

XDX COMPLIANCE POLICY

ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS

XDx, Inc. (the “Company” or “XDx”), is committed to complying with all federal, state, and local laws and regulations, and to maintaining a workplace that is free of retaliation for raising matters of legal compliance. As a medical device company, XDx is subject to a number of federal laws governing conflicts of interest, including but not limited to the federal anti-kickback statute (42 U.S.C. § 1320(a)-7(b)) and Stark II (Omnibus Budget Reconciliation Act of 1993). Effective September 1, 2009, XDx has adopted the AdvaMed Code of Ethics on Interactions with Health Care Professionals (the “AdvaMed Code”), which regulates the Company’s interactions with health care professionals. In some states, state law imposes additional restrictions on interactions with health care providers.¹ In particular, you are responsible for complying with Massachusetts regulation 105 CMR 970.000 with respect to interactions with health care providers in Massachusetts, a copy of which is attached to this compliance policy as Exhibit A and incorporated by this reference. In addition, in creating this compliance policy, XDx has supplemented the AdvaMed Code with certain provisions necessary to comply with state laws governing these interactions.

XDx employees are expected to familiarize themselves with XDx’s legal obligations. In addition, all XDx employees who interact with those individuals or entities involved in the provision of health care services and/or items to patients, or who purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe XDx’s products are required to complete regular training on this compliance policy.

At all times, you are required to abide by both the spirit and the letter of the AdvaMed Code and applicable law. Failure to comply with applicable law can result in serious consequences for both you and the Company, including imprisonment, civil and criminal penalties, and exclusion from participation in federal health care programs.

Should you ever have any question as to whether a particular activity violates applicable law or the AdvaMed Code, you are strongly encouraged to contact Human Resources, the Compliance Officer, or any member of the Compliance Committee before undertaking such activity. [The members of the Company’s Compliance Committee are listed on the Company’s website.]

Reporting and Investigation

The Company is committed to maintaining an atmosphere of open communication and trust between employees and management. If you reasonably believe that you are aware of conduct that violates the Company’s duties under applicable law or the AdvaMed Code, you should immediately contact your supervisor, Human Resources, the Compliance Officer, and/or any member of the Compliance Committee.

All complaints under this policy will be promptly and thoroughly investigated, and all information disclosed during the course of the investigation will remain confidential, except as necessary to conduct the investigation and take any remedial action, in accordance with applicable law. All employees and supervisors have a duty to cooperate in the investigation of reports of any conduct covered by this policy. In addition, an employee will be subject to disciplinary action, including the termination of their employment, if the employee fails to cooperate in an investigation or deliberately provides false information during an investigation.

¹ As of the date of this version of XDx’s compliance code, Massachusetts, Vermont, California and Nevada have imposed compliance and/or reporting requirements on medical device manufacturers.

Once the investigation is complete, the specific action taken in any particular case depends on the nature and gravity of the conduct or circumstances reported and the quality of the information provided. If an investigation determines that conduct in violation of the Company's legal duties has occurred, and, if appropriate, the persons responsible will be disciplined.

Prohibition on Discrimination, Retaliation or Harassment

The Company strictly prohibits discrimination, retaliation or harassment of any kind against any employee who, based on the employee's reasonable belief that a violation of the AdvaMed Code or applicable law have occurred or are occurring, reports that information in accordance with this policy. The Company also strictly prohibits any discrimination, retaliation or harassment against any person who participates in an investigation of such complaints.

Any complaint that any managers, supervisors or employees are involved in discrimination, retaliation or harassment related to the reporting or investigation of conduct in violation of the Company's legal duties will be promptly and thoroughly investigated in accordance with the Company's investigation procedures. If a complaint of discrimination, retaliation or harassment is substantiated, appropriate disciplinary action, up to and including termination, will be taken.

The Company may modify this policy as necessary to accommodate organizational changes or to maintain compliance with applicable law and the AdvaMed Code. This policy is not intended to supersede any other XDx policies relating to whistleblowing, discrimination, harassment or retaliation.

Version 1

Dated: September 1, 2009

**CODE OF ETHICS
ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS**

ADOPTED BY THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION

I. Preamble: Goal and Scope of AdvaMed Code

The Advanced Medical Technology Association (“AdvaMed”) represents companies that develop, produce, manufacture, and market medical products, technologies and related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities (“Medical Technologies”) in order to enable patients to live longer and healthier lives (collectively “Companies,” and individually “Company”). AdvaMed is dedicated to the advancement of medical science, the improvement of patient care, and, in particular, the contributions that high quality, innovative Medical Technologies make toward achieving these goals. AdvaMed recognizes the obligation to facilitate ethical interactions between Companies and those individuals or entities involved in the provision of health care services and/or items to patients, which purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Companies’ Medical Technologies in the United States (“Health Care Professionals”).

Medical Technologies

Medical Technologies are often highly 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. For example, implantable Medical Technologies are often placed in the human body to replace or strengthen a body part. Surgical Medical Technologies often serve as extensions of a physician’s hands. In other circumstances, Medical Technologies are noninvasive reagents, instrumentation and/or software to aid in the diagnosis, monitoring and treatment decisions made by Health Care Professionals. Some Medical Technologies work synergistically with other technologies, or are paired with other products that deploy devices in the safest and most effective manner. Many Medical Technologies require technical support during and after deployment.

Interactions with Health Care Professionals

The scope of beneficial interactions between Health Care Professionals and Companies is broad and includes interactions intended to:

- *Promote the Advancement of Medical Technologies.* Developing and improving cutting edge Medical Technologies are collaborative processes between Companies and Health Care Professionals. Innovation and creativity are essential to the development and evolution of Medical Technologies, which often occur outside a Company’s laboratory.
- *Enhance the Safe and Effective Use of Medical Technologies.* The safe and effective use of sophisticated electronic, *in vitro* diagnostic, surgical, or other Medical Technologies often requires Companies to provide Health Care Professionals appropriate instruction, education, training, service and technical support. Regulators often require this type of training as a condition of product approval.
- *Encourage Research and Education.* Companies’ support of *bona fide* medical research, education, and enhancement of professional skills improves patient safety and increases access to Medical Technologies.
- *Foster Charitable Donations and Giving.* Companies make monetary and Medical Technology donations for charitable purposes, such as supporting indigent care, as well as patient and public education. This increases access to—as well as the quality of—care and treatment in patient populations that may not otherwise be reached.

The Purpose of the Code of Ethics

AdvaMed recognizes that Health Care Professionals' first duty is to act in the best interests of patients. Companies can serve the interests of patients through beneficial collaborations with Health Care Professionals. To ensure that these collaborative relationships meet high ethical standards, they must be conducted with appropriate transparency and in compliance with applicable laws, regulations and government guidance. AdvaMed recognizes the obligation to facilitate ethical interactions between Companies and Health Care Professionals in order to ensure that medical decisions are based on the best interests of the patient. The ethical principles that govern these interactions are the subject of this Code of Ethics.² To that end, AdvaMed restates and amended its Code of Ethics and Frequently Asked Questions (collectively "Code of Ethics" or "Code"), effective July 1, 2009.

II. Code of Ethics Compliance

All Companies are strongly encouraged to adopt this Code and to implement an effective compliance program – one which includes policies and procedures that foster compliance with the Code with respect to their interactions with Health Care Professionals related to Medical Technologies. A Company that adopts the Code is strongly encouraged to submit to AdvaMed an annual certification that the Company has adopted the Code and has implemented an effective compliance program. This certification must be signed by the Company's Chief Executive Officer and Chief Compliance Officer or individuals with equivalent responsibilities within the certifying Company. AdvaMed will publish on its website a list of those Companies that have submitted the annual certification.

Companies that are AdvaMed members shall, and Companies that are non-members may, supply contact information for the Company's Compliance Department to facilitate reporting of possible violations of the Code. AdvaMed will publish on its website the contact information supplied by each such Company.

Companies are strongly encouraged to follow the seven elements of an effective compliance program, appropriately tailored for each Company, namely:

- (1) Implementing written policies and procedures;
- (2) Designating a compliance officer and compliance committee;
- (3) Conducting effective training and education;
- (4) Developing effective lines of communication (including an anonymous reporting function); (5) Conducting internal monitoring and auditing;
- (6) Enforcing standards through well-publicized disciplinary guidelines; and
- (7) Responding promptly to detected problems and undertaking corrective action.

Note. This Amended and Restated Code supersedes and replaces all previous AdvaMed Codes of Ethics. Companies adopting this Code shall communicate the principles of this Code to their employees, agents, dealers and distributors with the expectation that they will adhere to this Code. All Companies have an independent obligation to ensure that their interactions with Health Care Professionals comply with all applicable laws and regulations. The information provided by the Department of Health and Human Services, Office of Inspector General ("OIG"), as well as applicable laws or regulations, may provide more specificity than this Code, and Companies should address any additional questions to their own attorneys. This Code of Ethics is intended to facilitate ethical behavior, and is not intended to be, nor should it be, construed as legal advice. The Code is not intended to define or create legal rights, standards or obligations. Any interpretation of the provisions of this Code, as well as Companies' interactions with Health Care Professionals not specifically addressed in this Code, should be made in light of the following principle: Companies shall encourage ethical business practices and socially responsible industry conduct and shall not engage in any unlawful inducement.

² The principles of the Code are derived from a variety of authorities, including the federal Anti-kickback Statute. Throughout the Code, we refer to the concept of an "unlawful inducement" to reflect Anti-kickback Statute prohibitions.

III. Company-Conducted Product Training and Education

Companies have a responsibility to make training and education on their products and Medical Technologies available to Health Care Professionals. Companies may also provide education to Health Care Professionals.

“Training” means training on the safe and effective use of Medical Technologies.

“Education” means communicating information directly concerning or associated with the use of Companies’ Medical Technologies, *e.g.*, information about disease states and the benefits of Medical Technologies to certain patient populations.

Training and Education programs include, but are not limited to,

- “hands on” training sessions,
- cadaver workshops,
- lectures and presentations, and
- Grand rounds.

In fact, the U.S. Food and Drug Administration mandates training and education to facilitate the safe and effective use of certain Medical Technologies. Companies should adhere to the following principles when conducting training and education programs concerning Medical Technologies for Health Care Professionals:

- Programs and events should be conducted in settings that are conducive to the effective transmission of information. These may include
 - clinical,
 - educational,
 - conference, or
 - other settings, such as hotels or other commercially available meeting facilities.
 - In some cases, it may be appropriate for a Company representative to provide training and education at the Health Care Professional’s location.
- Programs providing “hands on” training on Medical Technologies should be held at training facilities, medical institutions, laboratories, or other appropriate facilities. The training staff used by the Company should have the proper qualifications and expertise to conduct such training. Training staff may include qualified field sales employees who have the technical expertise necessary to perform the training.
- Companies may provide Health Care Professional attendees with modest meals and refreshments in connection with these programs. Any such meals and refreshments should be modest in value and subordinate in time and focus to the training and/or educational purpose of the meeting.
- Where there are objective reasons to support the need for out-of-town travel to efficiently deliver Training and Education on Medical Technologies, Companies may pay for reasonable travel and modest lodging costs of the attending Health Care Professionals.
 - It is not appropriate for Companies to pay for the meals, refreshments, travel, or other expenses for guests of Health Care Professionals or for any other person who does not have a *bona fide* professional interest in the information being shared at the meeting.

Note under Massachusetts Law: Payment or reimbursement for reasonable expenses necessary for technical training on the use of a medical device is not prohibited, so long as the commitment to provide such expenses, and

the amounts or categories of such reasonable expenses to be paid, are *described in the written purchase agreement* between the health care practitioner³ and the device vendor for the purchase of the device.

Note under Vermont Law: Payment or reimbursement for reasonable expenses necessary for technical training of individual health care professionals⁴ on the use of a medical device is not prohibited, so long as the commitment to provide such expenses, and the amounts or categories of such reasonable expenses to be paid, are *described in the written agreement* between the health care professional and the manufacturer.

IV. Supporting Third-Party Educational Conferences

Bona fide independent, educational, scientific, and policymaking conferences promote scientific knowledge, medical advancement and the delivery of effective health care. These typically include conferences sponsored by national, regional, or specialty medical associations and conferences sponsored by accredited continuing medical education providers. Companies may support these conferences in various ways:

- *Conference Grants.* Companies may provide a grant to the conference sponsor to reduce conference costs. They may also provide grants to a training institution or the conference sponsor to allow attendance by medical students, residents, fellows, and others who are Health Care Professionals in training. Companies may provide grants when:
 - (1) The gathering is primarily dedicated to promoting objective scientific and educational activities and discourse; and
 - (2) The training institution or the conference sponsor selects the attending Health Care Professionals who are in training.

Such grants should be paid only to organizations with a genuine educational function and may be used to reimburse only the legitimate expenses for *bona fide* educational activities. Such grants also should be consistent with applicable standards established by the conference sponsor and any body accrediting the educational activity. The conference sponsor should independently control and be responsible for the selection of program content, faculty, educational methods, and materials.

Note under Massachusetts Law: A medical device company may not sponsor CME events that do not meet the Standards for Commercial Support as established by the Accreditation Council for Continuing Medical Education (“ACCME”) or equivalent commercial support standards, or that provide payment directly to a health care professional.

Note under Vermont Law: (A) A medical device company may make a payment to the sponsor of a significant educational, medical, scientific, or policy-making conference or seminar, provided: (i) the payment is not made

³ Under Massachusetts law, health care practitioner is defined as a person who prescribes prescription drugs for any person and is licensed to provide health care in the commonwealth, or a partnership or corporation comprised of such persons, or an officer, employee, agent or contractor of such person acting in the course and scope of his employment, agency or contract related to or in support of the provision of health care to individuals. Hospitals are not healthcare practitioners. Additionally, full time employees and board members of pharmaceutical or medical device manufacturers are not health care practitioners.

⁴ Under Vermont law, health care professional is defined as (i) a person who is authorized to prescribe or to recommend prescribed products and who either is licensed by this state to provide or is otherwise lawfully providing health care in this state; or (ii) a partnership or corporation made up of the persons described in subdivision (i); or (iii) an officer, employee, agent, or contractor of a person described in subdivision (i) who is acting in the course and scope of employment, of an agency, or of a contract related to or supportive of the provision of health care to individuals. The term shall not include a person described above who is employed solely by a manufacturer

directly to a health care provider; (ii) funding is used solely for bona fide educational purposes; and (iii) all program content is objective, free from industry control, and does not promote specific products. (B) A medical device company may make a payment of honoraria or the expenses of a health care professional who serves on the faculty at a bona fide significant educational, medical scientific, or policy-making activities; provided that the content of the presentation, including slides and written materials, is determined by the health care professional.

- *Conference Meals and Refreshments.* Companies may provide funding to the conference sponsor to support the provision of meals and refreshments to conference attendees. Also, Companies themselves may provide meals and refreshments for Health Care Professional attendees if such meals and refreshments are provided:

(1) To all Health Care Professional attendees (with the limited exception noted below), and

(2) In a manner that is consistent with applicable standards established by the conference sponsor and the body accrediting the educational activity.

Meals and refreshments may be provided to fewer than all Health Care Professional attendees if the Company providing such meals and refreshments satisfies all other principles related to meals set forth in Section VIII. Any meals and refreshments should be modest in value, subordinate in time and focus to the purpose of the conference, and clearly separate from the continuing medical education portion of the conference.

Note under Massachusetts Law: No medical device company may provide payment for meals directly to a health care practitioner at any CME event, third-party scientific or education conference, or professional meeting, although a CME provider or conference or meeting organizer may, at its own discretion, apply any financial support provided by a medical device company for the event to provide meals for all participants.

- *Faculty Expenses.* Companies may make grants to conference sponsors for reasonable honoraria, travel, lodging, and modest meals for Health Care Professionals who are *bona fide* conference faculty members.
- *Advertisements and Demonstration.* Companies may purchase advertisements and lease booth space for Company displays at conferences.

V. Sales, Promotional, and Other Business Meetings

Companies may conduct sales, promotional, and other business meetings with Health Care Professionals to discuss, for example, Medical Technology features, sales terms, or contracts. Often, these meetings occur close to the Health Care Professional's place of business. It is appropriate to pay for reasonable travel costs of attendees when necessary (*e.g.*, for plant tours or demonstrations of non-portable equipment) and/or to provide occasional modest meals and refreshments in connection with such meetings. However, it is not appropriate to pay for meals, refreshments, travel, or lodging of guests of Health Care Professionals or any other person who does not have a *bona fide* professional interest in the information being shared at the meeting. See Section VIII for additional principles related to the provision of meals associated with Health Care Professional business interactions.

VI. Consulting Arrangements with Health Care Professionals

Companies engage Health Care Professionals to provide a wide-range of valuable, *bona fide* consulting services through various types of arrangements, such as contracts for research, product development, development and/or transfer of intellectual property, marketing, participation on advisory boards, presentations at Company-sponsored training and other services. Companies may pay consultants fair market value compensation for performing these types of services, provided that they are intended to fulfill a legitimate business need and do not constitute an unlawful inducement. Companies should comply with the following standards in connection with consulting arrangements with Health Care Professionals:

- Consulting agreements should be written and describe all services to be provided. When a Company contracts with a consultant to conduct clinical research services, there should also be a written research protocol.
- Consulting arrangements should be entered into only where a legitimate need for the services is identified in advance and documented.
- Selection of a consultant should be made on the basis of the consultant's qualifications and expertise to meet the defined need.
- Compensation paid to a consultant should be consistent with fair market value in an arm's length transaction for the services provided and should not be based on the volume or value of the consultant's past, present or anticipated business.
- A Company may pay for documented, reasonable and actual expenses incurred by a consultant that are necessary to carry out the consulting arrangement, such as costs for travel, modest meals, and lodging. **Note under Massachusetts Law:** Any such compensation or reimbursement must be specified in, and paid for under, a written agreement.
- The venue and circumstances for Company meetings with consultants should be appropriate to the subject matter of the consultation. These meetings should be conducted in clinical, educational, conference, or other settings, including hotel or other commercially available meeting facilities, conducive to the effective exchange of information.
- Company-sponsored meals and refreshments provided in conjunction with a consultant meeting should be modest in value and should be subordinate in time and focus to the primary purpose of the meeting. Companies should not provide recreation or entertainment in conjunction with these meetings.
- A Company's sales personnel may provide input about the suitability of a proposed consultant, but sales personnel should not control or unduly influence the decision to engage a particular Health Care Professional as a consultant. Companies should consider implementing appropriate procedures to monitor compliance with this section.

Note under Massachusetts Law: Medical device companies must maintain records concerning all consulting arrangements with health care practitioners and make appropriate use of the services provided by the health care practitioners.

Provisions on Payment of Royalties. Arrangements involving the payment of royalties to a Health Care Professional should meet the contractual standards set forth above. Health Care Professionals, acting individually or as part of a group in which they are an active participant, often make valuable contributions that improve products or Medical Technologies. They may develop intellectual property, for example, patents, trade secrets, or know-how, under a product or technology development or intellectual property licensing agreement. A Company should enter into a royalty arrangement with a Health Care Professional 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. A significant contribution by an individual or group, if it is the basis for compensation, should be appropriately documented.

The calculation of royalties payable to a Health Care Professional in exchange for Intellectual Property should be based on factors that preserve the objectivity of medical decision-making and avoid the potential for improper influence. For example, royalties paid in exchange for Intellectual Property should not be conditioned on:

(1) a requirement that the Health Care Professional purchase, order or recommend any product or medical technology of the Company or any product or technology produced as a result of the development project; or

(2) a requirement to market the product or medical technology upon commercialization. (Companies may, however, elect to enter into separate consulting agreements with Health Care Professionals for marketing services if such services meet the requirements set forth in this Section VI above.) Companies are strongly encouraged to consider whether it is appropriate and practicable to exclude from the calculation of royalties the number of units purchased, used, or ordered by the Health Care Professional and/or members of the Health Care Professional's practice.

VII. Prohibition on Entertainment and Recreation

Company interactions with Health Care Professionals should be professional in nature and should facilitate the exchange of medical or scientific information that will benefit patient care. To ensure the appropriate focus on an educational and/or informational exchange and to avoid the appearance of impropriety, a Company should not provide or pay for any entertainment or recreational event or activity for any non-employee Health Care Professional.

Such activities include, for example,

- Theater,
- Sporting events,
- Golf,
- Skiing,
- Hunting,
- Sporting equipment, and
- Leisure or vacation trips.

Such entertainment or recreational events, activities, or items should not be provided, regardless of:

- (1) Their value;
- (2) Whether the Company engages the Health Care Professional as a speaker or consultant; or
- (3) Whether the entertainment or recreation is secondary to an educational purpose.

VIII. Modest Meals Associated with Health Care Professional Business Interactions

A Company's business interactions with Health Care Professionals may involve the presentation of scientific, educational, or business information and include, but are not limited to, the different types of interactions described in Sections III through VI of this Code of Ethics.

Such exchanges may be productive and efficient when conducted in conjunction with meals.

Accordingly, modest meals may be provided as an occasional business courtesy consistent with the limitations in this section.

Purpose. The meal should be incidental to the *bona fide* presentation of scientific, educational, or business information and provided in a manner conducive to the presentation of such information. The meal should not be part of an entertainment or recreational event.

Setting and Location. Meals should be in a setting that is conducive to *bona fide* scientific, educational, or business discussions. Meals may occur at the Health Care Professional's place of business. However, in some cases the place of business may be a patient care setting that is not available for, or conducive to, such scientific, educational, or business discussions. In other cases, it may be impractical or inappropriate to provide meals at the Health Care Professional's place of business, for example, (1) where the Medical Technology cannot easily be transported to the Health Care

Professional's location, (2) when it is necessary to discuss confidential product development or improvement information, or (3) where a private space cannot be obtained on-site.

Note under Massachusetts Law: Meals should not be offered, consumed or provided outside of the health care practitioner's office or hospital setting.

Participants. A Company may provide a meal only to Health Care Professionals who actually attend the meeting. A Company may not provide a meal for an entire office staff where everyone does not attend the meeting. A Company also may not provide a meal where its representative is not present (such as a "dine & dash" program). A Company may not pay for meals for guests of Health Care Professionals or for any other person who does not have a *bona fide* professional interest in the information being shared at the meeting.

Other principles. Depending on the type of business interaction or meeting, additional principles may apply, as described in other sections of this Code of Ethics. Specifically:

- Section III: Company-Conducted Product Training and Education.
- Section IV: Supporting Third-Party Educational Conferences.
- Section V: Sales, Promotional, and Other Business Meetings.
- Section VI: Consulting Arrangements with Health Care Professionals.

IX. Educational Items; Prohibition on Gifts

A Company occasionally may provide items to Health Care Professionals that benefit patients or serve a genuine educational function for Health Care Professionals. Other than medical textbooks or anatomical models used for educational purposes, any such item should have a fair market value of less than \$100. A Company may not provide items that are capable of use by the Health Care Professional (or his or her family members, office staff or friends) for non-educational or non-patient-related purposes, for example, a DVD player or MP3 player/I-Pod.

A Company may not give Health Care Professionals any type of non-educational branded promotional items, even if the item is of minimal value and related to the Health Care Professional's work or for the benefit of patients. Examples of non-educational branded promotional items include pens, notepads, mugs, and other items that have a Company's name, logo, or the name or logo of one of its Medical Technologies. Companies also may not provide Health Care Professionals with gifts such as cookies, wine, flowers, chocolates, gift baskets, holiday gifts or cash or cash equivalents.

This section is not intended to address the legitimate practice of providing products for evaluation and demonstration purposes, which is addressed in Section XII.

Note under Vermont Law: It is unlawful for any manufacturer of a prescribed product or any wholesale distributor of medical devices, or any agent thereof, to offer or give any gift⁵ to a health care provider. This prohibition does not apply

⁵ Under Vermont law, a gift is defined as (A) anything of value provided to a health care provider for free; or (B) any payment, food, entertainment, travel, subscription, advance, service, or anything else of value provided to a health care provider, unless (i) it is an "allowable expenditure;" or (ii) the health care provider reimburses the cost at fair market value.

"Allowable expenditures" means: (A) Payment to the sponsor of a significant educational, medical, scientific, or policy-making conference or seminar, provided: (i) the payment is not made directly to a health care provider; (ii) funding is used solely for bona fide educational purposes; and (iii) all program content is objective, free from industry control, and does not promote specific products. (B) Honoraria and payment of the expenses of a health care professional who serves on the faculty at a bona fide significant educational, medical, scientific, or policy-making conference or seminar, provided: (i) there is an explicit contract with specific

to: (A) product samples, (B) the loan of medical devices for evaluation purposes for a period not to exceed 90 days, (C) the provision of reasonable quantities of medical device demonstration or evaluation units, (D) the provision of peer-reviewed journal articles and other items that serve a genuine educational function for the benefit of patients, (E) scholarships or other support for medical students, residents and fellows to attend certain professional association conferences or seminars if the recipient is selected by the professional association, (F) rebates and discounts, and (G) approved labels.

X. Provision of Coverage, Reimbursement and Health Economics Information

As Medical Technologies have become increasingly complex, so have payor coverage and reimbursement policies. Patient access to necessary Medical Technology may be dependent on Health Care Professionals and/or patients having timely and complete coverage, reimbursement, and health economic information. Consequently, a Company may provide such information regarding its Medical Technologies if it is accurate and objective. A Company also may collaborate with Health Care Professionals, patients and organizations representing their interests, to achieve government and commercial payor coverage decisions, guidelines, policies, and adequate reimbursement levels that allow patients to access its Medical Technologies. Permissible activities involving the provision of coverage, reimbursement and health economic information may include, but are not limited to:

- Identifying the clinical value of the Company's Medical Technologies and the services and procedures in which they are used when providing coverage, reimbursement and health economics information and materials to Health Care Professionals, professional organizations, patient organizations, and payors.
- Collaborating with Health Care Professionals, their professional organizations, and patient groups to conduct joint advocacy on coverage, reimbursement and health economics issues; supporting Health Care Professionals and their professional organizations in developing materials and otherwise providing direct or indirect input into payor coverage and reimbursement policies.
- Promoting accurate Medicare and other payor claims by providing accurate and objective information and materials to Health Care Professionals regarding the Company's Medical Technologies, including identifying coverage, codes and billing options that may apply to those Medical Technologies or the services and procedures in which they are used.
- Providing accurate and objective information about the economically efficient use of the Company's Medical Technologies, including where and how they can be used within the continuum of care.

deliverables which are restricted to medical issues, not marketing activities; and (ii) the content of the presentation, including slides and written materials, is determined by the health care professional.

(C) For a bona fide clinical trial: (i) gross compensation for the Vermont location or locations involved; (ii) direct salary support per principal investigator and other health care professionals per year; and (iii) expenses paid on behalf of investigators or other health care professionals paid to review the clinical trial.

(D) For a research project that constitutes a systematic investigation, is designed to develop or contribute to general knowledge, and reasonably can be considered to be of significant interest or value to scientists or health care professionals working in the particular field of inquiry: (i) gross compensation; (ii) direct salary support per health care professional; and (iii) expenses paid on behalf of each health care professional.

(E) Payment or reimbursement for the reasonable expenses, including travel and lodging-related expenses, necessary for technical training of individual health care professionals on the use of a medical device if the commitment to provide such expenses and the amounts or categories of reasonable expenses to be paid are described in a written agreement between the health care provider and the manufacturer.

(F) Other reasonable fees, payments, subsidies, or other economic benefits provided by a manufacturer of prescribed products at fair market value.

- Providing information related to the Company's Medical Technologies regarding available reimbursement revenues and associated costs.
- Providing information relating to changes in coverage or reimbursement amounts, methodologies and policies and the effects of such changes in order to facilitate a Health Care Professional's decision to buy or use the Company's Medical Technologies.
- Providing accurate and objective information designed to offer technical or other support intended to aid in the appropriate and efficient use or installation of the Company's Medical Technologies.
- Facilitating patient access to the Company's Medical Technologies by providing Health Care Professionals with assistance in obtaining patient coverage decisions from payors. This assistance may include 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, at the request of a Health Care Professional to facilitate patient access to the Company's Medical Technology, and subject to appropriate privacy safeguards, the Company may assist the patient by facilitating the preparation and submission of requests for coverage determinations, prior authorizations, pre-certifications and appeals of denied claims, relating to a Company's own Medical Technology; however such assistance should not be provided as an unlawful inducement.

A Company may not interfere with a Health Care Professional's independent clinical decision-making or provide coverage, reimbursement and health economics support as an unlawful inducement. For example, a Company should not provide free services that eliminate an overhead or other expense that a Health Care Professional would otherwise of business prudence or necessity have incurred as part of its business operations if doing so would amount to an unlawful inducement. Further, a Company should not suggest mechanisms for billing for services that are not medically necessary, or for engaging in fraudulent practices to achieve inappropriate payment.

XI. Research and Educational Grants and Charitable Donations

A Company may provide research and educational grants and charitable donations. However, a Company may not provide such grants or donations as an unlawful inducement. Therefore, a Company should:

- adopt objective criteria for providing such grants and donations that do not take into account the volume or value of purchases made by, or anticipated from, the recipient;
- Implement appropriate procedures to ensure that such grants and donations are not used as an unlawful inducement; and
- Ensure that all such grants and donations are appropriately documented.

A Company's sales personnel may provide input about the suitability of a proposed grant or charitable donation recipient or program, but sales personnel should not control or unduly influence the decision of whether a particular Health Care Professional or institution will receive a grant or donation or the amount of such grant or donation. Companies should consider implementing procedures to monitor compliance with this section.

a. Research Grants

Research provides valuable scientific and clinical information, improves clinical care, leads to promising new treatments, promotes improved delivery of health care, and otherwise benefits patients. In furtherance of these objectives, a Company may provide research grants to support independent medical research with scientific merit. Such activities should have

well-defined objectives and milestones and may not be linked directly or indirectly to the purchase of Medical Technologies.

Company-initiated or directed research involving a Company's Medical Technologies (such as clinical study agreements) is addressed separately in Section VI.

b. Educational Grants

Educational grants may be provided for legitimate purposes, including, but not limited to, the examples below. As noted in Section IV, a Company may make educational grants to conference sponsors or training institutions. A Company may not make educational grants to individual Health Care Professionals.

- *Advancement of Medical Education.* A Company may make grants to support the genuine medical education of medical students, residents, and fellows participating in fellowship programs that are charitable or have an academic affiliation, or other medical personnel. (For additional considerations regarding educational grants, see Section IV.)
- *Public Education.* A Company may make grants for the purpose of supporting education of patients or the public about important health care topics.

c. Charitable Donations

A Company may make monetary or Medical Technology donations for charitable purposes, such as supporting indigent care, patient education, public education, or the sponsorship of events where the proceeds are intended for charitable purposes. Donations should be motivated by *bona fide* charitable purposes and should be made only to *bona fide* charitable organizations or, in rare instances, to individuals engaged in genuine charitable activities for the support of a *bona fide* charitable mission. Companies should exercise diligence to ensure the *bona fide* nature of the charitable organization or charitable mission.

XII. Evaluation and Demonstration Products

Providing products to Health Care Professionals at no charge for evaluation or demonstration purposes can benefit patients in many ways. These benefits include improving patient care, facilitating the safe and effective use of products, improving patient awareness, and educating Health Care Professional regarding the use of products. Under certain circumstances described below, a Company may provide reasonable quantities of products to Health Care Professionals at no charge for evaluation and demonstration purposes.

This section is limited to providing evaluation and demonstration products only and is not intended to address any other arrangement.

Company products that may be provided to Health Care Professionals for evaluation include single use (*e.g.*, consumable or disposable products) and multiple use products (sometimes referred to as "capital equipment"). These products may be provided 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. Company products provided for evaluation are typically expected to be used in patient care.

Single Use/Consumables/Disposables. The number of single use products provided at no charge should not exceed the amount reasonably necessary for the adequate evaluation of the products under the circumstances.

Multiple Use/Capital. Multiple use products provided without transfer of title for evaluation purposes should be furnished only for a period of time that is reasonable under the circumstances to allow an adequate evaluation. The terms

of an evaluation of such multiple use products should be set in advance in writing. Companies should retain title to such multiple use products during the evaluation period and should have a process in place for promptly removing such multiple use products from the Health Care Professional's location at the conclusion of the evaluation period unless the Health Care Professional purchases or leases the products.

Demonstration. Company 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. For example, a Health Care Professional may use a demonstration product to show a patient the type of device that will be implanted in the patient. Demonstration products typically are not intended to be used in patient care. Demonstration products also are typically identified as not intended for patient use by use of such designations as "Sample," "Not for Human Use," or other suitable designation on the product, the product packaging, and/or documentation that accompanies the product.

A Company should provide Health Care Professionals with documentation and disclosure regarding the no-charge status of evaluation and demonstration products.