of treatment.

It is appropriate for consultants who provide advisory services to be offered reasonable compensation for those services and reimbursement for reasonable travel, lodging, and meal expenses incurred as part of providing those services. Any compensation or reimbursement made in conjunction with a consulting arrangement should be reasonable and based on fair market value.

Token consulting or advisory arrangements should not be used to justify compensating healthcare professionals for their time or their travel, lodging, and out-of-pocket expenses. The following factors support the existence of a bona fide consulting arrangement (not all factors may be relevant to any particular arrangement):

- a written contract specifies the nature of the consulting services to be provided and the basis for payment of those services;
- a legitimate need for the services has been clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants;



- the criteria for selecting the consultants are directly related to the identified purpose and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular healthcare professionals meet those criteria;
- the number of healthcare professionals retained is not greater than the number reasonably required to achieve the identified purpose;
- the retaining company maintains records concerning and makes appropriate use of the services provided by consultants;
- the venue and circumstances of any meeting with consultants are conducive to the consulting services and activities related to the services and are the primary focus of the meeting; specifically, resorts are not appropriate venues;

While modest meals or receptions may be appropriate during company-sponsored meetings with healthcare professional commercial consultants, companies should not provide recreational or entertainment events in conjunction with these meetings.

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

7. SPEAKER PROGRAMS AND SPEAKER TRAINING MEETINGS

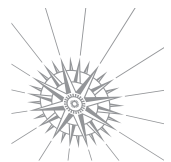
Healthcare professionals participate in company-sponsored speaker programs in order to help educate and inform other healthcare professionals about the benefits, risks, and appropriate uses of company medicines. Any healthcare professional engaged by a company to participate in such external promotional programs on behalf of the company will be deemed a speaker for purposes of this Code, and the requirements of Section 7 apply to company interactions with that healthcare professional in his or her capacity as a speaker.

Appendix

Company decisions regarding the selection or retention of healthcare professionals as speakers should be made based on defined criteria such as general medical expertise and reputation; knowledge and experience regarding a particular therapeutic area; and communication skills. Speaker training is an essential activity because the FDA holds companies accountable for the presentations of their speakers. It is appropriate for healthcare professionals who participate in programs intended to train speakers for company-sponsored speaker programs to be offered reasonable compensation for their time, considering the value of the type of services provided, and to be offered reimbursement for reasonable travel, lodging, and meal expenses. Such compensation and reimbursement should be offered only when (a) the participants receive extensive training on the company's drug products or other specific topic to be presented and on compliance with FDA regulatory requirements for communications; (b) this training will result in the participants providing a valuable service to the company; and (c) the participants meet the general criteria for bona fide consulting arrangements (as discussed in Section 6). Speaker training sessions should be held in venues that are appropriate and conducive to informational communication and training about medical information; specifically, resorts are not appropriate venues.

Any compensation or reimbursement made to a healthcare professional in conjunction with a speaking arrangement should be reasonable and based on fair market value. Each company should, individually and independently, cap the total amount of annual compensation it will pay to an individual healthcare professional in connection with all speaking arrangements.

Each company also should develop policies addressing the appropriate use of speakers, including utilization of speakers after training, and the appropriate number of engagements for any particular speaker over time.



Speaker programs may include modest meals offered to attendees and should occur in a venue and manner conducive to informational communication.

While speaker programs offer important educational opportunities to healthcare professionals, they are distinct from CME programs, and companies and speakers should be clear about this distinction. For example, speakers and their materials should clearly identify the company that is sponsoring the presentation; the fact that the speaker is presenting on behalf of the company; and that the speaker is presenting information that is consistent with FDA guidelines. Beyond providing all speakers with appropriate training, companies should periodically monitor speaker programs for compliance with FDA regulatory requirements for communications on behalf of the company about its medicines.

8. HEALTHCARE PROFESSIONALS WHO ARE MEMBERS OF COMMITTEES THAT SET FORMULARIES OR DEVELOP CLINICAL PRACTICE GUIDELINES

Healthcare professionals who are members of committees that set formularies of covered medicines or develop clinical practice guidelines that may influence the prescribing of medicines often have significant experience in their fields. That experience can be of great benefit to companies and ultimately to patients if these individuals choose to serve as speakers or commercial consultants for companies. To avoid even the appearance of impropriety, companies should require any healthcare professional who is a member of a committee that sets formularies or develops clinical guidelines and also serves as a speaker or commercial consultant for the company to disclose to the committee the existence and nature of his or her relationship with the company. This disclosure requirement should extend for at least two years beyond the termination of any speaker or consultant arrangement.

Upon disclosure, healthcare professionals who serve as speakers or consultants for companies should be required to follow the procedures set forth by the committee of which they

are a member, which may include recusing themselves from decisions relating to the medicine for which they have provided speaking or consulting services.

9. SCHOLARSHIPS AND EDUCATIONAL FUNDS

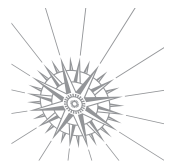
Financial assistance for scholarships or other educational funds to permit medical students, residents, fellows, and other healthcare professionals in training to attend carefully selected educational conferences may be offered so long as the selection of individuals who will receive the funds is made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

10. PROHIBITION OF NON-EDUCATIONAL AND PRACTICE-RELATED ITEMS

Providing items for healthcare professionals’ use that do not advance disease or treatment education—even if they are practice-related items of minimal value (such as pens, note pads, mugs and similar “reminder” items with company or product logos)—may foster misperceptions that company interactions with healthcare professionals are not based on informing them about medical and scientific issues. Such non-educational items should not be offered to healthcare professionals or members of their staff, even if they are accompanied by patient or physician educational materials.

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

Payments in cash or cash equivalents (such as gift certificates) should not be offered to healthcare professionals either directly or indirectly, except as compensation for bona fide services (as described in Sections 6 and 7). Cash or equivalent payments of any kind create a potential appearance of impropriety or conflict of interest.



Appendix

It is appropriate to provide product samples for patient use in accordance with the Prescription Drug Marketing Act.

11. EDUCATIONAL ITEMS

It is appropriate for companies, where permitted by law, to offer items designed primarily for the education of patients or healthcare professionals if the items are not of substantial value (\$100 or less), and do not have value to healthcare professionals outside of his or her professional responsibilities. For example, an anatomical model for use in an examination room is intended for the education of the patients and is therefore appropriate, whereas a DVD or CD player may have independent value to a healthcare professional outside of his or her responsibilities, even if it could also be used to provide education to patients, and therefore is not appropriate.

Items designed primarily for the education of patients or healthcare professionals should not be offered on more than an occasional basis, even if each individual item is appropriate.

12. PRESCRIBER DATA

Companies use non-patient identified prescriber data to facilitate the efficient flow of information to healthcare professionals. Such prescriber data, which do not identify individual patients, may serve many purposes, including enabling companies to (a) impart important safety and risk information to prescribers of a particular drug; (b) conduct research; (c) track adverse events of marketed prescription drugs; and (d) focus marketing activities on those healthcare professionals who would most likely benefit from information about a particular drug.

Companies that choose to use non-patient identified prescriber data to facilitate communications with healthcare professionals should use this data responsibly. For example, companies should (a) respect the confidential nature of prescriber data; (b) develop policies regarding the use of the data; (c) educate employees and agents about those policies; (d) maintain an internal contact person to handle inquiries regarding the use of the data; and (e) identify appropriate disciplinary actions for misuse of this data.

In addition, companies should respect and abide by the wishes of any healthcare professional who asks that his or her prescriber data not be made available to company sales representatives. Companies may demonstrate this respect by following the rules of voluntary programs that facilitate prescribers' abilities to make this choice.

13. INDEPENDENCE AND DECISION MAKING

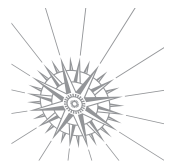
No grants, scholarships, subsidies, support, consulting contracts, or educational or practice-related items should be provided or offered to a healthcare professional in exchange for prescribing products, or for a commitment to continue prescribing products. Nothing should be offered or provided in a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

14. TRAINING AND CONDUCT OF COMPANY REPRESENTATIVES

Pharmaceutical company representatives play an important role in delivering accurate, up-to-date information on healthcare professionals about the approved indications, benefits, and risks of pharmaceutical therapies. These representatives often serve as the primary point of contact between the companies who research, develop, manufacture, and market life-saving and life-enhancing medicines and the healthcare professionals who prescribe them. As such, the company representatives must act with the highest degree of professionalism and integrity.

Companies should ensure that all representatives who are employed by or acting on behalf of the companies, and who visit healthcare professionals, receive training about the applicable laws, regulations, and industry codes of practice, including this Code, that govern the representatives' interactions with healthcare professionals.

In addition, companies should train their representatives to ensure that they have sufficient knowledge of general



science and product-specific information to provide up-to-date information, consistent with FDA requirements.

Companies should provide updated additional training in all of these areas as needed for their representatives who visit healthcare professionals.

Companies should also assess their representatives periodically to ensure that they comply with relevant company policies and standards of conduct. Companies should take appropriate action when representatives fail to comply.

15. ADHERENCE TO CODE

All companies that interact with pharmaceuticals should adopt procedures to assure adherence to this Code.

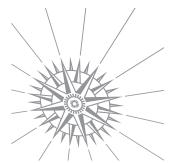
Companies that publicly announce their commitment to abide by the Code, and who complete an annual certification that they have policies and procedures in place to foster compliance with the Code, will be identified by PhRMA on a public Web site. The certification must be signed by the company's Chief Executive Officer and Chief Compliance Officer. The Web site will identify the companies who commit to abide by the Code; provide contact information for their Chief Compliance Officers; and, at the appropriate time, publish the status of each company's annual certification.

Any comments received by PhRMA relating to a company's observance of the Code or conduct that is addressed by the Code will be referred by PhRMA to the relevant company's Chief Compliance Officer.

In addition, companies are encouraged to seek external verification periodically, meaning at least once every three years, that the company has policies and procedures in place to foster compliance with the Code. PhRMA will prepare

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general guidance for such external verification and will identify on its Web site if a company has sought and obtained verification of its compliance policies and procedures from an external source.



Questions and Answers

Q. Under the Code, may items such as stethoscopes be offered to healthcare professionals?

- A. No. Under the code only items designed primarily for the education of patients or healthcare professionals may occasionally be offered to healthcare individuals, if the items are not of substantial value and do not have a value to healthcare professionals outside of their professional responsibilities. While medical equipment, such as stethoscopes, obviously play an important role in patient care, such equipment is primarily designed for the patient treatment, not patient or healthcare professional education, and therefore it would be inappropriate for companies to offer such equipment to healthcare professionals.

Q. Under the Code, could a company provide healthcare Professionals with pens or clipboards designed to be used by healthcare professional or patients in the healthcare professional's office along with brochures that provide educational information about the company's products?

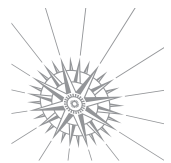
- A. No. The Code states that providing healthcare professionals with items that do not advance disease treatment education is not appropriate, even if the items are practice-related items of minimal value, such as clipboards, pens, mugs, or similar items with or without company logos or products names printed on them. Providing such non-educational items could foster misperceptions that the company's interactions with healthcare professionals are not based on providing information about products or health conditions, and therefore companies should not offer non-educational items to healthcare professionals or their staff, even if they are accompanied by educational materials. It would, however, be appropriate for a company to distribute educational brochures without pens or clipboards. These same guidelines apply with regard to the distribution of items to healthcare professionals at third-party scientific or educational conferences or professional meetings.

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

- A. No. As stated in the prior version of the Code, items intended for the personal benefit of a healthcare professional should not be offered.

Q. The Code states that company representatives or their immediate managers working in a company field sales organization may conduct informational presentations and discussions accompanied by occasional modest meals in the healthcare professional's office or hospital setting. What types of presentations and meals would this include?

- A. An informational presentation or discussion conducted by company representatives or their immediate managers working in field sales may be accompanied by an occasional modest meal in the office or hospital setting. Such modest meals may only be offered provided that the manner of presentation is conducted for a scientific or educational interchange and is not part of an entertainment or recreational event. For example, a sales representative who is providing scientific or educational information regarding a company's products to one or a few healthcare practitioners working in the same office, could provide a modest meal (e.g., sandwiches or pizza) to physicians and staff attending the representative's informational presentation in the physician's office at lunch time. Providing such modest meals on more than an occasional basis would not be appropriate.



Q. Can a field sales representative of Company B conduct an informational presentation accompanied by a meal for a healthcare professional in a restaurant down the street from a hospital?

- A. No. An informational presentation or discussion conducted by a field sales representative or their immediate manager may only be accompanied occasionally by a meal if the presentation is held in the healthcare professional's office or hospital. This is to ensure that any meals offered by field sales representatives or their managers are merely incidental to a substantive interaction with a healthcare professional in the office or hospital setting where the healthcare professional typically conducts professional conversations. In addition, any meals offered must be modest as judged by local standards; the presentation must not be part of an entertainment or recreational event; and the presentation must be provided in a manner conducive to informational communication. If a hospital practitioner does not have an office conducive to informational communication, then the presentation may be provided in a hospital cafeteria or other meeting space within the hospital and may be accompanied by a modest meal.

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

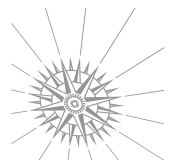
- A. Providing an occasional meal would be consistent with the Code if the representative will provide an informational presentation to the medical staff in conjunction with the meal of modest value, so long as the location of the in-office presentation is conducive to a scientific or educational communication.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

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

- A. No. While the presentation may present scientific or educational information, a company field sales representative should not provide even a modest meal to healthcare professionals outside of the office or hospital setting (except under limited circumstances where the field sales representative attends a company-sponsored speaker program to provide logistical support and help monitor compliance with the FDA requirements — see Question below). In addition, an open-ended gift certificate is a cash equivalent. A medical textbook or book on patient care or a gift certificate redeemable solely for a medical textbook or a book on patient care could be provided if it is not of substantial value (\$100 or less).

Q. A district sales manager at Company C invites 30 physicians to a corporate suite at a professional ball game for a 45-minute scientific and educational presentation followed by a buffet and a 3-hour game. Does this conform to the Code?

- A. No. The provision of entertainment and/or recreational activities, including entertainment at sporting events in connection with an educational or scientific presentation or discussion, is inconsistent with the Code, just as it is in the prior version. In addition, under the Code, informational presentations by company representatives or their immediate managers in field sales organizations may only be accompanied by modest meals if the presentations occur in the healthcare professional's office or hospital setting.



Q. Under the Code, could a senior business executive employed by a company provide a healthcare professional with an occasional meal outside the healthcare professional's office or hospital?

- A. The Code does not prohibit employees other than field sales representatives or their immediate managers from providing an occasional meal incidental to a substantive interaction with a healthcare professional outside of his or her office or hospital, as long as (a) the meal is modest as judged by local standards; (b) the meal is not part of an entertainment or recreational event; and (c) the interaction takes place in a venue and manner conducive to informational communication.

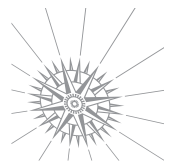
Q. Company Y would like to engage an expert physician to discuss recent advances in therapy for a group of local healthcare professionals, and would like to meet and provide a meal to attendees in the private room of a local restaurant. Under what circumstances can this comply with the Code? Could a local field sales representative in the company's sales organization attend the event for purposes of assisting the outside speaker and helping to assure that the content of the presentation complies with the Code? Could a local field sales representative in the company's sales organization attend the event for the purposes of assisting the outside speaker and helping to assure that the content of the presentation complies with FDA requirements?

- A. The Code contemplates that a company may engage a healthcare professional to provide medical or scientific information to a group of healthcare professionals on behalf of the company. Such speaker programs may include modest meals offered to attendees and may occur in locations outside of the office or hospital setting, as long as they occur in a venue or manner conducive to informational communication. In this case, Company Y's chosen location of a private room in a local restaurant may be conducive to informational discussion; the meal provided to attendees should be modest as judged by local standards. In addition, Company Y should follow the provisions of section 7 of the Code on speaker programs.

For example, Company Y should make sure the speaker is appropriately trained and that the speaker and his or her materials clearly identify the company sponsoring the presentation and the fact that the speaker is presenting on behalf of the company. In addition, Company Y should periodically monitor its speaker for compliance with FDA regulatory requirements. It would be appropriate for a local field representative in the company's sales organization to attend a speaker program for the purposes of assisting the speaker with logistics and helping to assure that the content of the presentation complies with FDA requirements.

Q. Under what circumstances would the Code permit a company to provide entertainment or recreational activities directly to healthcare practitioners?

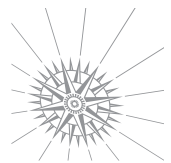
- A. Under the Code, companies may not provide entertainment or recreational activities to healthcare practitioners who are not employees of the companies in any context, including situations where those practitioners are providing a legitimate service to the companies, such as when they act as bona fide consultants on an advisory board or are trained at speaker-training meetings. Thus, companies should not invite healthcare professionals to sporting events, concerts or shows, or provide them with recreational activities such as hunting, fishing, boating, ski trips, or golf outings, even if those entertainment events or recreational events are intended to facilitate informational interchanges between the company representative and the healthcare professional. Similarly, it would be inappropriate to provide these types of entertainment and recreational events in conjunction with promotional scientific presentations by medical experts.



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

- A. No. This arrangement for engaging healthcare professionals to obtain advice on the company's commercial operations does not appear to comply with the Code. It is appropriate for companies to engage healthcare professionals to provide bona fide advisory services as long as the number of healthcare professionals is reasonably necessary to achieve the identified purpose, and they are paid compensation that is reasonable and at fair market value for the services provided. It would not be appropriate, however, to hold such a consultant meeting at a resort venue. In this case, the number of advisors seems reasonably small and the scope of services seems reasonably well defined. The advisors seem to be selected based on their expertise in the areas where their advice is needed. The compensation appears to be consistent with the Code's provision that the consultant fees should be reasonable and based on fair market value. Nevertheless, holding consultant meetings at resort locations is not appropriate under the Code. The facilities chosen should be conducive to the services provided as well as reasonable and appropriate to the conduct of the meeting. In addition, only modest meals may be offered to such consultants, and companies should not provide recreational or entertainment events to the healthcare professional consultants in conjunction with these meetings. It would not be appropriate to pay for the cost of the spouse of the advisor.

- Q. Company A considers whether to invite 300 physicians/consultants to a 2-day and 1-night speaker training program at a regional golf resort. All attendees would be compensated for their participation, and their expenses would be reimbursed. Prospective speakers would be selected based on recommendations of the Company's district managers and an assessment of their qualifications by the Company's medical or scientific personnel. Each of the attendees would be required to sign an agreement in advance covering the services they will provide. They would be educated by a faculty on the full range of data surrounding the disease state and the Company's drug product, on presentation skills, and on FDA regulatory requirements. The Company needs to train 300 speakers in order to ensure that enough speakers will actually be available when needed. Training sessions take both days, and the Company provides for a few hours of golf and expensive meals, such as lobster and filet mignon. Does this program conform to the Code? If so, is it appropriate to pay for a spouse of the healthcare professional as well?**
- A. No. This arrangement would not conform with the Code. Speaker training is an essential activity because the FDA holds companies accountable for the presentations of their speakers. However, the Code provides that speaker training meetings should be held at appropriate venues and specifically states that resorts are not appropriate venues for training speakers. Moreover, providing entertainment (e.g., golf) and expensive meals to a healthcare professional in a speaker-training program would not comply with the Code, although modest meals may be offered to attendees. The Company does appear to satisfy provisions in the Code that require potential speakers to be selected based on defined criteria such as medical expertise, knowledge, and experience, and to undergo extensive training that would result in a valuable service being provided to the company. The arrangement also appears to meet reasonable indicia of a bona fide consulting relationship.



Appendix

The number of speakers being trained is important; if significantly more participants were trained than the company plans to use as speakers, this arrangement would not comply with the Code. The amount of time spent training speakers should be reasonable in relation to the material that has to be covered. The compensation and lodging offered to prospective speakers should be evaluated to assure that it is reasonable compensation for their time and based on fair market value. It would not be appropriate to pay for the cost of the spouse of the healthcare professional. If the spouse attends, it should be at the cost of the healthcare professional.

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

A. No. As stated in the prior version of the Code, it is inconsistent with the Code to provide entertainment or recreational activities such as golf. In addition, occasional, modest meals provided by the representative or his or her immediate manager working in a field sales organization are limited to in-office or in-hospital settings in conjunction with informational presentations and discussions.

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

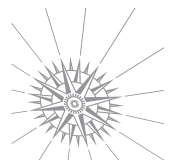
A. No. The Code provides that it is not appropriate to include a spouse or guest at a meal in connection with an informational presentation, regardless of who pays for their meal, unless the spouse or guest would independently qualify as a healthcare professional for whom the informational presentation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

Q. A company is asked to fund a CME program as a “platinum” level supporter. This level of support includes the opportunity for the company to directly sponsor a lunch at the event. May the company become a “platinum” level supporter?

- A. It is appropriate under the Code for a company to provide funding to a CME provider, which the provider can use at its discretion to provide meals for all participants. However, a company should not control how the provider spends the funding, and a company should not sponsor or host a meal directly at a CME program. A company may fund a CME program at a particular level of support designated by a CME provider and be publicized for providing that level of support, as long as the company does not separately promote, publicize, or otherwise take advantage of any option to be identified as the sponsor of a meal.

Q. A national specialty society is holding its 3-day annual conference which includes business meetings, entertainment, and a half day of educational programs for which physicians may receive CME credit. May a company sponsor a reception or lunch at the conference?

- A. The Code provides that a company should not provide or sponsor meals directly at CME events. However, at third-party conferences or professional meetings at which CME activities comprise only a part of the conference or a meeting, a company may sponsor a meal or a reception at the conference if it is permitted by the group holding the conference or the meeting, and is clearly separate from the CME portions of the program. In such cases, any meals or receptions should be modest and clearly subordinate to the amount of time spent at other aspects of the meeting. In addition, companies should be mindful of standards set forth by ACCME or other accrediting bodies that may apply in these circumstances.



Q. May a company publicize its interest in a general topic for a CME program for which a grant would be provided?

- A. Yes. A company may communicate to multiple CME providers or the public in general, a topic for a CME program that might be of interest to physicians. For example, a company may publicize that it will consider funding the topics of new treatments or disease management techniques in a particular therapy area such as diabetes or hypertension. However, the company should follow CME accreditation standards considering the nature and specificity of CME topics that the company may propose, keeping in mind the Code's statement that financial support for CME is intended to support education on a full range of treatment options and not a particular medicine. In addition, the company may not suggest the speakers or review or make any suggestions concerning the specific content of a particular CME program, even if asked by the CME provider.

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

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

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

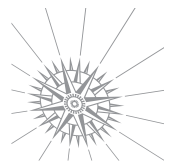
- A. If the consulting arrangement otherwise complies with the Code, and the fair market value of the items represents reasonable compensation for the services provided, this may be permissible. However, it would be important to comply with all applicable record keeping and reporting requirements, just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

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

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

Q. Does the Code address the issue of disclosure of company interactions with healthcare professionals who are members of committees that develop formularies or clinical practice guidelines?

- A. Yes. The Code states that to avoid even the appearance of impropriety, companies that have retained a healthcare professional member of a formulary or clinical practice committee as a commercial consultant or speaker should require the healthcare professional to disclose to the committee the existence and nature of his or her relationship with the company. This disclosure requirement should extend for at least 2 years beyond the termination of any consultant or speaker arrangement. Upon disclosure, healthcare professionals should be required to follow the procedures set forth by the committee of which they are a member; these procedures may include a requirement that the healthcare professional recuse themselves from making decisions relating to the medicine about which they provided speaking or consulting services. It is reasonable for a company to rely on a healthcare professional's judgment regarding how to implement these requirements regarding disclosure and subsequent interactions with the committees of which they are members.



Summaries of Relevant Laws

Federal Anti-Kickback Statute

The Anti-Kickback Statute is a criminal law that prohibits offering or paying remuneration to induce or reward the use of a healthcare product or service that is reimbursed by Medicaid, Medicare, or other federal healthcare programs. The term *remuneration* is defined very broadly to include anything of value including not only cash payments, but also goods, services, or the opportunity to earn compensation.

In interpreting the Anti-Kickback Statute, the Courts have held remuneration to be a violation if one purpose is inducement, even though there are many lawful purposes for the remuneration. Thus, the Anti-Kickback Statute must be considered anytime Ferring provides anything of value to a person in a position to influence the use of Ferring products.

The Anti-Kickback Statute has several provisions that describe arrangements in which remuneration will not be a violation. The rules set forth in this Field Guide are intended to structure any payments to physicians within these “safe harbors.”

Federal False Claims Act

The False Claims Act prohibits providing information to the government in connection with a claim for payment from the government. Pharmaceutical sales and marketing activities that might violate the FCA include, but are not limited to:

- Submitting or causing to be submitted false claims for government payment;
- Fraudulently reporting false pricing information to government agencies;
- Promoting pharmaceutical products for off-label uses.

The FCA provides for civil penalties of up to \$11,000 for each false claim submitted to the government.

The FCA also includes a provision under which individual citizens with evidence of fraud may sue on behalf of the government to recover the lost funds. These suits are known as *qui tam* or whistleblower suits. The law also prohibits retaliation against persons who file such suits.

Federal Food, Drug and Cosmetic Act

The Food, Drug and Cosmetic (FD&C) Act gives the Food and Drug Administration exclusive authority to approve the manufacture, marketing, sale, and distribution of pharmaceutical products in the United States. The FDA approves the labeling of drugs and prohibits any marketing practice which is not in strict conformance with that labeling. The penalty for violation of FDA regulations includes revocation of the product's approval.

The FD&C Act also contains a provision (known as the Prescription Drug Marketing Act or PDMA) that prohibits the sale of drug samples and provides rules pertaining to the distribution of samples.

