

AdvaMed Revises Code of Conduct

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On December 18, 2008, the Advanced Medical Technology Association, better known as AdvaMed, released the first major revision and substantial restatement of its Code of Ethics on Interactions with Health Care Professionals (“revised Code”).¹ The revised Code clarifies some of the existing elements of the original Code to provide more guidance to its members, and includes new provisions that address conduct that was either not addressed previously or remains susceptible to abuse. In the current enforcement environment, the revised Code provides an enhanced framework for Medical Technology² companies (“Companies”) to use in evaluating their practices involving Health Care Professionals (“HCPs”),³ revising their compliance programs where necessary, and determining their training priorities.

This Alert summarizes the revisions to the AdvaMed Code and suggests areas for follow-up by Companies.

Background

One of the objectives of the revised Code is to develop compliance principles that reflect the distinctive professional and business environment of the medical technology industry that sets it apart from other health care manufacturers, such as drug or biologics producers. The revised Code, along with a code of ethics adopted by the National Electrical Manufacturers Association for imaging technologies, help distinguish this sector of the health care industry and highlight particular activities that are seen by many, including government regulators, as integral, necessary, and appropriate for the medical device industry (e.g., FDA mandated training).

The revised Code adds a new section that distinguishes between “Medical Technologies” (defined as “medical products, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities”⁴) and “drugs and biologics” (terms that are not defined in the revised Code). Significantly, the revised Code provides that Medical Technologies are “often dependent upon ‘hands on’

Health Care Professional interaction from beginning to end – unlike drugs and biologics, which act on the human body by pharmacological, immunological or metabolic means . . . Many Medical Technologies require technical support during and after deployment.”⁵

Company Certification of Compliance With the Code

The revised Code adds a new section encouraging each member Company to file an annual certification that it complies with the Code and has implemented an effective compliance program. The certification would be signed by the member Company’s chief executive officer and compliance officer or committee, and would contain contact information for its compliance department.⁶

Although such a certification is not binding, it does attempt to close a gap in the overall compliance framework for medical technology Companies. At the present, the HHS Office of Inspector General has yet to publish compliance guidelines for medical technology Companies, and in some contexts such as training and education the concepts in its compliance guidance for pharmaceutical manufacturers may not be transferable.⁷ In addition, California, Nevada, and Massachusetts have adopted statutes that require certain medical technology manufacturers to adopt compliance programs.⁸ Nevertheless, these laws do not always address the interactions between HCPs and medical technology Companies that may be distinct from interactions with pharmaceutical manufacturers. A validation of the Company’s compliance program may help if the relationships between medical technology manufacturers and HCPs are ever questioned or become the focus of an investigation or litigation.

Company-Sponsored Training and Education

Unlike the OIG guidance and the PhRMA Code, the AdvaMed Code has expressly addressed the appropriate training and education of health care professionals in the use of medical devices. Training is now defined in the context of the safe and effective use of a medical technology, while education refers to communications related to the medical technology, such as its intended use for a particular ailment.⁹ Such training may be mandated under FDA regulations, and may be required by the Company in order to minimize the litigation risk under state product liability and negligence law if a patient suffers an injury involving its device. Examples of training and education programs include “hands on” training, cadaver work shops, lectures and presentations and grand rounds.¹⁰

The revised Code expands the concepts set out in the original version of the Code, and reflects the experience of Companies that have provided “hands-on” training. For example, the revised Code clarifies that clinical, educational, and conference sites remain acceptable venues, and that training and education may occur at the health care professional’s site as well.¹¹ The acceptable staff that can provide the training may now include “qualified field sales employees who have the technical expertise necessary to perform the training”, but Companies should be aware that some sites may prohibit individuals without minimum training and credentialing from conducting some forms of training (such as participating in procedures involving the

device). If the training requires that health care professionals attend a session that involves travel and lodging at the Company's expense, the revised Code notes that there must be an objective reason for these expenses.¹² This may occur when the technology is in its early stages and only a few sites have the necessary experience to train other professionals. At all such meetings, the Company may provide modest meals and refreshments for the health care professional only, and they must be subordinate to the training.¹³

Supporting Third-Party Educational Conferences

Many professional conferences receive support from a wide spectrum of sponsors, including medical technology Companies. To help promote the mission of the conferences and to preserve their integrity, trade associations such as AdvaMed have adopted guidelines for providing financial support to the conference sponsor. The revised Code generally tracks the descriptions of appropriate forms of support described in the original Code, but adds some clarifications based on the experience of its members.

Companies may provide grants to conference sponsors to help defray the overall cost of a conference, and may provide grants to allow HCPs in training to attend conferences. This support may include a general subsidy, but can also include grants for the travel, lodging, and honoraria for HCPs who will be faculty members at the conference.¹⁴ The conference must have a *bona fide* scientific or educational purpose, and the conference sponsor must be independent of the Company offering the grant. In addition, the sponsor must retain control over the program content, faculty, and materials.¹⁵ Under the Code, it would not be appropriate for a Company to subsidize the fees and costs of an HCP with whom the Company does business.¹⁶

In addition to the financial support described above, the Code also authorizes Companies to furnish modest meals and refreshments at the conference, subject to the standards established by the independent conference sponsor.¹⁷

In addition to these clarifications, a new FAQ states that it would be appropriate for a Company to sponsor a meeting for a sales, promotional, or other business purpose that is scheduled at approximately the same time as an educational conference but is conducted at a separate location.¹⁸ This reflects the practical concerns of Companies that may, for example, want to convene a meeting of its consultants at the same time as the conference. Such meetings may be beneficial to the Company's legitimate business goals and can be an efficient way of organizing the meeting.

Sales, Promotional, and Other Business Meetings

As with the original version of the Code, the revised Code acknowledges that it is appropriate for Companies to conduct sales, promotional, and other business meetings with HCPs to discuss medical technologies or to negotiate and enter into contracts. Nevertheless, the revised Code reminds Companies that payment for any travel by HCPs should be offered only when necessary (as in the case of demonstrating large non-portable equipment installed at a site), and that any meals should be modest, as

discussed in more detail in Section VIII. In addition, the revised Code directs Companies to offer meals, travel, or lodging only to the HCP or any other individual with a *bona fide* reason for attending the meeting.¹⁹

Consulting Agreements with HCPs

The revised Code restates much of the guidance provided in the original Code, which focused on the elements of a *bona fide* personal services agreement between a Company and an HCP. The revised Code contains additional guidance on these elements, and addresses royalty agreements for the first time.

The revised Code explains that a consulting agreement is any relationship between a Company and an HCP under which the HCP performs services and receives remuneration, except for research and educational grants.²⁰ The individual elements of a consulting agreement remain unchanged, but include the following clarifications:²¹

- The agreement should be in writing, and should describe the services to be performed. The revised Code explains that in the case of clinical research agreements, there should also be a written research protocol.
- There must be a legitimate need for the consulting services; the revised Code counsels that the need should be documented in advance of the request for services.
- The selection of consultants should be based on the individual's expertise; the revised Code clarifies that the expertise should match the previously defined need for the expertise.
- The revised Code explains that compensation should be based on the fair market value of the services, and should not vary based on the value or volume of any past, present, or anticipated business between the parties. This element tracks similar language in the Anti-Kickback safe harbor for personal service agreements. The revised Code also explains that although there is no single method of establishing fair market value, the Company should use objective criteria that can be verified through documentation.²²
- The Company may pay for reasonable expenses incurred by the consultant; the revised Code includes a requirement that these expenses should be documented.
- Meetings with consultants should be conducted in settings that are appropriate to the subject matter and are conducive to the intended exchange of information or work product.
- At any meeting with a consultant, the Company may furnish a modest meal or refreshment, as described elsewhere in the revised Code. However, the revised Code prohibits any entertainment or recreation at such meetings.²³
- The revised Code includes a new element addressing the permissible relationships between sales personnel and Health Care Professional consultants. It notes that while sales personnel may provide input to the Company regarding the qualifications or suitability of a prospective consultant, the sales staff cannot control or exert undue

influence over the selection of a consultant.²⁴ In addition, the revised Code encourages Companies to consider implementing procedures to monitor compliance with this standard.

Royalty agreements are treated in the revised Code as a special category of consulting agreement. These types of agreements have been present in the medical device industry for years. However, to date the Code and other industry codes have not squarely provided guidance on how the industry should manage these arrangements. The revised Code acknowledges that HCPs are often the source of the intellectual property that is then commercialized by a Company. As a result, the revised Code provides that royalty agreements with HCPs are appropriate “only where the Health Care Professional is expected to make or has made a novel, significant, or innovative contribution to, for example, the development of a product, technology, process, or method.”²⁵

The calculation of royalties payable to an HCP must be based on objective factors that avoid or deter any improper influence on the HCP’s independent decision-making; these factors also help deter any inference that the royalty payments are disguised kickbacks. Therefore, the revised Code recommends that royalty payments should not be conditioned on either a requirement that the HCP purchase or recommend the purchase of any product produced by the Company, or on a requirement that the HCP participate in the marketing of a medical technology using the HCP’s intellectual property.²⁶

Prohibition on Entertainment and Recreation

Similar to the revised PhRMA Code, the revised AdvaMed Code specifically prohibits a Company from providing or paying for any entertainment or recreational event or activity for any non-employee HCP.²⁷ The original Code did not address entertainment or recreation specifically, but allowed Members to pay for occasional hospitality in the form of modest meals and receptions for HCP attendees that were conducive to the exchange of information.²⁸ The original Code’s FAQ fleshed out the meaning of “modest” as being “moderate or low value” and “occasional” as “infrequent,” but the meaning of “hospitality” was less clear with the FAQ providing an example of hospitality as “modest and occasional receptions.”²⁹ Further, unlike the revised Code, the original Code did not make a distinction between employed HCPs and non-employee HCPs.

The revised Code provides clarifying examples of “entertainment and recreational events and activities” as “theater, sporting events, golf, skiing, hunting, sporting equipment, and leisure or vacation trips.”³⁰ Further, the revised Code states that entertainment, recreational events, activities and items may not be provided, regardless of (1) their value; (2) whether the Company engages the HCP as a speaker or consultant; or (3) whether the entertainment or recreation is secondary to an educational purpose.³¹ Again, employed HCPs are exempt from this general prohibition.

This prohibition on entertainment and recreational events, activities, and items reflects (1) a trend in government enforcement as the government generally views the provision of entertainment and recreational events to referral sources as a kickback,³² and (2) the debate within the health care industry involving potential conflicts of interest

between health care professionals and vendors resulting from gift-giving and other marketing practices.³³

Modest Meals Associated with Health Care Professional Business Interactions

Although the individual sections of the Code address specific rules regarding meals, the revised Code added a separate section to detail more general rules regarding when and how a Company may provide modest meals in conjunction with the presentation of scientific, educational, or business information.³⁴ Specifically, the purpose of the interaction with the HCP should be the *bona fide* presentation of scientific, educational or business information, and the meal should be incidental to that presentation. Further, the meal should not be part of an entertainment or recreational event, which the revised Code specifically prohibits.³⁵

As in the past, meals should be in a setting that is conducive to the scientific, educational, or business discussion. The revised Code suggests that the setting for the meal could be the HCP's place of business; but if, for example, the medical technology cannot easily be transported to that location, or when it is necessary to discuss confidential product information, or where a private space cannot be obtained on-site, then the meal site can be elsewhere.

As with the original Code, under the revised Code, a Company may provide the meal only to those HCPs that attend the meeting, e.g., no "dine-and-dash" meals. A Company may not pay for meals for an HCP's guests or for any other person without a *bona fide* professional interest in the information being provided during the meeting. In the FAQs, the Code also notes that it is not appropriate to provide a meal during a general discussion to build a good business relationship – mere development of goodwill or business relationships is not enough.³⁶

Educational Items and Prohibition on Gifts

As in the original AdvaMed Code, the revised Code allows Companies to occasionally provide items to HCPs that benefit patients or serve a genuine educational function for the HCP.³⁷ Any such item must have a fair market value of US\$100 or less with the exception of anatomical models or medical textbooks.³⁸ Examples of items that benefit patients include starter kits and educational brochures.³⁹

The revised AdvaMed Code allows a greater range of gifts to HCPs than does the PhRMA Code. Specifically, the AdvaMed Code states that a Company "occasionally may provide items to Health Care Professionals that benefit patients or serve a genuine educational function for Health Care professionals,"⁴⁰ while the PhRMA Code limits gifts to items that are "designed primarily for the education of patients or health care professionals."⁴¹ As such, the PhRMA Code limits gifts intended for patients to educational gifts, while the AdvaMed Code does not include such a limitation, merely stating that the gift must "benefit patients."

However, similar to the revised PhRMA Code, the revised AdvaMed Code prohibits Companies from giving HCPs any type of non-educational branded promotional

items, even if the item is of minimal value and related to the HCP's work or for the benefit of patients.⁴² Specific examples of "non-educational branded promotional items" include not only pens, notepads and mugs with the Company's logo, but also cookies, wine, flowers, chocolates, gift baskets, holiday gifts or cash or cash equivalents.⁴³

The revised AdvaMed Code also provides in new FAQ 36 that like the Company, the Company's employees and agents are prohibited from paying for entertainment or recreation for an HCP, even if the Company neither pays for the entertainment or recreation nor reimburses the employee or agent.⁴⁴ As such the Company's employees/agents are treated no differently from the Company under the revised Code. Similarly, an HCP's staff is treated no differently from the HCP, so the same limitations that apply to gifts to an HCP apply to gifts to the HCP's staff.⁴⁵

Coverage, Reimbursement and Health Economics Information

In the revised Code, AdvaMed substantially expanded its discussion of reimbursement support and related activities. Generally, the AdvaMed Code permits Companies to provide coverage, reimbursement, and health economic information as long as it is accurate and objective. Further, under the revised Code, Companies may collaborate with HCPs, patients, and organizations representing patients' and HCPs' interests to achieve payor coverage decisions, guidelines, policies, and adequate reimbursement levels that allow patients access to their products.

The revised AdvaMed Code also includes several detailed examples of permissible activities involving the provision of coverage, reimbursement, and health economic information including:

- Providing information on changes in coverage or reimbursement, and the resulting impact of any such changes in order to allow a HCP to make an informed decision to buy or use the Company's Medical Technologies.
- Assisting HCPs in obtaining coverage decisions from health plans and third-party payors for procedures or treatment using the Company's medical technologies. This assistance may take the form of providing information and/or training on payor policies and procedures for obtaining prior authorization, and providing sample letters and information on medical necessity and appeals of denied claims. In addition, the Company may assist individual patients in seeking coverage determinations, prior authorizations, pre-certifications, and appeals of denied claims for procedures or treatment involving the Company's medical technologies, provided that the assistance is requested by the HCP and that all applicable privacy rules are satisfied. However, the revised Code warns that any such assistance should not be furnished as an "unlawful inducement."⁴⁶

With regard to the second bulleted example above, in addition to warning Companies to avoid providing assistance to HCPs as "an unlawful inducement," the revised Code separately warns Companies to avoid providing services that eliminate an overhead or other expense that a HCP would have otherwise incurred.⁴⁷ Companies should consult

with their health care regulatory counsel before offering or providing such assistance because unless properly implemented, it could be viewed as a violation of the federal Anti-kickback Statute, which is subject to criminal fines and penalties and possible exclusion from the Medicare and Medicaid programs.⁴⁸

Research and Educational Grants and Charitable Donations

a. Research Grants

The revised Code expands on the principles established in the original Code that sought to provide criteria distinguishing the support of legitimate clinical research activities from arrangements that could be construed as improper financial inducements or even violations of the Anti-Kickback Statute. As with the original Code, a *bona fide* clinical research agreement with a health care professional should have a written protocol for the research and should meet all of the criteria for a consulting agreement as described above.⁴⁹

The revised Code also adds new language discussing research grants and attempts to include criteria designed to deter instances where such grants have been used as improper financial inducements. Specifically, the Code instructs that Companies should not award grants based on past or anticipated business between the Company and any recipient, that they should adopt internal operating procedures to safeguard against the use of grants as an improper inducement, and should have appropriate documentation and monitoring procedures for grant awards. Another revision, which is borrowed from the PhRMA Code, is the recommendation that the award of research grants should be independent of the Company's sales and marketing divisions. In addition, the revised Code expressly addresses the content of grant awards. It instructs that no Company should award an unrestricted research grant; rather, grants should have defined objectives and milestones (which should appear in a legitimate research protocol).⁵⁰

b. Educational Grants

As in its original version, the revised Code expressly endorses financial support of educational programs as long as that support does not involve grants to individual HCPs. For example, while a Company may make a grant to a conference sponsor to help defray the cost of a scientific meeting, it cannot subsidize the registration fee of a physician to attend the meeting.⁵¹

The revised Code permits educational grants for "legitimate purposes"; although this term is not defined in the Code, it can include grants for the advancement of medical education, which is limited to the training of medical students, residents, fellows, and other medical personnel participating in programs that have an affiliation with an academic institution or charitable organization. Grants can also be made for public education on important health care issues.⁵²

c. Charitable Donations

The revised Code retains the general approval of charitable donations to *bona fide* organizations for *bona fide* charitable purposes, and provides additional guidance to Companies. Examples of appropriate donations include indigent patient care, patient education, and sponsorship of events to benefit the charity.⁵³ In addition to these principles, the revised Code expands the definition of a charitable donation to include in-kind donations involving Medical Technologies.⁵⁴

The revised Code also provides guidance to Companies to help deter any donations that may be perceived as unlawful inducements. The Code instructs Companies to exercise some diligence to ensure that the recipient of any donation and its charitable mission are genuine.⁵⁵

Provision of Evaluation and Demonstration Products

The revised Code includes a new section that offers guidance on the ways in which Companies may provide “reasonable quantities” of products to HCPs at no charge for “evaluation and demonstration.” The revised Code provides that “evaluation and demonstration” products can benefit patients in many ways that “include improving patient care, facilitating safe and effective use of products, improving patient awareness, and educating Health Care Professionals regarding the use of the products.”⁵⁶

The revised Code distinguishes between “evaluation” products and “demonstration” products and provides that:

1. “Evaluation” products are typically expected to be used in patient care, and
2. “Demonstration” products are “typically unsterilized single use products or mock-ups of such products that are used for Health Care Professional and patient awareness, education, and training” and are “not intended to be used in patient care.”⁵⁷

With respect to “evaluation” products, the revised Code allows Companies to furnish these products at no charge to allow “Health Care Professionals to assess the appropriate use and functionality of the product and determine whether and when to use, order, purchase, or recommend the product in the future.”⁵⁸ The revised Code also distinguishes between “single use/consumable/disposable” products and “multiple use/capital/capital equipment” products and provides that “single use products provide at no charge should not exceed the amount reasonably necessary for the adequate evaluation of the products under the circumstances.”⁵⁹ With respect to “multiple use/capital/capital equipment” products, the revised Code provides that the products should only be furnished for a “time reasonably necessary”, the terms of the evaluation should be set out in advance, Companies should retain title to the product(s), and there should be a process in place to “promptly” remove the product(s) at the conclusion of the evaluation period unless the HCP leases or purchases the product(s).⁶⁰ Although the revised Code does not state whether “evaluation and demonstration” products may be billed or charged to third-party payors, it does caution that “the Company should

provide the Health Care Professional with documentation about the product to allow the Health Care Professional to appropriately address any obligation to report for reimbursement purposes.”⁶¹ Lastly, the revised Code provides that “evaluation and demonstration” products are not gifts and, therefore, would not be subject to the guidance concerning gifts in Section IX.⁶²

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In summary, the revised and restated Code provides industry with additional guidance on topics addressed by the original Code and also delves into new areas of importance to medical technology companies. The revised and restated Code explicitly prohibits certain conduct (i.e., gifts) that may have been historically interpreted as permissible. Therefore, we suggest that medical technology companies review the revised and restated Code and consider whether their practices, policies, and procedures may need to be modified before the July 1, 2009 effective date. We suggest that this review start as soon as possible, especially when the company plans to schedule compliance training programs before the July 1 effective date.

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Endnotes

- ¹ The Revised Code of Ethics on Interactions with Health Care Professionals (the “Revised Code”) and a comparison chart against the previous Code (the “Original Code”) can be found at: <http://www.advamed.org/MemberPortal/About/code/>.
- ² See infra note 4 and accompanying text.
- ³ AdvaMed specifically states that “[t]he phrase ‘Health Care Professionals’ is intended to be a broad one.” It is defined to include “individuals or entities: (1) which are involved in the provision of health care services and/or items to patients; and (2) which purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies’ Medical Technologies in the United States. The phrase Health Care Professional includes both persons providing services (such as licensed physicians) and persons who do not provide services directly but who are involved in the decision to purchase, lease, or recommend a medical Technology. These individuals include, for example, purchasing agents, physician’s practice managers and management within group purchasing organizations (‘GPOs’).” Revised Code Frequently Asked Questions (“FAQ”) 2.
- ⁴ Revised Code at 1.
- ⁵ *Id.*
- ⁶ Revised Code at 2-3.
- ⁷ The OIG’s compliance guidance for pharmaceutical manufacturers is available at: <http://www.oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf>.
- ⁸ Calif. Health & Safety Code §§ 119400 – 119402; Mass. Gen. L. ch. 111N, § 2; Nev. Rev. Stat. § 639.570. In addition, Maine, Minnesota, Vermont, West Virginia and the District of Columbia require that manufacturers disclose gifts or compensation paid to physicians.
- ⁹ Revised Code at 3.
- ¹⁰ *Id.*
- ¹¹ Revised Code at 4.
- ¹² *Id.* and FAQ 17.
- ¹³ Original Code at 2; Revised Code at 4.
- ¹⁴ Original Code at 2-3; Revised Code at 5.
- ¹⁵ Revised Code at 4
- ¹⁶ *Id.* FAQ 19.
- ¹⁷ Revised Code at 5.
- ¹⁸ *Id.* FAQ 21.
- ¹⁹ Original Code at 3; Revised Code at 5.
- ²⁰ Revised Code FAQ 31.
- ²¹ Original Code at 3-4; Revised Code at 5-6.
- ²² Revised Code FAQ 34.
- ²³ See text accompanying notes 27-33.
- ²⁴ Revised Code at 6.
- ²⁵ *Id.*
- ²⁶ Revised Code at 6-7. Companies may still enter into separate consulting agreements with HCPs for marketing provided that they meet all other criteria specified in the Code.
- ²⁷ *Id.* at 7. The revised PhRMA Code provides a similar prohibition on entertainment and recreation with the similar exception for employed HCP. See Pharmaceutical Research and Manufacturers of America (“PhRMA”), Code on Interactions with Healthcare Professionals (“PhRMA Code”) at 5 (eff. Jan. 1, 2009), available at <http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf>.
- ²⁸ Original Code at 3.
- ²⁹ *Id.* FAQ 8.
- ³⁰ Revised Code at 7. Note the inclusion of “sporting equipment,” an example of which was included in the original Code in a FAQ regarding promotional items of minimal value that are neither related to the HCP’s work or the benefit of patients – golf balls. Original Code FAQ 27.
- ³¹ Revised Code at 7.
- ³² See OIG News, *OIG Settles Largest Ever Civil Monetary Penalty Case: Lincare Pays \$10 Million and Signs 5-Year CIA to Resolve Allegations of Kickbacks and Self-Referral Violations* (May 15, 2006), available at www.oig.hhs.gov/publications/docs/press/2006/Lincare051506.pdf (last viewed Jan. 7, 2009).

Endnotes, *cont.*

- 33 See Jana Kolarik Anderson et al, *Vendor-Healthcare Professional Gift Giving, Marketing, and Compliance* (AHLA Member Briefing, Corporate Governance Task Force, Dec. 2007).
- 34 Revised Code at 7-8.
- 35 *Id.* at 7 (Sections VII and VIII).
- 36 *Id.* FAQ 37.
- 37 Original Code at 4; Revised Code at 8. The PhRMA Code allows the provision of items to HCPs that are designed primarily for the education of patients or health care professionals. See PhRMA Code at 12 (Jan. 1, 2009).
- 38 *Id.*
- 39 Revised Code FAQ 42.
- 40 *Id.* at 8.
- 41 See PhRMA Code at 12 (Jan. 1, 2009).
- 42 Compare Revised Code at 8 with Original Code at 4; see also PhRMA Code at 11-12 (eff. Jan. 1, 2009).
- 43 Revised Code at 8. The original Code allowed gift baskets or flowers upon a significant life event like a birth, death or serious illness. See Original Code FAQ 28. This prohibition does not extend to the Company's provision of products for evaluation and demonstration purposes, which are dealt with in another section of the revised Code.
- 44 Revised Code FAQ 36. The revised PhRMA Code has a similar prohibition within the text of the Code. See PhRMA Code at 11 (eff. Jan. 1, 2009).
- 45 Revised Code FAQ 39.
- 46 Revised Code at 9 (emphasis added).
- 47 See *id.* at 9 and 10.
- 48 See 42 USC § 1320a-7b(b). Violations of the anti-kickback statute are punishable by criminal fines up to \$25,000 per offense, and/or five years imprisonment with a felony conviction and civil monetary penalties of up to \$50,000 for each violation plus treble damages.
- 49 Original Code at 4; Revised Code at 5 and FAQs 33 and 35.
- 50 Revised Code at 5-6, 10 and FAQ 49.
- 51 Revised Code FAQ 45.
- 52 Original Code at 5; Revised Code at 10-11.
- 53 Original Code at 5; Revised Code at 11 and FAQs 44-51.
- 54 Revised Code at 11 and FAQ 44.
- 55 Revised Code at 11 and FAQ 51.
- 56 Revised Code at 11.
- 57 *Id.* at 11 – 12.
- 58 *Id.* at 11.
- 59 *Id.* at 11.
- 60 *Id.* at 11.
- 61 *Id.* FAQ 52.
- 62 *Id.* FAQ 54.