DEROYAL INDUSTRIES, INC.
MARKETING CODE OF CONDUCT
FOR INTERACTIONS WITH HEALTH CARE PROFESSIONALS

I. Preamble: Goal and Scope of DeRoyal Marketing Code of Conduct

DeRoyal Industries, Inc. ("DeRoyal") is a worldwide manufacturer of healthcare products such as prescription medical devices, custom-designed surgical kits and other technologies, services, and therapies used to diagnose, treat, monitor, manage, and alleviate health conditions and disabilities ("Medical Technologies"). Each of its Medical Technologies must be prescribed by professionals who are licensed by appropriate state authorities to provide health care services to prescribe prescription drugs or devices. Its three divisions, acute care, patient care, and wound care, design and manufacture products that are used by health care professionals to diagnose, treat, monitor, manage and alleviate health conditions and disabilities thereby improving the condition of their patients.

DeRoyal is an innovative company dedicated to research and development in the healthcare industry and to creating the highest quality of healthcare technologies using the best materials, methods, and ideas. DeRoyal is equally committed to customer service, giving health care professionals the tools that they need to better serve consumers. DeRoyal understands its ethical obligation to the health care industry as a manufacturer of medical devices and repackager of prescription pharmaceuticals. Accordingly, DeRoyal recognizes its obligation to facilitate ethical interactions between itself and those individuals who prescribe prescription drugs for any person and is licensed to provide health care, or a partnership, or such person acting in the course and scope of his employments, agency or contract related to or in support of the provision of health care to individuals ("Health Care Professionals"). For purposes of this documents, Hospitals are not Health Care Professionals. DeRoyal also recognizes the need for transparency in its sales and marketing practices directed towards individuals or entities authorized to prescribe, dispense, or purchase its prescription drugs or medical devices in the United States, including a hospitals, nursing home, pharmacist, health benefit plan administrator or Health care Professional ("Recipients).

Medical Technologies

DeRoyal'sMedical Technologies depend upon the interaction of Health Care Professionals from beginning to end—unlike drugs and biologics which act on the human body by pharmacological, immunological or metabolic means. Medical TechnologiesFor example, its surgical Medical Technologies often serve as extensions of a physician's hands. Other Medical Technologies are noninvasive reagents, instrumentation, or software used to aid Health Care Professionals in their

diagnosis, monitoring, and treatment decisions. Many of DeRoyal's Medical Technologies work in concert with or are paired with other Medical Technologies to deploy the technologies in the safest and most effective manner. Many Medical Technologies require technical or medical support during and after deployment. Many require medical monitoring during the course of their use by patients.

Interactions with Health Care Professionals

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

- *Promote the Advancement of Medical Technologies*. Developing and improving cutting edge Medical Technologies require ongoing collaboration between DeRoyal and Health Care Professionals. The innovation and creativity essential to developing and improving Medical Technologies often occur outside DeRoyal's research and development facilities.

- *Enhance the Safe and Effective Use of Medical Technologies*. For Heath Care Professionals to use DeRoyal's sophisticated electronic, anesthetic, surgical, or other Medical Technologies in a safe and effective manner, DeRoyal must provide appropriate instruction, education, training, service and technical support to Health Care Professionals. Regulators often require this type of training as a condition of product approval.

- *Encourage Research and Education*. DeRoyal's 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*. At times, DeRoyal makes monetary and Medical Technology donations for charitable purposes, such as supporting indigent care, and for patient and public education. These donations increase access to and the quality of care and treatment in patient populations that may not otherwise have such an opportunity.

Purpose of the DeRoyal Marketing Code of Conduct

DeRoyal recognizes that Health Care Professionals' first duty is to act in the best interests of patients. DeRoyal 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 comply with applicable federal and state laws, regulations, and government guidance. DeRoyal recognizes its obligation to facilitate ethical interactions between itself and Health Care Professionals to ensure that the best interests of the patient govern health care decisions. The ethical principles that govern these

interactions are the subject of DeRoyal's Marketing Code of Conduct.[1] To that end, DeRoyal restates and amends its Marketing Code of Conduct and Frequently Asked Questions (collectively "Code of Conduct" or "Code"), effective July 1, 2009.

II. Marketing Code of Conduct Compliance

To effectuate compliance with this Code, DeRoyal undertakes the following:

1. Implements written policies and procedures for investigating non-compliance with this Code, for taking corrective action in response to noncompliance, and for reporting instances of non-compliance to the appropriate state authorities;
2. Designates a compliance officer to implement, monitor, and enforce the Code and, if required by state or federal law, to certify DeRoyal's compliance with the Code;
3. Develops effective lines of communication, including an anonymous reporting function;
4. Conducts internal monitoring and auditing;
5. Enforces the Code's standards through well-publicized disciplinary guidelines;
6. Responds promptly to detected problems and, if necessary, undertakes corrective action; and
7. Conducts effective training and education for all representatives of DeRoyal, including sales and marketing staff ("Representatives") who both act on behalf of the company and visit Health Care Professionals. Accordingly, DeRoyal implements its Marketing Code of Conduct Training Program ("the Program"). The Program is designed to ensure that these Representatives are familiar with (1) the Code, (2) the general science of DeRoyal's products, and (3) product-specific information including accurate, up-to-date information consistent with state law and FDA requirements. The Program also provides for regular assessments of Representatives to ensure that they comply with the Code and with relevant state and federal law, regulations, and guidelines.

The specifics of the Program are detailed in the DeRoyal Marketing Code of Conduct Training Program.

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> Note: This Amended and Restated Code supersedes and replaces all previous DeRoyal Marketing Codes of Conduct. This Code 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 DeRoyal's interactions with Health Care Professionals not specifically addressed in this Code, should be made in light of the following principle: DeRoyal encourages ethical business practices and socially responsible industry conduct and shall not engage in any unlawful inducement.

[1] The principles of the Code are derived from a variety of authorities, including the Code of Ethics on Interactions with Health Care Professionals adopted by the Advanced Medical Technology Association, applicable state laws, and the federal Anti-kickback Statute. Throughout the Code, we refer to the concept of an "unlawful inducement" to reflect Anti-kickback Statute prohibitions.

III. DeRoyal-Conducted Product Training and Education

DeRoyal has a responsibility to make training and education on its products and Medical Technologies available to Health Care Professionals. Accordingly, DeRoyal may provide education to Health Care Professionals on these subjects. "Training" means training on the safe and effective use of DeRoyal's Medical Technologies. "Education" means communicating information directly concerning or associated with the use of DeRoyal's Medical Technologies, e.g., information about the benefits of certain Medical Technologies to specific 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 (the "FDA") mandates training and education to facilitate the safe and effective use of certain Medical Technologies. When conducting training and education programs for Health Care Professionals concerning Medical Technologies, DeRoyal shall adhere to the following principles:

- Programs and events shall be conducted in venues 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 representative to provide Training and Education at the Health Care Professional's location.

- Programs providing "hands on" training for Medical Technologies shall be held at training facilities, medical institutions, laboratories, or other appropriate facilities. The training staff used by DeRoyal shall have the proper qualifications and expertise to conduct such training and may include qualified field sales employees who have the technical expertise necessary to perform the training.

- On an occasional basis, DeRoyal may provide Health Care Professional attendees with modest meals and refreshments in connection with these Educational and Training programs. If provided, any such meals and refreshments shall be modest in value and subordinate in time and focus to the training or educational purpose of the meeting. However, DeRoyal shall not pay Health Care Professional attendees directly for any meals and refreshments provided at an Educational or Training program and shall not pay for a meal for a Health Care Professional's spouse or other guest. Unless otherwise provided herein, all meals to Health Care Professional attendees shall be provided at the Professional's place of business, at a hospital, or at a specialized training facility designed to approximate the conditions of a surgical suite or the conditions of a working clinical laboratory or to provide medical training on large or technical medical devices ("Specialized Training Facility").

- Where there are objective reasons to support the need for out-of-town travel to efficiently deliver Training and Education on Medical Technologies, DeRoyal may pay for reasonable travel and modest lodging costs of the attending Health Care Professionals. DeRoyal's commitment to provide such expenses and the amounts or categories of reasonable expenses to be paid shall be memorialized in a written agreement, executed

between DeRoyal and the Health Care Professional attendee, for the purchase of the Medical Technology that is the subject of the Training or Education. It is not appropriate for DeRoyal or any of its rRpresentatives 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.

IV. Supporting Third-Party Educational Conferences, Professional Meetings and Continuing Medical Education (CME) events

Bona fide independent, educational, scientific, and policymaking conferences and meetings promote scientific knowledge, medical advancement and the delivery of effective health care. These typically include conferences and professional meetings sponsored by national, regional, or specialty medical associations and conferences sponsored by accredited continuing medical education providers (:Conference"). At its discretion, DeRoyal may support these Conferences in various ways.

- *Conference Grants*. DeRoyal may provide a grant to the Conference sponsor or organizer to pay for a portion of the Conference. It may not 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. DeRoyal may provide grants only 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 legitimate expenses for *bona fide* educational activities. Such grants also should be consistent with applicable standards established by the Conference sponsor and the relevant 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.

- *Conference Meals and Refreshments.* DeRoyal may provide funding to a Conference sponsor that is used by the Conference sponsor to provide modest meals and refreshments to all Conference attendees. However, such funding shall be made directly to the Conference sponsor, and the decision to apply DeRoyal's funds to pay for attendee meals and refreshments shall be solely at the discretion of the Conference sponsor.

- *Faculty Expenses.* DeRoyal 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 such as speakers or those who provide actual and substantive services as faculty organizers or academic program consultants ("Faculty"). DeRoyal may also compensate or reimburse such *bona fide* Conference faculty members based on the reasonable fair market value of their services if such compensation complies with the standards for commercial support as established by the relevant accreditation entity.

- *Non-Faculty Expenses*. DeRoyal does not provide funding for the costs of travel, lodging, or other personal expenses of Health Care Professional attendees who are not *bona fide* Conference Faculty. Neither does DeRoyal provide funding to compensate for the time spend by Health Care Professionals participating in any CME event, third-party scientific or educational Conferences, or professional meeting.

- *Advertisements and Demonstrations.* At its discretion, DeRoyal may purchase advertisements and lease booth space for its displays at Conferences or CME programs under the policies and procedures set by the conference or CME organizers and relevant accreditation entity.

- *Specific Policy for Sponsorship of CME Events*. If DeRoyal offers a grant to fund a CME event, its grant-making function for CMEs shall be separate from its sales and marketing departments. Additionally, DeRoyal shall not provide any advice or guidance to the CME provider regarding the content or faculty for a particular CME program funded by DeRoyal. Finally, DeRoyal's sponsorship of a CME –whether accredited or not—shall meet the Standards for Commercial Support established by ACCME or equivalent commercial support standards of the relevant continuing education accrediting body, and DeRoyal shall not sponsor or pay for a CME event by providing payment directly to a Health Care Professional who is not a Faculty member.

V. Sales, Promotional, and Other Business Meetings

At times, DeRoyal 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. DeRoyal may pay for occasional modest meals and refreshments in connection with such meetings if the meal is offered, consumed and provided at the Health Care Professional's office, a hospital, or a Specialized Training Facility. However, DeRoyal does not pay for meals or refreshments for 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

DeRoyal may 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 or transfer of intellectual property, marketing, participation on advisory boards, presentations at company-sponsored training, and other services. DeRoyal intends to pay such consultants fair market value compensation for performing these types of services and such payments are intended to fulfill a legitimate business need and not to constitute an unlawful inducement. Accordingly, DeRoyal adopts the following standards in connection with consulting arrangements with Health Care Professionals:

- Consulting agreements must be written and must describe all services to be provided by the Health Care Professional Consultant ("Consultant"). When DeRoyal contracts with a consultant to conduct clinical research services, a written research protocol shall be created.

- Consulting arrangements shall be entered into only after a legitimate need for the services is identified and documented in advance.

- Selection of a Consultant shall be made on the basis of the consultant's qualifications and expertise to meet the documented need.

- The number of Consultants that DeRoyal retains to address any documented need shall be no greater than is reasonably necessary to achieve the identified purpose of the consulting arrangement.

- If a Consultant is a member of a committee that sets formularies or develops clinical guidelines, DeRoyal shall require, as a term of the consulting contract, that the Consultant disclose to the committee the nature and existence of his or her relationship with DeRoyal and shall disclose such information to any such committee for at least two (2) years after the consulting arrangement with DeRoyal has terminated.

- Compensation paid to a Consultant shall be consistent with fair market value in an arm's length transaction for the services provided and shall not be based on the volume or value of the consultant's past, present or anticipated business.

- DeRoyal 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. However, DeRoyal's obligation to make such payment must be specified in the written consulting agreement. DeRoyal may also reimburse a Consultant for documented, reasonable, and actual expenses if such reimbursement is a provision of the written consulting agreement.

- The venue and circumstances for meetings between DeRoyal representatives and Consultants should be appropriate to the subject matter of the consultation.

- Meals and refreshments provided in conjunction with a Consultant meeting shall be modest in value and subordinate in time and focus to the primary purpose of the meeting. DeRoyal will not provide recreation or entertainment in conjunction with these meetings.

- DeRoyal's sales personnel may provide input about the suitability of a proposed Consultant, but sales personnel shall not control or unduly influence the decision to engage a particular Health Care Professional as a Consultant. The designated compliance officer shall monitor compliance with this section of the Code.

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 DeRoyal's 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. DeRoyal shall 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 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 shall be based on factors that preserve the objectivity of medical decision-making and avoid the potential for improper influence. Royalties paid in exchange for intellectual property shall not be conditioned on the Health Care Professional purchasing, ordering or recommending any of DeRoyal's products or Medical Technologies or any product or Medical Technology produced as a result of the development project. Additionally, royalties shall not be conditioned on a requirement to market the product or Medical Technology upon commercialization. However, at its discretion, DeRoyal may 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.

VII. Prohibition on Entertainment and Recreation

DeRoyal intends for its interactions with Health Care Professionals to be professional in nature and to facilitate the exchange of medical or scientific information that will benefit patient care. To ensure that these interactions properly focus on an educational or informational exchange and to avoid the appearance of impropriety, DeRoyal shall not provide admission to or pay for any entertainment or recreational event or activity for any Health Care Professional who is not a salaried DeRoyal employee. Such activities include admission to theater, sporting events, golf, skiing, hunting or the provision of sporting equipment or trips that are not for *bona fide* business purposes. Such entertainment or recreational events, activities, or items shall not be provided, regardless of (1) their value, (2) whether DeRoyal 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

DeRoyal'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. 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 shall 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 shall not be part of an entertainment or recreational event.

Setting and Location. Meals shall 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, at a hospital, or at a training center. It is appropriate for DeRoyal representatives to provide meals at a restaurant located on the premises of a hospital or Specialized Training Facility. 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. In these cases, DeRoyal representatives may not provide a meal for Health Care Professionals unless the meal can be brought to the Health Care Professional's place of business, a hospital, an academic medical center or a Specialized Training Facility.

Participants. DeRoyal shall provide a meal only to Health Care Professionals who actually attend the meeting. Its Representatives may not provide a meal for an entire office staff if everyone does not attend the meeting. Also, DeRoyal funds may not be used to provide a meal where its Representative is not present (such as a "dine & dash" program). Finally, DeRoyal Representatives 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. Specifically:

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

IX. Educational Items; Prohibition on Gifts

Occasionally, DeRoyal may provide items to Health Care Professionals that benefit patients or serve a *bona fide* 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 fifty dollars ($50). DeRoyal shall not provide items that a Health Care

Professional, his or her family members, office staff or friends could use for non-educational or non-patient-related purposes such as a DVD player or MP3 player unless those items constitute *bona fide* compensation for the Health Care Professional's services.

DeRoyal shall not give Health Care Professionals any type of non-educational branded promotional items, even if the item is of minimal value and is 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 DeRoyal's name, logo, or the name or logo of one of its Medical Technologies. DeRoyal also shall not provide Health Care Professionals with gifts such as cookies, wine, flowers, chocolates, gift baskets, holiday gifts, cash or cash equivalents.

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

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 depend on Health Care Professionals or patients having timely and complete coverage, reimbursement, and health economic information. Consequently, DeRoyal may provide such accurate, objective information regarding its Medical Technologies. To facilitate this goal, DeRoyal 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. Accordingly, DeRoyal may provide coverage, reimbursement and health economic information including, but not limited to the following:

- Identifying the clinical value of the DeRoyal'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 DeRoyal'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 DeRoyal's Medical Technologies, including where and how they can be used within the continuum of care.

- Providing information related to DeRoyal's Medical Technologies regarding available reimbursement revenues and associated costs.

- Providing information related to changes in coverage or reimbursement amounts, methodologies and policies and the effects of such changes on a Health Care Professional's decision to buy or use DeRoyal'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 DeRoyal's Medical Technologies.

- Facilitating patient access to DeRoyal's Medical Technologies by providing Health Care Professionals with assistance in obtaining patient coverage decisions from payors. This assistance may include providing information 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. To further facilitate patient access to DeRoyal's Medical Technology, at the request of a Health Care Provider and subject to appropriate privacy safeguards, DeRoyal 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 DeRoyal's own Medical Technology. Such assistance is not intended to be an unlawful inducement.

In no way does DeRoyal intend to interfere with a Health Care Professional's independent clinical decision-making or provide coverage, reimbursement and health economics support as an unlawful inducement. None of the actions described above should be construed as intended to be an unlawful inducement. For example, DeRoyal will 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, DeRoyal will 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

At times, DeRoyal may provide research and educational grants and charitable donations to Health Care Professionals. However, DeRoyal shall not provide such grants or donations as an unlawful inducement and any such grants or donations are not intended and should not be construed as an attempt at unlawful inducement. Accordingly, DeRoyal has (a) adopted 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; (b) implemented appropriate procedures to ensure that such grants and donations are not used as an unlawful inducement; and (c) ensured

that all such grants and donations are appropriately documented. Although DeRoyal's sales personnel may provide input about the suitability of a proposed grant or charitable donation recipient or program, sales personnel shall 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. Compliance with this section shall be monitored by the designated compliance officer.

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, DeRoyal may provide research grants to support independent medical research with scientific merit. Such activities shall have well-defined objectives and milestones and shall not be linked directly or indirectly to the purchase, prescription, disbursement, or use of DeRoyal's Medical Technologies.

Research involving DeRoyal's Medical Technologies that is either initiated or directed by DeRoyal (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, DeRoyal may make educational grants to conference sponsors or training institutions but not educational grants directly to individual Health Care Professionals.

- *Advancement of Medical Education*. DeRoyal 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*. DeRoyal may make grants for the purpose of supporting education of patients or the public about important health care topics.

c. Charitable Donations

DeRoyal 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. Such donations are motivated by *bona fide* charitable purposes and will 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. Accordingly, DeRoyal exercises 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 Professionals regarding the use of products. Under certain circumstances described below, DeRoyal 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.

DeRoyal's 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. DeRoyal expects that its products provided for evaluation will typically be used in patient care.

Single Use/Consumables/Disposables. The number of single use products provided at no charge shall 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 shall 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 shall be set in advance in writing. During the evaluation period, DeRoyal shall retain title to such multiple use products and shall promptly remove 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. DeRoyal's 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, or documentation that accompanies the product.

DeRoyal provides Health Care Professionals with documentation and disclosure regarding the no-charge status of evaluation and demonstration products.

XIII. Communications with Health Care Professionals

Maintaining professional and open lines of communication with Health Care Professionals is vital to ensuring that Health Care Professionals receive the most current information on the proper usage of DeRoyal's Medical Technologies. This enhances the Health Care Professional's ability to provide education and the highest quality of health care services to their patients. Maintaining records of prescriber data contributes to these communications by enabling DeRroyal to impart important safety and risk information to prescribers of a particular drug or device, conduct research, track adverse events of marketed drugs, biologics, or devices, and comply with FDA mandated risk management plans requiring DeRoyal to identify and interact with Heath Care Professionals who prescribe certain drugs or devices. DeRoyal may also use this data for marketing purposes to provide Health Care Professionals with scientific, educational, or business information regarding DeRoyal's Medical Technologies that are most pertinent to the patients that they serve.

DeRoyal understands the sensitive and confidential nature of this data and also recognizes that some Health Care Providers may prefer to limit the use of their prescriber data. Accordingly, DeRoyal has adopted the following standards for compiling and using prescriber data.

- All prescriber data shall be kept secure, confidential, and accessible only to authorized DeRoyal personnel pursuant to corporate procedures. All inquiries regarding the use of provider data shall be directed to the designated compliance officer.

- Before utilizing prescriber data for marketing purposes, DeRoyal shall give Health Care Professionals the opportunity to request that their prescriber data (1) be withheld from DeRoyal sales representatives and (2) not be used for marketing purposes.

- If a Health Care Professional requests that its prescriber data be withheld from DeRoyal's sales representatives and not be used for marketing purposes, DeRoyal shall honor that request and remove that Professional's data from information distributed to DeRoyal's sales representatives or used for marketing purposes.

- Prescriber data shall be used for the following purposes:
    - To impart safety and risk information regarding particular Medical Technologies to prescribers of the Medical Technologies;
    - To conduct important and necessary research regarding DeRoyal's Medical Technologies;
    - To track adverse events of DeRoyal's Medical Technologies
    - To comply with FDA mandated risk management plans.
    - Unless otherwise requested by individual Health Care Professionals, to engage in reasonable advertising or promotion of DeRoyal's Medical Technologies so long as such activity complies with the other provisions of this Code.

All of DeRoyal's employees or agents who may have access to prescriber data shall be educated regarding DeRoyal's standards for compiling and using prescriber data and the disciplinary

consequences for misuse of such data. Compliance with this section shall be enforced by the designated compliance officer.

XIV. Disclosure and Transparency

Promoting transparency in sales and marketing activities ensures that DeRoyal's goals of promoting the advancement of Medical Technologies, enhancing the safe and effective use of Medical Technologies, encouraging research and education, and fostering charitable donations and giving never interfere with a Health Care Professional's primary duty to exercise his/her independent judgment on behalf of his/her patients. Such transparency should also govern DeRoyal's interactions with those individuals or entities that prescribe, dispense or purchase its Medical Technologies including hospitals, nursing homes, pharmacists, health benefit plan administrators, or Health Care Professionals ("Health Care Entities").

To promote this level of transparency, DeRoyal has adopted procedures that shall govern disclosure of all sales and marketing activities including advertising, promotion, or other activity that is intended to be used:

- To influence sales or the market share of a prescription drug, biologic, or medical device;
- To influence or evaluate the prescribing behavior of a Health Care Entity to promote a prescription drug, biologic, or medical device;
- To market a prescription drug, biologic, or medical device;
- To evaluate the effectiveness of a professional pharmaceutical or medical device detailing sales force;
- To educate or train Health Care Entities on matters related to DeRoyal's Medical Technologies when such education or training is designed or sponsored by DeRoyal's marketing division and is intended solely for marketing, product promotion, or advertising purposes; or
- To conduct research on matters related to DeRoyal's Medical Technologies when such research is designed or sponsored by DeRoyal's marketing division unless the research involves clinical trials or research whose primary purpose is to generate data to support an application filed with the FDA for approval of a new drug, biologic, or medical devices.

These procedures do not require that DeRoyal disclose payments in conjunction with genuine research and clinical trial, price concessions such as rebates and discounts, or Medical Technology donated solely and exclusively for use by patients, demonstration or evaluation units, or in-kind items used to provide charity care.

DeRoyal's disclosure procedures are as follows:

- Beginning July 1, 2009, all DeRoyal sales and marketing personnel shall keep record of any fee, payment, subsidy, gift, or other economic benefit ("Benefit") valued at $50[2] or

[2] In Vermont, the provision of any Benefit is prohibited unless such Benefit falls within a few narrow exceptions. Furthermore, all allowable Benefits, must be reported pursuant to 18 Vermont Statutes Annotated § 4632 regardless of their value.

greater provided to a Health Care Entity whether DeRoyal funds are used to provide the Benefit or not.

- Annually, DeRoyal's sales and marketing personnel shall submit a report to the designated compliance officer describing every Benefit valued at $50[3] or greater given to a Health Care Entity. The annual report shall disclose the value of the Benefit, the nature of the Benefit, the purpose for giving the Benefit, and the recipient (including license number) of the Benefit.
- To determine if a Benefit reaches the $50[4] threshold requirement, DeRoyal personnel shall calculate the value of separate events or transactions involving a single Health Care Entity rather than aggregating a series of events or transactions involving a Health Care Entity.
- DeRoyal's sales and marketing personnel shall not structure Benefits to Health Care Entities in a way that would purposefully circumvent these disclosure requirements.
- Annually, and as required by state or federal authorities, DeRoyal's designated compliance officer shall file a disclosure report, accompanied by any required fees, detailing any Benefits, valued at $50[5] or greater, provided to Heath Care Entities in the preceding year.
- Annually, and as required by state or federal authorities, DeRoyal's designated compliance officer shall certify that, to the best of DeRoyal's knowledge, information, and belief, the disclosure report is true and accurate.

[3] Id.
[4] Id.
[5] Id.