OBAMA-BIDEN TRANSITION PROJECT

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Code on Interactions with Healthcare Professionals

PhRMA

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Preamble

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

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

Appropriate 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 to help advance appropriate patient use,
- provide scientific and educational information,
- support medical research and education, and
- obtain feedback and advice about our products through consultation with medical experts.

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

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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 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 will take effect in January 2009.

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1 Basis of Interactions

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

Promotional materials provided to healthcare professionals by or 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 (a) are modest as judged 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 sales representatives or their immediate managers should also be limited to in-office or in-hospital settings.

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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 to avoid the appearance of impropriety, companies should not provide 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 benefits should not be offered, regardless of (1) the value of the items; (2) whether the company engages the healthcare professional as a speaker or consultant, or (3) 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 as described in relevant sections of this Code.

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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 program funded by the company is a bona fide educational program and 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 the 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 apply the financial support provided by a company for a CME event to provide meals for all participants.

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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. Companies use this advice to inform their efforts to ensure that the medicines they produce and market are meeting the needs of patients. Decisions regarding the selection or retention of healthcare professionals as consultants should be made based on defined criteria such as general medical

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expertise and reputation, or knowledge and experience regarding a particular therapeutic area. Companies should continue to ensure that consultant 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 other out-of-pocket expenses. The following factors support the existence of a bona fide consulting arrangement (not all factors may be relevant to any particular arrangement):

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

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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. 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 communications skills. Companies should continue to ensure that speaking arrangements are neither inducements nor rewards for prescribing a particular medicine or course of treatment.

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 only be offered when (1) 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; (2) this training will result in the participants providing a valuable service to the company; and (3) the participants meet the general criteria for bona fide consulting arrangements (as discussed in Section 6 above). Speaker training sessions should

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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

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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.

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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.

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 professional 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.

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12 Prescriber Data

Companies use non-patient identified prescriber data to facilitate the efficient flow of information to healthcare professionals. Such prescriber data, which does 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) comply with FDA mandated risk management plans that require drug companies to identify and interact with physicians who prescribe certain drugs; (d) track adverse events of marketed prescriptions drugs; and (e) 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' ability 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.

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14 Training and Conduct of Company Representatives

Pharmaceutical company representatives play an important role in delivering accurate, up-to-date information to 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 accurate, up-to-date information, consistent with FDA requirements.

Companies should provide updated or 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 healthcare professionals about 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

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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 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.

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PhRMA CODE Questions & Answers

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Q.1

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 professionals, 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 plays an important role in patient care, such equipment is primarily designed for patient treatment, not for patient or healthcare professional education, and therefore it would be inappropriate for companies to offer such equipment to healthcare professionals.

Q.2

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

A. No. The Code states that providing healthcare professionals with items that do not advance disease or treatment education is not appropriate, even if these items are practice-related items of minimal value, such as clipboards, pens, mugs or similar items with or without company logos or product 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 and educational conferences or professional meetings.

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Q.3

Under the Code, what are examples of permissible items that may be provided to educate healthcare professionals?

A. The Code states that it is appropriate for companies, where permitted by law, to occasionally offer items primarily designed for the education of patients or healthcare professionals, as long as such items are not of substantial value ($100 or less) and do not have a value to the healthcare professionals outside of their professional responsibilities. For example, companies may provide educational items such as a medical text book, a subscription to a relevant scientific journal, or copies of relevant clinical treatment guidelines.

Q.4

Under the Code, what types of patient education items may companies provide to healthcare professionals to help them in educating their patients?

A. Where permitted by law, companies may occasionally offer to healthcare professionals items designed to help educate patients, such as anatomical models for examination rooms, informational sheets and brochures, patient self-assessment and tracking tools, or written materials that inform patients about adherence to medicine regimens, healthy lifestyle choices or the availability of patient assistance programs. Such items should not be of substantial value, i.e. they should be $100 or less.

Companies may also provide to healthcare professionals educational items designed for use by patients to assist in the administration of their treatment or management of their conditions. Such items should only be provided to healthcare professionals for patients where the items are permitted by law, may be considered essential to proper treatment or compliance and where delivery through a healthcare professional is an appropriate method of delivery to the patient. For example, companies may provide through healthcare professionals patient starter kits that help enhance the patients' appropriate use of the prescribed medicine. Providing non-educational items to healthcare professionals for patient use is not appropriate, even if these items are of minimal value, such as pedometers, stopwatches, or other general fitness items.

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Q.5

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, golf balls and sports bags, even if of minimal value, do not advance disease or treatment education and therefore should not be offered, regardless of whether they bear a company or product name.

Q.6

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

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.7

The Code states that company representatives or their immediate managers working in company field sales organizations 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 conducive to a scientific or educational interchange and is not part of an entertainment or recreational event. For example, a sales

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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.8

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 her 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 meal offered by field sales representatives or their managers is 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 meal 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 a presentation may be provided in a hospital cafeteria or other meeting space within the hospital and may be accompanied by a modest meal.

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Q.9

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

A. Providing an occasional meal would be consistent with the Code if the sales 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 scientific or educational communication. Merely dropping off food for the office staff, however, would not be consistent with the Code.

Q.10

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

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 the limited circumstances where the field sales representative attends a company-sponsored speaker program to provide logistical support and help monitor compliance with FDA requirements – see Question 13 below). In addition, an open-ended gift certificate is a cash equivalent. A medical textbook, a book on patient care, or a gift certificate redeemable solely for a medical textbook or book on patient care could be provided if it is not of substantial value ($100 or less).

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Q.11

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

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 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 a modest meal if the presentations occur in the healthcare professional's office or hospital setting.

Q.12

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

A. The Code does not prohibit company 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 (1) the meal is modest as judged by local standards; (2) the meal is not part of an entertainment or recreational event; and (3) the interaction takes place in a venue and manner conducive to informational communication.

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Q.13

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 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 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 and 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, and 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 that the speaker is appropriately trained and that the speaker and 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 programs 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 purposes of assisting the speaker with logistics and helping to assure that the content of the presentation complies with FDA requirements.

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Q.14

Under what circumstances would the Code permit a company to provide entertainment or recreational activities 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 a speaker-training meeting. Thus, companies should not invite healthcare professionals to sporting events, concerts, or shows, or provide them with recreational activities such as hunting, fishing, boating, ski trips, or golf outings, even if those entertainment events or recreational activities are 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.15

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 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

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advisory services as long as the number of healthcare professionals is reasonably necessary to achieve an 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 to be reasonably well defined. The advisors seem to have been selected based on their expertise in the areas where advice is needed. The compensation appears consistent with the Code's provision that 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. If the spouse attends, it should be at the cost of the advisor.

Q.16

Company A considers whether to invite 300 physicians/consultants to a two-day and one-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?

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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. 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.17

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

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 a representative or his immediate manager working in a field sales organization are limited to in-office or in-hospital settings in conjunction with informational presentations and discussions.

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Q.18

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.19

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 the 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.

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Q.20

A national specialty society is holding its three-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 meeting, a company may sponsor a meal or reception at the conference if it is permitted by the group holding the conference or meeting and is clearly separate from the CME portions of the program. In such cases, any meals or receptions sponsored by a company 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.21

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 a general 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 the 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 to promote 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.

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Q.22

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

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.23

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

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

Q.24

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

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

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Q.25

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 guidelines committee as a commercial consultant or speaker should require the health care 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 two years beyond the termination of any consultant or speaker arrangement. Upon disclosure, healthcare professionals should be required to follow the procedures set by the committee of which they are a member; these procedures may include a requirement that healthcare professionals recuse themselves from decisions relating to the medicine about which they provided speaking or consulting services. It is reasonable for a company to rely on healthcare professionals' judgment regarding how to implement these requirements regarding disclosure and subsequent interactions with the committees on which they are members.

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950 F Street, NW • Washington, DC 20004 www.phrma.org

Revised July 2008