

## **CONDUCTING BUSINESS WITH HEALTH CARE PROFESSIONALS.**

### **A. General.**

This policy governs the interactions between Company personnel and health care professionals. The term “health care professional” means any individual or entity that provides health care services to patients, and to facilitate that activity purchases, leases, uses, recommends or prescribes the Company’s products in the United States.

The Company recognizes that health care professionals play an essential role in the development, testing and training involved in producing safe and effective medical devices. We also recognize that the best interests of the patient can be well served by a collaborative relationship with health care professionals. The goal in developing this policy is to ensure that the Company’s collaborative relationships meet high ethical standards and are conducted with appropriate transparency and in compliance with applicable laws, regulations and government guidance.

This policy is modeled on the Code of Ethics On Interactions with Health Care Professionals, adopted by the Advanced Medical Technology Association (AdvaMed) and revised effective as of July 1, 2009. This policy also is intended to conform to the Massachusetts Pharmaceutical and Medical Device Manufacturer Code of Conduct (Massachusetts Marketing Code). Where this requires a greater restriction on the Company’s activities, it is separately identified, and applies only to activities that take place in Massachusetts or involve a health care professional licensed in Massachusetts. This policy applies to all employees and agents of the Company doing business in the United States. The Corporate Compliance Officer will be responsible for administering this policy in accordance with Section 14.L. below.

### **B. Gifts To Health Care Professionals.**

The Company occasionally may provide items to health care professionals that benefit patients or serve a genuine educational function. Any such items must have a fair market value of less than \$100. Occasionally, items of more than \$100 that benefit patients or serve a genuine educational function, such as medical textbooks or anatomical models, may be given, but permission must be received in advance from the Legal Department. The Company may not provide items that are capable of personal use by the health care professional (or his or her family members, office staff or friends) for noneducational or non-patient-related purposes.

The Company may not give health care professionals branded promotional items such as pens, notepads, mugs, or other items that have a company name or logo, or the name or logo of a company product. The Company also may not give health care professional gifts such as cookies, wine, flowers, chocolates, gift baskets, electronic products (such as I-Pods), holiday gifts, or cash or gift certificates, regardless of the occasion.

*Massachusetts Marketing Code.* The Company will not give health care professionals located in or licensed by Massachusetts any gifts, regardless of type or value.

This section is not intended to address the legitimate practice of providing products for evaluation purposes, which is addressed in Section 14.J. below.

### **C. Prohibition on Entertainment and Recreation.**

The Company may not pay directly or indirectly for any entertainment or recreational event or activity for any non-employee health care professional. Examples of prohibited activities include theater, sporting events, golf, skiing, hunting, and leisure or vacation trips. Such activities can divert attention from the legitimate exchange of medical or scientific information between the Company and health care professionals and can create an appearance of impropriety.

The Company may provide modest meals for health care professionals only in connection with bona fide meetings with Company personnel as described in Section 14.F or educational conferences as described in Section 14.G.

### **D. Gifts and Entertainment with Regard to Government Personnel.**

The Company may not provide or offer to provide any gifts, meals, money or entertainment, regardless of value, to any government employee. Even a modest lunch at a restaurant is not permitted under federal, state and/or local law. It is also unlawful under United States law to provide anything of value, whether it is money, entertainment, services or other amenities, to foreign government officials or representatives if a purpose of the gift is to influence government decisions and business. See Section 3 (Policies on Transacting International Business) for more information.

### **E. Engaging Health Care Professionals As Consultants.**

Healthcare professionals acting as consultants to the Company can provide valuable bona fide services, including research, product development and/or transfer of intellectual property, marketing, participation on advisory boards, presentations at Company-sponsored training, and product collaboration. It is appropriate to pay consultants fair market value compensation for performing these services. However, consulting agreements must not be disguised programs to incentivize the purchase of Company products or services or to influence such purchasing decisions. The following are required for any arrangement between the Company and consultants:

- Consulting arrangements must be in writing, approved by the Legal Department, signed by the parties and specify all services to be provided. If the contract is for clinical research services, there must also be a written research protocol.
- Consulting arrangements should be entered into only where a legitimate need and purpose for the services is identified in advance and documented. The number of health care professionals retained must not be greater than the number reasonably necessary to achieve the identified purpose.
- Selection of a consultant should be on the basis of the consultant's qualifications and expertise to address the identified purpose, and should not be on the basis of volume or value of the consultant's past, present or anticipated business. The Company's sales personnel may provide input about the suitability of a proposed consultant, but sales

personnel may not control or attempt to influence the decision to engage a particular consultant.

- Compensation paid to a consultant should be consistent with fair market value in an arm's length transaction for the services provided, and may not be tied to the volume of purchases or referrals or other business with the Company. Records of the services provided by the consultants should be maintained by the Company.
- The Company may pay, in accordance with a written agreement, for documented, reasonable and actual expenses incurred by the consultant in carrying out the subject of the consulting arrangement, including reasonable and actual travel and lodging, and modest meals. The Company may not reimburse meals or travel expenses for the consultant's guests, nor provide recreation or entertainment in conjunction with these meetings.
- The place and circumstances for 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. Meetings with consultants at lavish hotels or resort locations is not appropriate.

If a consultant has developed or contributed to the development or improvement of a product, it may be appropriate to pay the consultant a royalty. Any such royalty arrangement must be in writing, comply with the standards set forth above, and meet the following additional requirements:

- The contribution by the consultant must be novel, significant and innovative, and must be appropriately documented.
- Royalties may not be conditioned on a requirement that the consultant purchase, order or recommend any of the Company's products or any product produced as a result of the development project.
- Royalties may not be conditioned on a requirement to market the product upon commercialization. However, the Company may elect to enter into a separate consulting agreement with the consultant for marketing services if such services meet the requirements set forth above.

#### **F. Meetings For Promotion of Sales And Training On Use Of Products.**

Company personnel may meet with health care professionals for the purpose of discussing product features, negotiating terms of sale, and providing training and education in the safe and effective use of the Company's products. Meetings for training may be provided to individuals or groups. All such meetings will adhere to the following criteria:

- (1) Meetings should be conducted in clinical, educational, conference, or other settings, including hotel or other commercially available facilities that are conducive to the effective transmission of knowledge or negotiation of a sales

transaction. Programs requiring “hands on” training in medical procedures should be held at training facilities, medical institutions, laboratories, or other appropriate facilities. The training staff should have the proper qualifications and expertise to conduct such training.

- (2) The Company may provide health care professionals with modest meals and refreshments in connection with these meetings and training programs. Any such meals and refreshments should be modest in value and subordinate in time and focus to the education or training purpose of the meeting.
- (3) Where there are objective reasons to support the need for out-of-town travel to efficiently deliver training and education on the Company’s products, the Company may pay for reasonable travel and modest lodging costs incurred by health care professionals attending the meeting, but not 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.

*Massachusetts Marketing Code.* For health care professionals located in or licensed by Massachusetts, the Company will not:

- provide or pay for meals in connection with a meeting unless the meeting is on the premises of the health care professional’s office or hospital setting, and a Company employee or agent is present; or
- pay or reimburse for travel or lodging expenses in connection with training on use of the Company’s products unless payment for such expenses is described in the contract of sale of the relevant Company product.

#### **G. Supporting Conferences For Health Care Professionals Sponsored By Third Parties.**

The Company may contribute to or sponsor the cost of third party continuing medical education conferences and professional meetings, provided such conferences or meetings are primarily dedicated to promoting objective scientific, medical or other educational activities or discourse. Control over the selection of content of presentations, faculty, educational methods and materials must remain with the organizer of the conference. The Company may not contribute to programs sponsored by a health care professional unless the program is accredited for continuing medical education credits or is sponsored by the health care professional’s charitable foundation. Subsidies must be paid directly to the conference sponsor, not an attendee, and cannot be used to reduce the registration expenses for designated participants.

- *Out-of-Pocket Expenses.* Except as provided below with regard to faculty expenses, the Company may not reimburse out-of-pocket expenses or make educational grants directly to attendees in connection with attendance at third party educational conferences.
- *Educational Grants.* The Company may provide a grant directly to the conference sponsor to reduce conference costs. The Company also may make a payment to the conference sponsor that is designated to subsidize attendance by medical students,

residents, fellows, and others who are in training provided that the conference sponsor selects the attendees who will receive the benefit of the subsidy.

- *Conference Meals and Refreshments.* The Company may provide funding to the conference sponsor to support the provision of meals and refreshments to conference attendees. Also, the Company itself may provide meals and refreshments for all attendees, but only if it is provided in a manner that is also consistent with the guidelines of the conference sponsor and the body accrediting the educational activity. 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.
- *Faculty Expenses.* The Company may make grants to conference sponsors for reasonable speaking or teaching fees, travel, lodging, and modest meals for bona fide conference faculty members. The Company may not make the grant directly to the faculty member, unless the faculty member is subject to a written consulting agreement entered into in accordance with this policy (Engaging Health Care Professionals as Consultants, above), the speaking arrangement is part of the services being provided to the Company under that agreement, and the faculty member discloses to the conference sponsor that his/her expenses and/or fees are being paid by the Company under a consulting agreement.
- *Advertisements and Demonstration.* The Company may purchase advertisements and lease booth space for company displays at conferences.

*Massachusetts Marketing Code.* For health care professionals located in or licensed by Massachusetts, the Company will not:

- provide sponsorship or payment for continuing medical education (CME) that is not accredited by the Accreditation Council for Continuing Medical Education or an equivalent accrediting body;
- make any payment directly to the health care professional; or
- provide meals directly to a health care professional at any CME event, educational conference or professional meeting, although the meeting or event sponsor may apply financial support provided by the Company to provide meals for all participants.

If the Company makes a payment to the sponsor of a healthcare conference that is designated to subsidize attendance by medical students, residents, fellows, and others in training, the Company will request that the subsidy not be used for the benefit of any health care professional licensed by Massachusetts.

## **H. Charitable Donations.**

The Company may make donations for a charitable purpose, such as supporting indigent care, patient education, public education, or the sponsorship of events where proceeds are intended for charitable purposes.

- Charitable donations may only be made to charitable organizations, which may include charitable foundations affiliated with health care professionals, as long as the foundation is a bona fide separate entity from the health care professional. No donation may be made directly to a health care professional, unless (1) the health care professional is a charitable organization, (2) the purpose of the donation is charitable, and (3) the donation is not an unlawful inducement.
- All requests for charitable contributions must be supported by a letter from the entity requesting the contribution. The letter must describe the purpose of the contribution and confirm that the requesting party is a charitable entity. The letter should have as much supporting information as possible in order that the Company may conduct its due diligence on the request.
- No donation may be made in exchange for a purpose of inducing a health care professional to purchase or lease or to recommend the purchase or lease of Company products or services. The Company should not fund a charitable request from a health care professional in which that health care professional describes its past or future purchases of Company products as a reason for the Company to provide charitable funds.
- Company employees may not make charitable donations on behalf of the Company.
- Sales, marketing or service personnel may provide input about the suitability of a proposed charitable donation recipient or program, but such personnel may not approve requests for charitable donations or attempt to influence Company decision-making with respect to a request for a charitable donation.

Employees must submit all requests for donations to the Legal Department for review and approval prior to making or committing to make any such donations.

## **I. Research Grants.**

The Company may make research grants to support independent medical research with scientific merit. When the Company contracts with a health care professional for research, the research relationship must be clearly spelled out in a written contract. A research grant may come in the form of equipment, services and supplies, and/or monetary/non-capital support. All research grants must have the following elements:

- A comprehensive written contract between the institution and the Company including a research protocol specifying the equipment, services and supplies, and/or monetary support to be provided by the Company to the institution, subject matter and scope of the research, identities of the principal investigator(s), deliverables, handling of intellectual property rights, milestone timing, and relevance to the Company. The proposed research must be evaluated by, and any resulting research agreements must be negotiated and managed by, Company employees who have no role in selling products or services to the research institution.
- There can be no conditions linking the research funding with the research institution's purchase of products or services from the Company (unless the products or services are

being purchased for that research). The research funding must be unrelated to past, present or future sales of Company products or services to the research institution.

- The amount of the grant must not be unreasonable in light of such factors as the work to be undertaken, the proposed budget, and the intended benefit to the Company.
- The purpose of the study must not be to educate a physician in the use of Company equipment.
- Any payments must be directly to the institution, not to a physician.

In determining which research grants to approve, no consideration will be given to the institution's past or future proposed purchases from the Company. Unrestricted research grants are not permitted.

#### **J. Evaluation Products.**

The Company may provide reasonable quantities of products to health care professionals at no charge for evaluation purposes under the following circumstances:

- *Single Use/Consumables/Disposables.* The number of single use products provided at no charge may not exceed the amount reasonably necessary for the adequate evaluation of the products under the circumstances.
- *Multiple Use Products/Capital Equipment.* Such products provided without transfer of title for evaluation purposes may 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 products must be set in advance in writing, and the contract must provide that the Company will retain title to such products during the evaluation period and that the products must be returned to the Company at the conclusion of the evaluation period unless the health care professional chooses to purchase or lease the products.

Appropriate documentation and disclosure should be provided to health care professionals regarding the no-charge status of evaluation products.

#### **K. Provision of Reimbursement and Other Economic Information.**

The Company may support accurate and responsible billing to Medicare and other payors by providing reimbursement information to health care professionals regarding the Company's products, including the identification of appropriate coverage, coding, or billing of procedures using those products (Reimbursement Information). Company personnel will ensure that the health care professional assumes responsibility for accurate coding and billing and that the Reimbursement Information provided is complete and accurate. The Company may also provide to health care professionals: (i) information designed to offer technical or other support intended to aid in the appropriate and efficient use or installation of the Company's products, and (ii) information relating to estimated costs, savings, and revenues associated with use of the Company's products (Economic Information) to assist health care professionals in evaluating

whether it is economically effective to purchase those products. Economic Information will be based on reasonable business and clinical workflow assumptions.

**L. Implementation of This Policy.**

The Corporate Compliance Officer will administer this policy, including interpreting and applying it to specific situations in which questions may arise, as follows:

- (1) The Company will provide to all personnel who interact with health care professionals, periodic training on the substantive provisions of this policy.
- (2) The Company will endeavor to communicate its commitment to conform to the standards set forth in this policy to its distributors and sales representatives that comprise the indirect channel through which the Company's products are sold to health care professionals.
- (3) Suspected violations of this policy will be reported and investigated, and the training referenced in item (1) of this section will include information about the procedure for reporting suspected violations or complaints based on this policy. Violations of this policy will subject Company personnel to disciplinary action in accordance with Company's policies on employee conduct. The Company will take all action necessary to assure that no retaliation is taken against any employee who in good faith reports a suspected violation or complaint under this policy.
- (4) The Corporate Compliance Officer will periodically audit this policy and its implementation. Any recommendation for change in the means of implementing the policy will be submitted to Welch Allyn's key executives for action, and any recommendations for change in the policy itself will be submitted to the Audit Committee of the Board of Directors.