

UNITED THERAPEUTICS CORPORATION

**UNITED STATES COMPREHENSIVE COMPLIANCE PROGRAM FOR
APPROVED PHARMACEUTICAL PRODUCTS**

Effective February 1, 2009

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INTRODUCTION

The promotion, marketing, and sale of prescription drugs, biologics and medical devices that have been approved for marketing in the United States (together referred to as “pharmaceutical products”) are subject to an array of legal and ethical standards. United Therapeutics and its subsidiaries (together referred to as “United Therapeutics” or the “Company”) are committed to strictly complying with all applicable United States laws and regulations and adhering to the highest ethical standards in the conduct of its marketing and promotional activities.

These Policies apply to United States laws and regulations only and only to pharmaceutical products that have been approved for marketing in the United States. As United Therapeutics’ pharmaceutical products are approved for marketing in other countries, United Therapeutics intends to develop similar policies on a country-by-country basis. Unless specifically identified otherwise, these Policies do not apply to investigational pharmaceutical products that are not yet approved for marketing in the United States.

The Comprehensive Compliance Program Policies are designed to provide guidance to United Therapeutics employees on permissible marketing and sales activities as well as financial arrangements with customers for the Company’s marketed pharmaceutical products in the United States. As used in these Comprehensive Compliance Program Policies, the term “customers” means all prescribers, purchasers and payers of United Therapeutic’ marketed pharmaceutical products, including without limitation, physicians, investigators, distributors, insurance companies, health maintenance organizations and patients. These policies will be reviewed periodically.

While these Policies provide standards for many routine sales and marketing activities, they do not cover all types of arrangements and activities that are potentially affected by the health care Fraud and Abuse laws and related ethical standards. **If an employee is uncertain about how a Policy applies to a particular arrangement, or he or she encounters a situation that does not seem to be covered by any Policy, that employee should discuss it with the Company's Director, Human Resources who is the Compliance Officer for these Policies, that employee's supervisor, or United Therapeutics General Counsel's office.**

Contact information for questions relating to these Policies are as follows:

Alyssa Friedrich Compliance Officer	afriedrich@unither.com	240-821-1730
Paul Mahon General Counsel	paul@unither.com	202-483-7000
Andrew Fisher Deputy General Counsel	andy@unither.com	202-483-7000
Rachel Turow Associate Counsel	rturow@unither.com	202-742-1200

These Policies will be interpreted and enforced by United Therapeutics' Compliance Committee. The Compliance Committee consists of four standing members who, in order to provide for flexibility and efficiency of Company resources, will supplement their membership on an as-needed basis with representatives from functional areas of the Company in order to help deal with specific issues or investigations. The Compliance Committee standing members are:

General Counsel;

Deputy General Counsel;

Associate Counsel & Director of Legal Affairs;

CFO and Treasurer; and

VP, Human Resources & Community Relations.

All United Therapeutics employees involved in sales, marketing, patient and physician education, clinical development of marketed pharmaceutical products and related activities in the United States are expected to have reviewed, understand, and adhere to these Policies. Appropriate disciplinary action up to termination may be taken against any employee whose conduct violates these Policies or applicable laws and regulations, in addition to other remedies.

A. Laws And Standards That Affect the Sale and Marketing of United Therapeutics' Products

As a pharmaceutical manufacturer, United Therapeutics is subject to federal and state health care antikickback laws prohibiting the payment of remuneration to influence prescribing or purchasing decisions, and federal and state laws prohibiting false claims and statements to health care programs. Certain United Therapeutics' customers are subject to laws and professional ethical standards prohibiting the receipt of remuneration from health care suppliers in connection with prescribing or treatment decisions. These laws and standards are discussed below.

Antikickback Laws: The federal health care program antikickback law makes it illegal to offer or pay any remuneration to induce a person

- to refer an individual for an item or service reimbursed under a federal health care program; or
- to purchase or order, or to recommend or arrange for the purchase or order of, a reimbursable item or service.

The term "Federal health care programs" includes Medicare, Medicaid, the Department of Veterans Affairs health care facility network, Tricare, the Indian Health Service, maternal and child health block grant programs, and other federally financed programs. A violation of the statute can lead to severe penalties including criminal and/or civil fines for United Therapeutics or individuals, imprisonment of individuals, and exclusion of United Therapeutics' marketed pharmaceutical products from eligibility for reimbursement under Medicare and Medicaid. Most states have antikickback laws that apply to items and services reimbursed under Medicaid and

other state programs, and several states have antikickback laws that apply to all items and services, even those not reimbursed under a government program.

The courts have construed the federal antikickback law broadly to apply where one purpose of an arrangement is to induce referrals or purchases, even if that is not the primary purpose. Therefore, the antikickback law potentially applies whenever a United Therapeutics employee offers anything of value to a practitioner, institution, pharmacy, or any other person or entity who can affect utilization of United Therapeutics' marketed pharmaceutical products. The law contains several exemptions, and regulations have established additional "safe harbors" describing activities that are protected from prosecution. An arrangement that does not meet the conditions of an exemption or safe harbor is not necessarily illegal, but it is subject to scrutiny by the government on a case-by-case basis. If an employee has any questions or is unsure about such "safe harbors", he or she should contact the Compliance Officer or the General Counsel's office.

False Claims Laws: Federal and state laws prohibit submitting, or causing to be submitted, false claims to government programs or private insurers. Violation can result in criminal and civil fines, imprisonment, and/or exclusion from government health care programs. In addition, United Therapeutics could face liability for causing false claims to be submitted if United Therapeutics employees provide inaccurate information to customers concerning coding and billing of government programs, or otherwise encourage customers to engage in questionable billing practices.

Food and Drug Administration ("FDA") Restrictions on Promotion: The FDA regulates the labeling and advertising of United Therapeutics' pharmaceutical products. Promotional materials must not be false, misleading, lacking in fair balance, and must not make unsubstantiated claims. In addition, with certain narrow exceptions, promotional materials may not discuss unapproved pharmaceutical products, or unapproved uses of approved pharmaceutical products. Any employee who is uncertain or has additional questions concerning promotional materials should direct them to the appropriate Regulatory Affairs office for each subsidiary or functional area of United Therapeutics.

Policy XII, “Policy on Advertising and Promotional Materials and Activities”, in conjunction with United Therapeutics’ then-current standard practices for review of labeling and advertising materials, is intended to ensure that promotional materials comply with FDA requirements. However, FDA’s restrictions on promotion not only apply to promotional materials distributed by United Therapeutics, but also may apply to information on United Therapeutics’ pharmaceutical products that is presented at meetings and seminars conducted or funded by United Therapeutics. The FDA has issued a Guidance For Industry on Industry-Supported Scientific and Educational Activities (the “CME Guidance”), which establishes criteria FDA uses to determine whether scientific and educational programs funded by industry are independent from the funding company, and therefore not subject to FDA’s restrictions on promotion (so that, for example, the funding company will not be penalized for off-label discussions during the program). Policies V and VI, relating to meetings and seminars, seek to ensure that such programs either comply with the criteria for independence in the CME Guidance, or alternatively, meet FDA’s restrictions on promotion.

Health Care Professional Licensing Laws: Health care professionals may be regulated by state practice licensing laws which provide for license revocation or other disciplinary action to be taken against a practitioner who engages in unprofessional conduct. Many states define unprofessional conduct to include soliciting or receiving remuneration in return for referrals or for ordering or promoting pharmaceutical products. These laws penalize licensed practitioners rather than manufacturers, but United Therapeutics’ policy is not to engage in any activity that could cause its customers to violate their professional or ethical obligations.

AMA Guidelines on Gifts to Physicians From Industry: The American Medical Association has adopted Guidelines on Gifts to Physicians From Industry (the “AMA Guidelines”), which are annotated guidelines describing when physicians may and may not accept items of value from pharmaceutical and device companies. In broad terms, the AMA Guidelines provide:

- A physician may accept a gift that entails a benefit to patients and is not more than \$100 in value (e.g., textbooks, stethoscopes). In addition, gifts of minimal value may be accepted (e.g., pens and notepads). Cash payments are not acceptable;

- Subsidies for continuing medical education programs should be given to the program sponsor rather than attending physicians. Travel and lodging expenses and honoraria should not be accepted by a physician to attend a meeting. However, such expenses and reasonable honoraria can be accepted by faculty;
- Travel and lodging expenses and honoraria may be accepted by physicians providing genuine consulting services (see Policy VIII below); and
- No gifts may be accepted if there are “strings” attached – for example, where a gift is related to increases in prescribing volume.

Although the AMA Guidelines apply only to physicians, it is United Therapeutics’ policy to adhere to the AMA Guidelines in its promotional interactions with other health care professionals (e.g., nurses and pharmacists) as well.

PhRMA Code on Interactions with Healthcare Professionals: The Pharmaceutical Research and Manufacturers Association (PhRMA) has issued the PhRMA Code on Interactions with Healthcare Professionals (the “PhRMA Code”), with which the member companies of PhRMA have voluntarily undertaken to comply. The PhRMA Code is similar in many respects to the AMA Guidelines. Among other things, it provides that:

- Entertainment and recreational events (such as golf or sporting events) aimed at health care professionals may not be sponsored by pharmaceutical companies;
- Occasional meals provided by sales representatives to health care professionals may be offered in conjunction with a program or a detail, provided the meals are modest as judged by local standards, occur in in-office or in-hospital settings, and provide scientific as well as educational value;
- Consulting agreements are appropriate and compensation and reimbursement may be given to a health care professional, provided that the health care professional is rendering legitimate services for the pharmaceutical company and the compensation reflects fair market value for the services provided;
- Items may be given to health care professionals if they are not of substantial value (\$100 or less) and are primarily for the education of patients or healthcare practitioners (e.g., anatomical models, medical reference textbooks). Items of minimal value such as pens or notepads may not be offered ; and
- Items intended for the personal benefit of health care professionals (e.g., floral arrangements, artwork, music CDs or tickets to sporting events) or that are cash or cash equivalents (e.g., gift certificates) may not be given.

Although United Therapeutics is not a member of PhRMA, United Therapeutics' policy is to treat the PhRMA Code as binding on United Therapeutics with respect to pharmaceutical products that have been approved for marketing in the United States. United Therapeutics employees should take the PhRMA Code into account in their interactions with health care professionals. The PhRMA Code is also being adopted as state law in many jurisdictions throughout the country, such as Massachusetts and California.

Office of Inspector General (OIG) Compliance Program Guidance for Pharmaceutical Manufacturers: The OIG has issued a guidance document entitled "Compliance Program Guidance for Pharmaceutical Manufacturers" which sets forth OIG's general views on the elements that should be included when developing and implementing an effective compliance program. These elements are:

- written policies and procedures, comprising a general code of conduct and detailed substantive policies and procedures;
- designation of a compliance officer;
- education and training;
- effective lines of communication to report complaints or ask questions;
- compliance audits and monitoring;
- policies for disciplinary action for non-compliance; and
- policies for investigating non-compliance

Additionally, the OIG identified three major categories of risk areas that should be addressed in pharmaceutical manufacturer's written policies and procedures: (1) the integrity of data used by state and federal governments to establish government reimbursement; (2) kickbacks and other illegal remuneration; and (3) compliance with laws regulating drug samples.

California Compliance Plan Law: California has enacted a law that requires pharmaceutical manufacturers to implement a comprehensive compliance program consistent with the OIG Compliance Program Guidance and the PhRMA Code, and to certify compliance with the

company's comprehensive compliance program and the California law. This law also requires the establishment of a specific annual dollar limit on gifts, promotional materials, or items or activities that the pharmaceutical company may give or otherwise provide to a health care professional.

B. Elements of United Therapeutics' Comprehensive Compliance Program

United Therapeutics has implemented a Comprehensive Compliance Program (CCP), which is consistent with the OIG Compliance Program Guidance and the PhRMA Code. The CCP consists of the following elements:

- United Therapeutics has developed written policies and procedures addressing the specific risk areas identified in the OIG Compliance Program Guidance. Among other things, these Comprehensive Compliance Program Policies incorporate the guidelines in the PhRMA Code.
- United Therapeutics has designated a compliance officer, Alyssa Oberman, and a compliance committee.
- United Therapeutics conducts compliance training of all newly hired sales representative and recertification is required annually.
- As described more fully below, United Therapeutics has developed effective lines of communication to report complaints and ask questions regarding these policies, and to make anonymous complaints. A United Therapeutics employee is required to report any suspected violation of, or questions regarding, the CCP and the Policies to his or her supervisor, management, the Compliance Officer or the General Counsel's office.
- United Therapeutics has a compliance committee in place for the review and approval of all grant activities and promotional materials. Additionally, "for cause" audits are undertaken as appropriate.
- All United Therapeutics employees involved in sales or marketing are expected to be familiar with and adhere to the CCP. Appropriate disciplinary action, up to and including termination, may be taken against any employee whose conduct violates any of the policies or applicable laws and regulations.

- All reported violations and detected problems are investigated and responded to promptly. If corrective action is required, it is undertaken promptly.

C. Compliance with California Compliance Program Law

In addition to these elements of our CCP, pursuant to the California compliance program law, United Therapeutics has set an annual spending limit on gifts, promotional materials, or items or activities that United Therapeutics may give or otherwise provide to a health care professional located in California, subject to permitted exclusions, at \$500.00 per health care professional.

United Therapeutics' declaration of compliance with the California compliance program law can be found at <http://www.unither.com/corpgov/declaration.pdf>. A copy of this declaration of compliance may also be obtained by calling 1-866-466-4372.

D. Reporting of Violations

Every United Therapeutics employee is required to report to the Compliance officer, his or her supervisor, management or the General Counsel's office any violation of the health care Fraud and Abuse laws or of these Policies which he or she reasonably believes to have occurred. Supervisors and other managers are expected to report any suspected violation of the fraud and abuse laws or of these Policies to the Compliance Officer or the General Counsel's office.

Employees reporting suspected violations will not be required to give their names. All communications regarding any suspected violation of the Fraud and Abuse laws or of these Policies with supervisors, managers or the General Counsel's office will be handled in strict confidence within the boundaries of the law. No employee who in good faith reports suspected wrongdoing will be subject to retaliation or discipline for having done so, even if the information incriminates other management, supervisors or employees, or even if the report ultimately is established to be erroneous. Such retaliation by a manager, supervisor, or any other employee will be grounds for disciplinary action, up to and including termination. If an employee who

reports a violation is directly involved in a violation of the law or of these Policies, the fact that he or she reported the violation will be given appropriate consideration in any resulting disciplinary action. Failure to report wrongdoing of which an employee has knowledge may, in itself, be a basis for disciplinary action.

Although United Therapeutics will take appropriate disciplinary action where a violation of law or of these Policies is established, it is possible for someone to unintentionally violate the law or these Policies. Most often, an employee may not be aware of, or does not understand, a particular law, regulation, or Policy. By reporting suspected violations, an employee may save another employee from repercussions by allowing management to educate that employee concerning the practice in question, helping to ensure that problems are resolved early.

I. POLICY ON GRANTS TO CUSTOMERS FOR RESEARCH

A. General

Physicians or institutions sometimes request assistance from United Therapeutics in the form of free product or funding for clinical or basic research of their own where United Therapeutics is not the sponsor of these studies. Nevertheless, United Therapeutics may provide support for such studies under the circumstances set forth below if, in the opinion of the Compliance Committee, the grant is not intended to influence any individual practitioner's purchasing, prescribing, or treatment decisions in favor of United Therapeutics' marketed pharmaceutical products.

B. Processing Grant Requests

1. Written requests for free product or funding must be submitted to the Compliance Committee for review where the proposed recipient of such free product or funding is a customer or is reasonably likely to become a customer of any marketed United Therapeutics product. A United Therapeutics employee may forward a written grant request from an institution or physician to the Compliance Committee. The request must include a summary of the project to be funded, copies of any related protocols, the names of the researchers involved, and a description of how the funding provided by United Therapeutics will be used.

2. For each grant request, the Compliance Committee will supplement its membership with appropriate representatives from the relevant functional areas of United Therapeutics in order to assess the scientific merit of the proposed research and whether the amount requested is reasonable for the scope of research, taking into account the duration of the study, the proposed number of patients, and other relevant factors. The Compliance Committee may request that the proposal be modified as a condition of approval. The Compliance Committee will document any decision to approve or reject a grant request.

3. The requesting institution's history of, or potential for, purchasing or prescribing United Therapeutics pharmaceutical products may not be taken into account in determining whether to approve a request.

4. The Compliance Committee may approve a series of related grants, in which event individual applications for subsequent proposed grants within an approved series need not be made.

C. Written Agreement

If a grant request is approved by the Compliance Committee, a grant agreement in a form approved by the General Counsel's office will be sent to the requesting institution. The requesting institution must agree to the terms of the agreement in order to receive the grant, as such agreement may be reasonably be negotiated and approved by the General Counsel's office. The agreement will:

- Require that copies of published or manuscripts intended for publication, including abstracts, resulting from the research be submitted to United Therapeutics upon completion, and at least 21 days before submission to a relevant journal or meeting, in order to provide comment for scientific accuracy;
- Require at a minimum a semi-annual report on the status of the research until the research is completed, and a final report upon completion;
- Provide that funds and any pharmaceutical products, equipment or supplies provided to the institution not used as proposed in the grant request are subject to refund;
- If free product is provided, prohibit the grant recipient from (i) billing a patient or any third party payer for the drug, or (ii) providing pharmaceutical products to patients who are not enrolled in the study; and
- State that the grant award imposes no obligation, express or implied, to purchase, prescribe, provide favorable formulary status for, or otherwise support United Therapeutics' pharmaceutical products.

The agreement will be reviewed by the General Counsel's office before being sent to the grant recipient, and all changes requested by the grant recipient will be approved by the General Counsel's office prior to execution of the agreement.

D. Payment

Funds for an approved grant will be paid by check issued to the requesting institution, and not to any individual physician.

E. Follow-Up

Where a grantee fails to provide a report on the research as required, follow-up letters will be sent requesting status reports and manuscripts or other summaries of research conclusions. If the grantee fails to respond, actions will be taken to obtain a refund of funds and supplies.

II. POLICY ON GRANTS TO CUSTOMERS TO FUND PATIENT EDUCATION PROJECTS

A. General

United Therapeutics may provide grants to customers to support bona fide educational programs, activities, or materials or education for patients. Grants may not be provided for activities designed to promote the customer's services, nor to support patient programs that the customer already provides in the ordinary course of its business. Patient education grants are subject to the following procedures.

B. Processing Requests

1. Written requests for patient education grants must be submitted to the Compliance Committee or a designated member of the Compliance Committee. All requests must include a summary description of the project to be funded, how the project will benefit patient care, knowledge, or other public health objectives, and how the funding provided by United Therapeutics will be used.

2. Requests for patient education grants must be submitted to:
- The Compliance Committee if the requested grant exceeds \$10,000; and
 - A designated member of the Compliance Committee if the requested grant is less than \$10,000.

3. For each grant request, the Compliance Committee or designated member of the Compliance Committee will assess the propriety of the proposed project to patient care and/or the public health and whether the amount requested is reasonable for the scope of the project. The requesting institution's history or potential for purchasing or prescribing United Therapeutics pharmaceutical products will not be taken into account. All decisions to approve or reject a grant request will be documented.

4. Patient education materials should disclose, if the organization developing the materials so chooses, that the materials were supported by a grant from United Therapeutics.

5. Grants to support patient education projects may also be provided to professional and patient organizations in accordance with Policy III on “Grants and Contributions to Professional and Patient Organizations.”

6. The Compliance Committee or designated member of the Compliance Committee may approve a series of related grants, in which event individual applications for subsequent proposed grants within an approved series need not be made.

C. Written Agreement

If a grant request is approved, a grant agreement in a form approved by the General Counsel’s office will be sent to the requesting institution. The requesting institution must agree to the terms of the grant agreement in order to receive the grant, as such agreement may reasonably be negotiated and approved by the General Counsel’s office. The agreement will:

- Require that the grant recipient provide United Therapeutics with copies of any educational materials developed using grant funds;
- Require at a minimum a semi-annual report on the status of the project until the project is completed, and a final report upon completion;
- Provide that funds not used as proposed in the grant request are subject to refund; and
- State that the grant award imposes no obligation, express or implied, to purchase, prescribe, provide favorable formulary status for, or otherwise support United Therapeutics pharmaceutical products.

D. Payment

Funds for an approved grant will be paid by check issued to the requesting institution, and not to any individual physician.

III. POLICY ON GRANTS AND CONTRIBUTIONS TO PROFESSIONAL AND PATIENT ORGANIZATIONS OR TO CHARITABLE ORGANIZATIONS

A. General

Unrestricted contributions may be made to the general fund of a professional or patient organization, if in the opinion of the Compliance Committee the organization permits such contributions and if the contribution does not have the potential to influence any individual practitioner's purchasing, prescribing, or treatment decisions in favor of United Therapeutics' marketed pharmaceutical products. Additionally, individual employees may give charitable contributions to not-for-profit entities in their own discretion. However, no charitable contribution may be made by the Company or an individual if the intent is to induce the recipient to purchase, prescribe, or arrange for the purchasing or prescribing of United Therapeutics' products.

B. Processing Requests

Requests for contributions that are received by United Therapeutics employees will be referred to the Compliance Committee for review where the proposed recipient of such contributions is a customer or is reasonably likely to become a customer of any marketed United Therapeutics product. The request must be accompanied by a letter from the organization requesting the grant and stating that the organization is tax-exempt. The Compliance Committee may approve a series of related grants or contributions, in which event individual applications for subsequent proposed grants within an approved series need not be made.

C. Selection of Recipient

United Therapeutics employees may not offer to make a charitable contribution to an organization selected by a customer, other than as may be directed by a consultant in accordance with bona fide consulting agreement (see Policy VIII, "Policy on Consulting and Service Agreements with Customers").

D. Payment and Documentation

Contributions must be paid by check issued to the organization. The check will be accompanied by a letter that is in a form approved by the General Counsel's office which will state that the check represents an unrestricted contribution to the organization.

E. Charitable Contributions

No United Therapeutics employee who is in a position to influence the manufacturing, sales and marketing or development of United Therapeutics' products or in a position to influence the financial position of United Therapeutics may give a charitable contribution, using either Company or individual funds, to a customer or potential customer, prescriber or potential prescriber for whom the employee has either direct or reporting responsibility. Additionally, all charitable contributions to customers or potential customers, prescribers or potential prescribers made by an employee of United Therapeutics that exceed \$1,000 must be submitted reviewed by the Compliance Committee in accordance with the committee review process.

IV. POLICY ON COMPENSATION TO INVESTIGATORS IN POST-MARKETING STUDIES

A. General

Compensation may be paid under this Policy to physicians who are investigators in United Therapeutics-sponsored post-marketing clinical trials of a United Therapeutics product. This Policy does not apply to compensation paid to investigators in United Therapeutics-sponsored clinical studies of United Therapeutics' pharmaceutical products prior to marketing or to marketed products under an FDA-sanctioned IND. This Policy also does not apply to free product or funding offered by United Therapeutics to physicians for clinical or basic research of their own. (For the latter type of assistance, see Policy I on "Grants To Customers For Research.")

B. Study Characteristics

The trial must have a genuine clinical research purpose, be designed in a manner adequate to achieve the purpose, and have a written protocol. The number of investigators and subjects must be reasonable in light of the study objective and design. It is preferable that free study drugs be given to patients.

C. Selection of Investigators

Investigators will be selected based on their expertise and their ability to meet enrollment requirements, adhere to the investigational protocol, maintain required data, and meet other research-related criteria. Marketing or sales employees may not make the final determination of whether to use an investigator. A physician's history of, or potential for, purchasing or prescribing United Therapeutics' pharmaceutical products may not be taken into account in the selection of investigators.

D. Written Agreement

Each investigator must execute a written agreement, which will specify the investigational services to be performed and the compensation to be paid. The agreement must comply with Policy VIII on "Consulting and Service Agreements with Customers" in a form

approved by the General Counsel's office. Each investigator must agree to provide data in accordance with the terms of the protocol. Each investigator must agree not to bill the patient or third party payer for any medical evaluations for which the physician is being compensated under the investigation or any pharmaceutical products supplied free of charge by United Therapeutics. In addition, each investigator must agree that copies of published or manuscripts intended for publication, including abstracts, resulting from the trial be submitted to United Therapeutics upon completion, and at least 21 days before submission to a relevant journal or meeting, in order to provide comment for scientific accuracy and to permit United Therapeutics to remove any confidential or proprietary information.

E. Compensation

1. The compensation paid to each investigator must be reasonable for the investigational services to be performed. Compensation may be paid on a per-patient basis, but must be commensurate with the services to be performed beyond those reimbursed by the patients' medical insurance. For example, an investigator should not be compensated for performing a medical evaluation that is ordinarily or normally performed as part of an office visit and reimbursed by medical insurance.

2. The amount or rate of compensation may not take into account the history or potential of the investigator to purchase or prescribe United Therapeutics pharmaceutical products.

F. Oversight

The appropriate Regulatory Affairs office for each subsidiary or functional area of the United Therapeutics is responsible for ensuring compliance with this Policy IV.

V. POLICY ON FUNDING TO SUPPORT INDEPENDENT, THIRD-PARTY EDUCATIONAL OR SCIENTIFIC MEETINGS

A. General

United Therapeutics may provide grants to support meetings, seminars, conferences, and other programs designed to communicate the most current health care information to practitioners and promote scientific interchange (the “Programs”). Programs are conducted by institutions, professional organizations, or accredited continuing medical education (CME) providers. The content is non-promotional and is not controlled by United Therapeutics. If United Therapeutics’ support is consistent with FDA’s CME Guidance and this Policy, information on off-label uses or other information provided at the Program will not be attributed to United Therapeutics. Therefore, if a United Therapeutics-funded Program might include discussion of unapproved United Therapeutics’ pharmaceutical products or unapproved uses of approved United Therapeutics’ pharmaceutical products, the Program must be provided in accordance with this Policy.

This Policy does not cover promotional programs. Promotional programs are those that are either (1) organized and conducted by United Therapeutics itself, or (2) organized and conducted by a third-party with funding from United Therapeutics but whose content is controlled by United Therapeutics. Promotional programs are covered in Policy VI, “Policy on Promotional Meetings”.

B. Policy

1. *Provider Control Over Content*

United Therapeutics may limit support to those Programs that involve topics of interest to the Company, but may not suggest potential topics to a Program provider. The Program provider shall maintain control over the content of the Program and the selection of the Program’s faculty or speakers. United Therapeutics may not offer suggestions for speakers even at the request of the Program provider. United Therapeutics employees or organizations acting on behalf of United Therapeutics may not solicit program providers to conduct specific programs regarding United Therapeutics products. United Therapeutics employees or organizations acting on behalf

of United Therapeutics may not prepare scripts for speakers, target points for emphasis, or otherwise seek to influence the content of the program.

2. *Written Agreement*

Each Program must be provided (*i.e.*, organized and conducted) by a Program provider that is an entity independent from United Therapeutics. The Program provider must execute a written agreement in a form approved by the General Counsel's office. United Therapeutics employees must comply with the terms and conditions of such agreement.

3. *Compliance With ACCME Standards*

If the Program is accredited, it must, in addition to other requirements of this Section B, comply with the "Standards for Commercial Support of Continuing Medical Education" issued by the Accreditation Council for Continuing Medical Education (ACCME).

4. *Processing Requests*

Program providers must submit requests for financial assistance for Programs in writing to the Compliance Committee. A United Therapeutics employee may forward a written grant request from a customer to the Compliance Committee. The written request must contain a description of the Program, including the following information:

- The title
- The topics to be covered
- The proposed date and location
- The names of faculty, if known
- The anticipated number of attendees
- Whether the Program will be accredited by the ACCME

Copies of the proposed agenda, if available, should be attached to the written request.

In determining whether financial assistance will be provided, the Compliance Committee will supplement its membership with appropriate representatives from the relevant functional areas of the Company in order to assess whether the proposed Program has a legitimate scientific

and/or educational purpose, whether the Program topic is within United Therapeutics' scope of interest, and whether the Program provider is reputable. The Program provider's purchasing, prescribing, or formulary practices may not be taken into account in determining whether assistance will be provided.

In certain instances, Program providers delegate administrative and logistical responsibilities for programs to a third party. If United Therapeutics receives written notice from the Program provider of such a delegation of responsibility, the Company may provide the same types of assistance to the third party as it could to the Program provider.

5. *Payment*

Financial assistance under this Policy will be paid by check issued to the entity providing the Program, not any individual speaker.

6. *Attendees*

United Therapeutics employees may not take primary responsibility for determining the list of attendees, and may not reimburse attendees for travel and lodging expenses, time spent, or registration fees.

7. *Social Events*

United Therapeutics may not sponsor social events (including meals) in connection with a Program. However, at an independent program in which CME activities comprise only part of the meeting, United Therapeutics may sponsor a meal or reception if it is permitted by the sponsor and is clearly separate from the CME portions of the meeting.

8. *Financial Assistance To Physicians To Attend Programs*

a. *General Rule*

Funds may not be paid directly to a physician to defray expenses (e.g., travel expenses, registration expenses, compensation for time expended) of attending a Program.

b. *Exception for Medical Students, Residents, and Fellows*

Funds may be provided to a medical institution to defray the reasonable travel and lodging expenses of its medical students, residents, or fellows to attend:

- A major educational, scientific, or policy meeting of an international, national, regional or specialty medical association; or
- An educational experience that cannot be obtained at such international, national, regional or specialty association meetings and that cannot be obtained through residency/medical training.

The attendees must be selected by the medical institution and not by United Therapeutics. Requests for such funds will be reviewed by the Compliance Committee. The medical institution's purchasing, prescribing, or formulary practices may not be taken into account in determining whether assistance will be provided.

9. Enduring materials

United Therapeutics employees may not distribute enduring materials from a CME Program, unless such materials have been cleared for distribution in accordance with Policy XII.

VI. POLICY ON PROMOTIONAL MEETINGS

A. Scope of Policy

This Policy covers promotional meetings of approved pharmaceutical products. For purposes of this Policy, the term “promotional meetings” means educational or informational meetings, seminars, conferences, and other programs concerning marketed pharmaceutical products that are either (1) organized and conducted by United Therapeutics itself (see Section B, below), or (2) conducted by a third-party with funding from United Therapeutics and whose content is controlled by United Therapeutics (see Section C, below). A program sponsored by a third-party with funding from United Therapeutics that does not meet the conditions of FDA’s CME Guidance is considered a promotional meeting, and is covered under this Policy rather than Policy V, “Policy on Funding to Support Independent, third-Party Educational or Scientific Meetings.” This Policy does not cover sales representative details, which are addressed in Policy VII, “Policy on Gifts, Meals, and Entertainment for Physicians and other Healthcare Practitioners”.

B. Educational or Informational Meetings Conducted by United Therapeutics

These promotional meetings are organized and conducted by United Therapeutics (on- or off-site) to educate practitioners about United Therapeutics’ marketed pharmaceutical products. Since they are considered by FDA to be promotional, they must comply with FDA restrictions on advertising. These meetings differ from the promotional meetings discussed in Section C, below, because United Therapeutics actually conducts these meetings rather than providing funds to a third party to conduct them. Also, these meetings differ from consultants’ or investigators’ meetings described in Policy VIII. F and G, because the attendees do not provide services to United Therapeutics.

1. *Program Content*

Program faculty should avoid discussion about unapproved Company pharmaceutical products or unapproved uses of approved Company pharmaceutical products. Any speakers who

are not United Therapeutics employees must be advised not to discuss such information. The educational or scientific portion of the meeting should account for a substantial majority of the meeting, in accordance with the AMA Guidelines. The agenda should facilitate discussion among attendees and faculty.

2. *Payment to Faculty*

Reasonable travel expenses and honoraria may be paid to practitioners who participate as faculty in a promotional program conducted by United Therapeutics. Faculty must be selected based on their expertise, without taking into account their history or potential for purchasing or prescribing United Therapeutics pharmaceutical products. Non-United Therapeutics faculty should be asked to sign an agreement that meets the conditions in Policy VIII on “Consulting and Service Agreements with Customers.”

3. *Attendees*

Travel expenses may not be reimbursed and honoraria may not be paid to physicians who attend, but do not participate as faculty in, a promotional program conducted by United Therapeutics (either on- or off-site).

C. Support for Promotional Programs Conducted by Third Parties

In certain instances, United Therapeutics may provide funding for a program organized and conducted by a customer or other third party but United Therapeutics has control over the content of the program. A program for which United Therapeutics specifically engages a speaker to discuss a United Therapeutics product is an example of such a program. Another example is a program conducted by a third party that engages the speakers itself, but at which the material covered is determined by United Therapeutics. Statements made by speakers at these programs will be considered by FDA to be promotion on behalf of United Therapeutics. Therefore, the content of these programs must comply with FDA restrictions on advertising.

1. *Program Content*

Support may be provided under this Section C only where United Therapeutics can be assured that no discussion about unapproved Company pharmaceutical products or off-label uses will be initiated at the program by the speaker(s). In some cases, assurances may be obtained by written agreement with the program provider or faculty that (1) no discussions of unapproved pharmaceutical products or uses will be initiated by the faculty; and (2) faculty will respond to any audience inquiries about unapproved pharmaceutical products or uses in accordance with United Therapeutics' then-current standard operating procedures.

2. *Written Agreement*

The program provider faculty should be asked to sign a service agreement that meets the conditions in Policy VIII on "Consulting and Service Agreements with Customers." The speaker(s) may be paid a fee and reimbursed for their expenses, in accordance with that Policy.

3. *No Link to Prescribing Practices*

The purchasing, prescribing, or formulary practices of the program provider or of the speaker(s) may not be taken into account in determining whether assistance will be provided to a program provider or whether service fees will be paid to a speaker.

4. *Attendees*

United Therapeutics and its employees may not reimburse attendees for travel and lodging expenses, time spent, or registration fees.

5. *Social Events*

United Therapeutics may provide modest meals as judged by local standards in connection with promotional programs. No other entertainment or recreation may be provided.

D. Approval Procedure

United Therapeutics employees who wish to organize and conduct a promotional program, or who wish to provide funding for a promotional program conducted by a third party, must obtain prior approval from the Compliance Committee.

VII. POLICY ON GIFTS, MEALS, AND ENTERTAINMENT FOR PHYSICIANS AND OTHER HEALTHCARE PRACTITIONERS

A. General

All gifts, meals, and entertainment provided by United Therapeutics employees to physicians who are or are likely to be prescribers of the Company's marketed pharmaceutical products must comply with the AMA Guidelines and the PhRMA Code. Although the AMA Guidelines apply only to physicians, and United Therapeutics is not a member of PhRMA, United Therapeutics' policy is to apply these guidelines to gifts offered to all healthcare practitioners who are or are likely to be prescribers of the Company's marketed pharmaceutical products. Gifts, meals, and entertainment provided to physicians and other practitioners who are employees of federal, state, or local government must comply with ethical restrictions applicable to such government employees.

B. Modest Value Items

United Therapeutics employees may provide practitioners who are or are likely to be prescribers of the Company's marketed pharmaceutical products with gifts of modest value (\$100.00 or less) if they are designed primarily for the education of patients or healthcare practitioners (e.g., a medical textbook, anatomical model or a patient starter kit). Items pertaining to patient treatment (e.g., medical equipment) and non-educational items for patients (e.g., pedometers) are not permitted. Cash payments are never acceptable.

C. Minimal Value Items

United Therapeutics employees may not provide such practitioners with gifts of minimal value such as pens, notepads, and similar reminder items with United Therapeutics or product logos that are not designed for the education of patients or healthcare practitioners.

D. Entertainment and Recreational Events

Entertainment and recreational events (e.g., concerts, sporting events, golf) are prohibited by the PhRMA Code and may not be provided to health care professionals. United

Therapeutics employees should also not provide such practitioners with gift certificates or entertainment tickets for their own use.

E. Meals and Refreshments

Wherever permitted by these Policies, meals should be of reasonable value as judged by local standards and should take place in a manner conducive to communication of educational information. Lavish meals should be avoided.

1. Connection with Detailing – Representatives and their Managers

Meals or refreshments may be provided by sales representatives or their immediate managers only in conjunction with a detail or other informational presentation or discussion. Such meals may be provided in the healthcare practitioner's office or facility, but may not be provided in restaurants or other off-site locations. A representative or their manager must use that opportunity to educate healthcare practitioners and discuss and promote United Therapeutics' pharmaceutical products.

2. Other United Therapeutics Employees

Other United Therapeutics employees (e.g., senior business executives) may provide occasional modest meals to a healthcare practitioner outside the office or hospital in connection with an informational presentation.

3. Regional Business Directors

Regional Business Directors serve two functions as United Therapeutics employees: 1) a supervisory sales role, and 2) a senior business executive role. When acting in their supervisory sales role, they are expected to adhere to Section E.1. above. When acting in their senior business executive role, they will be treated as senior business executives for purposes of Section E.2., above, and PhRMA Code compliance. If circumstances arise that draw into question which role a Regional Business Director is fulfilling, please contact Rachel Turow, rturow@unither.com or 202-742-1200.

F. No Strings Attached

Permitted gifts, refreshments, or meals may not be conditioned expressly or implicitly on an agreement by the healthcare practitioner to purchase or prescribe, or to recommend the purchasing or prescribing of, United Therapeutics' marketed pharmaceutical products; or used to reward such a practitioner for purchasing or prescribing United Therapeutics' pharmaceutical products.

G. Spouses or Guests

United Therapeutics will not offer to pay for the travel costs, or for meals for such a practitioner's spouse or guest.

H. Group Meetings

An event for a group of healthcare practitioners involving a social event in conjunction with a discussion or presentation is subject to Policy VI, "Policy on Promotional Meetings." An employee who wishes to arrange such a group event must obtain approval from the Compliance Committee accordance with the then-current procedures for review and approval of Promotional Meetings.

I. Expense Reporting

United Therapeutics employees shall ensure that all expense reimbursement requests comply with United Therapeutics' current expense reimbursement policy.

VIII. POLICY ON CONSULTING AND SERVICE AGREEMENTS WITH CUSTOMERS

A. General

United Therapeutics may enter into consulting or service arrangements with customers for services provided to United Therapeutics, such as research, marketing services, participation in focus groups or advisory boards, or speaking engagements. Consulting and service agreements are permissible as long as they require the performance of genuine services for United Therapeutics, compensation is consistent with fair market value and is not related to prescribing or purchasing volume or formulary treatment, and the performance of the services is documented. Every consultant must sign a written consulting agreement, as described in Section E, below. Consulting arrangements in connection with advisory boards must also comply with Policy XVIII, “Policy on Advisory Boards.”

B. Review

All consulting or service arrangements must be submitted to the General Counsel’s office for prior review and approval.

C. Commercially Reasonable Objective

The services contracted for must not exceed those that are necessary to achieve a commercially reasonable purpose for United Therapeutics.

D. No Link to Prescribing or Purchasing

Consulting and service agreements may not be used as vehicles to make payments intended to induce prescribing, purchasing, or favorable formulary treatment of United Therapeutics’ pharmaceutical products. Consultants and service providers must be selected based on their expertise and experience, and whether their fees are competitive, without taking into account prescribing or purchasing history or potential.

E. Written Agreement

The consulting or service arrangement must be set out in a written agreement signed by the consultant and an authorized representative of United Therapeutics. United Therapeutics employees who wish to obtain the consulting services of a health care professional, health care provider, or managed care organization should contact the General Counsel's office to obtain an agreement to use. The agreement will contain the following elements:

1. The agreement must provide that its material terms (for example, the compensation and services to be performed) may not change within one year;
2. The agreement must describe the work to be performed by the consultant, and, as specifically as possible, the schedule under which the work will be performed. Where possible, the agreement should cover all of the services the consultant will provide to United Therapeutics during the term;
3. The agreement must set forth the compensation to be paid to the consultant over the term of the agreement. Flat fee or per diem agreements are preferable, and hourly rate agreements also are acceptable;
4. The compensation must be consistent with the fair market value of the services to be performed, and must be determined in a manner that does not take into account the volume of purchases or prescriptions of United Therapeutics' pharmaceutical products, or business otherwise generated for the Company by the consultant. Fees based on numbers of patients or volume or value of United Therapeutics' pharmaceutical products dispensed or prescribed are generally unacceptable. However, per-patient payments to investigators for United Therapeutics-sponsored clinical trials are acceptable as long as the amount is reasonable in light of the unreimbursed work to be performed by the investigator;
5. The agreement must require the consultant to keep adequate records of, and periodically to report to United Therapeutics on, the time, personnel and resources used in performance of the agreement. If the consultant is compensated based on an hourly rate, the consultant must be required to keep, and make available for review by United Therapeutics, records showing the number of hours spent performing work required under the agreement.

In appropriate cases where United Therapeutics does not have other means of assessing the progress of work performed by a consultant, the agreement must require the consultant to submit to the Company periodic (at least semi-annually) reports on the progress of the work; and

6. The agreement must state that it imposes on the consultant no obligation, express or implied, to purchase, prescribe, or otherwise support United Therapeutics' pharmaceutical products.

7. The agreement must state that consultants (including speakers) who also sit on formulary committees or clinical practice guideline committees must be required to disclose their affiliation with United Therapeutics to their committees. This requirement will extend for two years beyond the termination of the consulting agreement.

G. Consultants' Meetings

Reasonable compensation for time and travel expenses may be paid to physician consultants to attend a meeting conducted by United Therapeutics (either on- or off-site). Consultants' meetings may not be held at resort locations and may not include entertainment or recreation. Examples of resort locations are facilities that offer golf courses, ski facilities, or gambling casinos. The physicians must provide bona fide scientific, market research, or other consulting services. Participating consultants must be selected based on their knowledge, experience, and other skill-based qualifications, and not on the basis of their history of, or potential for, purchasing or prescribing United Therapeutics' pharmaceutical products. A written service agreement meeting the conditions of Section E, above, should be entered into, or should already be in effect, for each consultant.

Discussion by United Therapeutics employees of unapproved pharmaceutical products or uses should be non-promotional and scientific in nature. It should be made clear to attendees that the product or use under discussion is investigational.

G. Investigators' Meetings

United Therapeutics may pay reasonable compensation for time and travel expenses of investigators in United Therapeutics-sponsored clinical investigations to attend a meeting conducted by the Company to discuss issues relating to the investigation and the product being investigated. The discussions must be non-promotional and serve a genuine research purpose. The scientific portion of the meeting should account for a substantial majority of the total meeting time, in accordance with the AMA Guidelines. Investigators' meetings may not be held at resort locations and may not include entertainment or recreation.

H. Speaker Training Meetings

Reasonable compensation for time and reimbursement for reasonable travel, lodging, and meal expenses may be paid to physicians to attend a meeting for the purpose of training the physicians to act as speakers on behalf of United Therapeutics. Such training must include extensive training on United Therapeutics' products or other subjects to be presented and on compliance with FDA regulatory requirements for communications made on behalf of pharmaceutical companies. The number of speakers trained must be no greater than reasonably needed to make the presentations anticipated. Speaker training meetings may be held on- or off-site, but may not be held at resort locations, and may not include entertainment or recreation.

IX. POLICY ON PROVIDING REIMBURSEMENT INFORMATION TO CUSTOMERS

United Therapeutics may provide customers and patients with recommendations or advice regarding third-party reimbursement for United Therapeutics' pharmaceutical products or related medical services or procedures, although all such reimbursement services are currently the responsibility of the Company's pharmaceutical product distributors. However, any such recommendations or advice must be reviewed for accuracy, must reflect conservative interpretations of relevant coding policy, and must contain a disclaimer advising customers that they are responsible for selection of appropriate codes and for following billing requirements under third party reimbursement programs.

United Therapeutics employees may not "market the spread." Marketing the spread (or reimbursement profit) occurs when employees inform prescribers or other customers about the difference between the reimbursement rate for a particular United Therapeutics product and the purchase price for the same product, as an inducement to utilize the United Therapeutics' pharmaceutical products over competing products. This is prohibited even if no mention is made of the spread for competing products. United Therapeutics employees may, if asked about reimbursement rates, refer the requester to their distributor of Company pharmaceutical products.

X. POLICY ON FREE PRODUCT

A. General

United Therapeutics employees may provide free product to customers under three circumstances: (1) as professional samples; (2) as assistance to independent sponsors of clinical trials (see Policy I, “Grants To Customers for Research”); and (3) under indigent patient assistance programs. For purposes of this Policy, a “free product” does not include free product that is contingent on a purchase – for example, a buy-one-get-one-free arrangement. Such free goods are to be treated as discounts which may be permitted under Policy XI, “Policy on Discounts, Rebates, and Administrative Fees,” if the conditions of that Policy are met.

B. Sampling

In the United States, United Therapeutics employees may distribute free samples to physicians and other prescribers who are authorized under state law to receive and dispense samples, if the sampling program meets the requirements of the Prescription Drug Marketing Act of 1987 (“PDMA”) and implementing FDA regulations, as well as United Therapeutics’ then-current standard operating procedure on sampling. In addition, employees and the sampling documentation must advise physicians in writing that they may not charge a patient or bill a third party payer for United Therapeutics’ pharmaceutical products provided as free samples. Free samples may not be provided on condition, or with a mutual understanding, that the customer will purchase or prescribe United Therapeutics’ pharmaceutical products.

C. Free Product For Independent Investigators

United Therapeutics may provide free product to investigators who are eligible for Company support for clinical trials that they are sponsoring, as provided in Policy I, “Grants To Customers for Research.” The agreement with the investigator must contain a provision prohibiting the investigator from billing the patient or any third party payer for the drug provided. Free drug may not be provided on condition, or with the understanding, that the customer will purchase or prescribe United Therapeutics’ pharmaceutical products.

D. Indigent Patient Programs

Under United Therapeutics' indigent patient assistance programs, the Company provides free product to patients for whom payment for the drug would present a financial hardship. These programs are currently administered by United Therapeutics' distributors and are intended to ensure that patients of limited means have access to needed therapy. They are not intended or designed to benefit, subsidize, or guarantee payment to physicians.

Free product may be provided to patients under an indigent patient assistance program administered by United Therapeutics' distributors under the following conditions:

1. A determination of financial need must be made for each patient, in accordance with the program's established criteria for financial need. The determination must be based on documentation (for example, income tax returns) provided by the applicant. Eligibility must be reassessed at intervals prescribed under the program, but no less frequently than annually.
2. Free product may be provided to eligible patients either through a pharmacy or the patient's physician, depending on the product. The patient should be free to select the pharmacy or physician from whom the patient will receive the drug.
3. The patient, and the pharmacy or physician (as the case may be), may not submit claims to insurers or health plans for the product provided.

XI. POLICY ON DISCOUNTS, REBATES AND ADMINISTRATIVE FEES

A. General

United Therapeutics may offer discounts, rebates, and credits on its pharmaceutical products to customers who are approved in advance by the Finance Department. Although discounts are inducements to purchase United Therapeutics' pharmaceutical products, they are exempted from antikickback prohibitions because they are regarded as beneficial in bringing down costs to providers and government programs. However, under "safe harbor" regulations issued by the federal government, in order for the exemption to apply, United Therapeutics and the customer receiving the price reduction must meet certain documentation and reporting requirements. United Therapeutics may also pay administrative fees to group purchasing organizations under certain conditions.

B. Discounts

1. *Definition*

Discounts are price reductions made at the time of the sale by United Therapeutics to a wholesaler or an end user. The price reduction may be calculated as a certain amount per unit or container, or as a percentage off the pharmaceutical product's established list price to such approved customer.

2. *Reporting*

United Therapeutics does not currently make direct sales to purchasers other than to its wholesale distributors. Nevertheless, in the event of any future direct sales, the price net of discounts must be reported on the United Therapeutics invoice or other appropriate documentation. Undocumented discounts are not permissible. In addition, the invoice or other appropriate documentation must contain a statement notifying the customer of its obligation to report the discount on claims or cost reports submitted to federal and state government health care programs to the extent required, and to provide the invoices and/or other appropriate documentation to the government on request.

Where a discount is offered under a contract with an end user who buys United Therapeutics' pharmaceutical products from a wholesaler (e.g., through a chargeback arrangement), the wholesaler, rather than United Therapeutics, will be invoicing the end user.

C. Rebates

1. *Definition*

A rebate is a price reduction that is given after the time of sale. Usually it is calculated based on the customer's achievement during a specified period (e.g., a quarter) of specified performance measures such as a specified volume of purchases or a specified market share. Rebates to managed care entities are sometimes conditioned on equal or favorable formulary treatment. A rebate may be paid by check or in the form of credits, as determined by the Finance Department.

2. *Prior Disclosure of Terms*

The terms of a rebate arrangement must be fixed and disclosed to the customer prior to the first sale that is subject to rebate.

3. *Prebates*

An "up-front" rebate, or "prebate," is a rebate paid upon the execution of a contract and before the customer has met any performance measures of the rebate program. Typically, the prebate is paid on the assumption that the customer will meet the performance target required for the rebate, and the customer must subsequently return all or part of the rebate to United Therapeutics if the performance requirement is not met. United Therapeutics does not currently offer "prebates" and employees may not offer "prebates" without prior review by both the Finance Department and the General Counsel's office.

4. *Reporting and Documentation*

Where United Therapeutics is invoicing the customer (i.e., in a direct sale), the invoice should include a statement that the prices on the invoice may be subject to subsequent rebate.

The invoice and the rebate agreement should contain a statement notifying the customer of its obligation to report price reductions, as discussed in Section B.2, above.

After the end of the performance period when the amount of the rebate becomes known, a reconciliation statement must be sent along with the rebate check or credit notice. The reconciliation statement must explain how the rebate was calculated and identify the pharmaceutical products to which it applies. The reconciliation statement should include the statement discussed above regarding the customer's reporting obligations.

5. *Rebates to Pharmacy Benefit Managers (PBMs) and Other Reimburers*

Rebates to PBMs and other managed care entities that reimburse, rather than purchase, United Therapeutics' pharmaceutical products might not be protected under the federal antikickback law safe harbor for discounts. Therefore, it may be appropriate to exclude patients who are reimbursed under government health care programs from the rebate calculation and from any formulary restrictions the reimburer agrees to impose in return for the rebate. United Therapeutics employees must consult the General Counsel's office and Finance Department when offering rebates to PBMs or other reimburers.

D. Effect on Government Prices

Under the Medicaid Prescription Drug Rebate Program, United Therapeutics is required by law to provide a rebate to states each quarter on units of United Therapeutics' pharmaceutical products dispensed to Medicaid patients. United Therapeutics is also required by statute to provide a specified discount to the Department of Veterans Affairs and other government agencies that purchase United Therapeutics' pharmaceutical products. The rebates or discounts under these statutes are calculated based on United Therapeutics' prices to non-government customers. Therefore, a large discount or rebate to a non-government customer may inadvertently cause an increase in United Therapeutics' Medicaid Rebates or increase the discount United Therapeutics must provide to federal government purchasers. Accordingly, it is important for United Therapeutics employees not to deviate from United Therapeutics' discounting and pricing policies.

E. Administrative Fees

1. *Group Purchasing Organizations*

A group purchasing organization (“GPO”) is an entity that acts as a purchasing agent for a number of hospitals or other providers that are members of the GPO. The administrative fees paid to a GPO are intended to compensate the GPO for negotiating pricing with its members. Typically, a GPO will charge an administrative fee that is a percentage of the volume of sales of United Therapeutics’ pharmaceutical products to the GPO’s members.

Administrative fees may be paid to GPOs under the following conditions:

- The GPO must be acting as a purchasing agent under a written agreement with its members, and must not own, nor be sister affiliates with, the member facilities;
- The agreement between the GPO and its members must disclose that the GPO receives administrative fees from manufacturers of 3 percent or less, or if the GPO receives more than 3 percent, the agreement must disclose the amount the GPO receives from each vendor; and
- The GPO must disclose annually to its members the actual amount of administrative fees it has received from each vendor.

United Therapeutics’ agreements with GPOs in a form approved by the General Counsel’s office will require the GPO to represent and warrant that it will meet these requirements.

2. *Administrative Fees to Purchasers*

In some instances, contract administration fees based on purchase volume are requested by entities that purchase pharmaceutical products, such as chain pharmacies or wholesalers. Unlike administration fees paid to GPOs (which broker prices but do not purchase pharmaceutical products), administrative fees paid to purchasers are treated by United Therapeutics as rebates rather than service fees. Accordingly, they must comply with the documentation and other requirements for rebates in Section B, above.

XII. POLICY ON ADVERTISING AND PROMOTIONAL MATERIALS AND ACTIVITIES

A. General

It is United Therapeutics' policy that all labeling, advertising, and promotional materials for United Therapeutics' marketed pharmaceutical products comply with the Federal Food, Drug, and Cosmetic Act and FDA regulations and policies, and other applicable federal and state regulations.

B. Review of Promotional Materials

All labeling, advertising, and promotional materials, including reprints, slide and computer presentations, audiovisual materials, materials for distribution at programs, and branded press materials relating to United Therapeutics' marketed pharmaceutical products, must be submitted to the appropriate Regulatory Affairs office for each subsidiary or functional area of the Company for review and approval, in accordance with United Therapeutics or its subsidiaries' then-current standard operating procedures.

C. Use of Promotional Materials Not Approved For Distribution

1. All United Therapeutics employees involved in the promotion or sales of United Therapeutics' pharmaceutical products are prohibited from making or distributing to individuals outside the Company any promotional materials or detailing pieces that have not been approved by the appropriate Regulatory Affairs office for each subsidiary or functional area of the Company under United Therapeutics' then-current review and approval procedures. Sales or marketing personnel who design and wish to distribute or use materials that describe, refer to, or promote any United Therapeutics' pharmaceutical products must submit these materials for approval by the appropriate Regulatory Affairs office for each subsidiary or functional area of the Company under United Therapeutics' then-current procedures. The distribution outside of the Company of "home-made" materials without proper approval is unlawful and is strictly prohibited.

2. Certain materials used as sales training aids or background information are intended for internal educational purposes only, and are identified as such by the Company. United Therapeutics employees are prohibited from distributing them or showing them to a customer during a detail.

D. Promotion of Unapproved Uses

1. With certain narrow exceptions, the FDA prohibits drug manufacturers from promoting an unapproved product, or from promoting an approved product for uses that are not described in the approved labeling (“off-label uses”). No United Therapeutics employee may promote any unapproved Company product or any approved product for an unapproved use. The only exception to this policy is that employees may distribute certain scientific reprints from peer-reviewed journals that discuss off-label uses, after the reprints have been approved by the appropriate Regulatory Affairs office for each subsidiary or functional area of the Company.

2. United Therapeutics employees may not respond to any requests from health care professionals for information about off-label uses of Company pharmaceutical products, but must instead refer such inquiries to appropriate United Therapeutics Research and Development personnel. Nor may United Therapeutics personnel solicit these inquiries.

XIII. POLICY ON FIELD-BASED CLINICAL STAFF

A. General

“Field-based clinical staff” refers to medical information associates or liaisons and other personnel with similar responsibilities. These personnel have strong backgrounds in medicine, pharmacology, pharmacy, or other relevant scientific disciplines. They provide scientifically-based therapeutic information to healthcare professionals and other customers.

B. Key Considerations

1. Compensation

Field-based clinical staff should not receive a bonus, incentive, or other compensation based on product sales or utilization in their territory. They may, however, receive compensation based on the overall performance of United Therapeutics.

2. Compliance With Applicable Policies

Field-based clinical staff must comply with all legal requirements and policies relating to FDA, fraud and abuse, medical privacy, and antitrust laws and regulations. For example, although field-based clinical staff do not promote products, FDA promotional rules apply to all United Therapeutics personnel; therefore, field-based clinical staff may only discuss uses outside of FDA labeling in response to an unsolicited request for medical information.

3. Scope of Activities

a. *Clinical Investigators.* Field-based clinical staff may approach physicians regarding their potential interest in participating in a clinical investigation provided that they are *bona fide* candidates for such participation based on their training, experience, patient base, institution, and other relevant factors. The number of physicians contacted must bear a reasonable relationship to the number needed to serve as investigators. An approved packet of limited information regarding the study may be used to recruit investigators, but more detailed information cannot be supplied except to physicians who have entered into contracts to serve as investigators for the particular study. Field-based clinical staff also may interact with physicians seeking United Therapeutics’ support for their own studies, in compliance with the Company policy regarding investigator-initiated trials.

b. *Responding to Unsolicited Requests for Information.* Field-based clinical staff may respond to a request from a healthcare professional for information that requires the presentation of off-label information under the following circumstances:

- The request must be unsolicited; in other words, not prompted by a sales representative, field-based clinical staff, or anyone else acting on behalf of United Therapeutics.
- The specific request must be documented in writing in all cases. In the case of a medical information request form, the request must be signed and dated by the requesting health care professional. In the case of a direct in person request, where it may be impracticable to obtain a physician signature, the request and subject matter should be documented in an activity log.
- The response may be made in person, on the phone, or in writing, although written responses are preferable. Regardless of the method, written materials must be provided to the healthcare professional that include an approved cover letter, as well as a copy of the current approved package insert. The response must remain within the scope of the unsolicited request, be factual, objective, non-promotional, fairly balanced, and must disclose that the information being provided is outside the approved package insert. Even in response to a question, pricing or reimbursement information should not be provided.
- A response may not be made to more than one healthcare professional at the same time, except that, at the healthcare professional's request, a second professional in the same practice may join. In addition, a response to more than one professional may be provided in the context of responding to a formulary committee or similar hospital or managed care entity that has submitted an unsolicited request.
- No meals or entertainment may be provided by United Therapeutics when field-based clinical staff are providing responses to unsolicited requests.

c. Medical Conventions. Field-based clinical staff may attend medical conventions and respond to unsolicited requests for medical information as discussed above at a

booth or other location that is separate from any booth or location staffed by sales or marketing personnel.

d. Promotional Activities. Field-based clinical staff may not engage in any promotional activities in support of United Therapeutics products. Field-based clinical staff may not possess or distribute samples; they may not attend meetings of sales or marketing personnel with customers; and a sales representative may not accompany field-based clinical staff on a visit to a healthcare professional except for purposes of providing a brief introduction.

XIV. POLICY ON INTERACTION WITH GOVERNMENT EMPLOYEES

A. Scope

This Policy is applicable to interactions between United Therapeutics employees and all United States federal and state government officials, including, but not limited to, physicians (including residents), pharmacists, other healthcare practitioners, and purchasing personnel, employed by the Department of Veterans Affairs, Department of Defense (including uniformed military personnel), Indian Health Service, Public Health Service, and other federal and state agencies.

B. Gifts and Meals

United Therapeutics personnel may give modest gifts and provide modest meals to government employees in accordance with this Policy and Policy VII, regarding gifts and meals to healthcare practitioners. Under no circumstances, however, may gifts or meals exceed \$20.00 in value per government employee, per occasion. Additionally, government employees are precluded from accepting, in aggregate, more than \$50.00 per year in gifts or meals from a single source, which is defined to mean a single company, not each employee of that company. United Therapeutics personnel are therefore expected to track their expenditures to ensure that they do not exceed this limit. A United Therapeutics employee who intends to provide a gift or meal to a government employee should confer with other United Therapeutics employees that may have provided gifts or meals to that government employee to ensure that the aggregate limit has not yet been exceeded. United Therapeutics employees may never give a gift or provide a meal, regardless of value, with the intent of inducing the government employee to perform a favorable act for United Therapeutics.

C. Meetings

Government employees may be invited to attend promotional or educational meetings and conferences that include lunch or dinner, provided that the value of the meal is less than or

equal to \$20.00, as discussed above. Travel expenses may not be paid for government employees to attend meetings.

D. Consulting Fees and Honoraria

Under most circumstances, honoraria and consulting fees may not be paid to government employees. If a government employee is being considered for a speaking engagement or as a consultant, an employee must contact the General Counsel's office to determine if this is permissible before such speaking opportunity or consulting work is offered to the government employee.

XV. POLICY ON REPORTING OF PRICING INFORMATION

A. Scope and Purpose

This Policy applies to the reporting of pricing information to the Centers for Medicare & Medicaid Services (CMS) for the Medicaid Drug Rebate Program and Medicare, and to the Department of Veterans Affairs (DVA) for government acquisition purposes. The purpose of this Policy is to ensure that such reporting is done in compliance with applicable laws and regulations.

1. Medicaid Drug Rebate Reporting

Medicaid is a joint federal and state program that provides medical benefits for qualifying low-income families and individuals. As a condition of reimbursement for the covered outpatient drugs of a pharmaceutical manufacturer under Medicaid, the pharmaceutical manufacturer must sign a Medicaid Rebate Agreement with CMS in which it agrees to pay rebates to state Medicaid programs. In order to calculate the rebates, the manufacturer must submit some pricing information to CMS on a monthly and other pricing information on a quarterly basis, including the best price to non-federal customers, and the average manufacturer price, which is a weighted average of prices to wholesalers that sell to the retail pharmacy class of trade.

2. Medicare Average Sales Price Reporting

Medicare is a federal program that provides medical benefits for individuals age 65 and older, certain disabled individuals, and end stage renal disease patients. Certain drugs are reimbursed by Medicare Part B on the basis of Average Sales Price. ASP is reported quarterly to CMS by drug manufacturers and is the weighted average of prices to all customers, excluding sales that are excluded from the determination of best price under the Medicaid Drug Rebate Program.

3. *Non-FAMP Reporting*

DVA provides medical benefits for qualifying veterans. A pharmaceutical manufacturer participating in the Medicaid Drug Rebate Program is required to enter into a master agreement with DVA in which it agrees to: (1) make each of its “covered drugs” available for procurement on the Federal Supply Schedule (FSS) of the General Services Administration; (2) enter into a pharmaceutical pricing agreement with DVA in which the manufacturer agrees to sell its covered drugs to DVA, the Department of Defense, the Public Health Service, the Coast Guard and certain other federal agencies at no more than a statutorily determined federal ceiling price (FCP); and (3) sell its covered drugs to state homes receiving funds from DVA at the negotiated FSS price. Because the FCP is determined based on the manufacturer’s non-federal average manufacturer price (non-FAMP), which is a weighted average price to wholesalers, a manufacturer must report quarterly non-FAMP to DVA on a quarterly basis, and annual non-FAMP following the close of the third quarter.

B. Policy

1. *Compliance with Applicable Laws and Regulations*

It is United Therapeutics’ policy to comply with all applicable laws, regulations, and policies, in calculating pricing data and reporting such data to CMS and DVA. Any price reductions that could affect the price reporting to CMS and DVA, including discounts, rebates, contract pricing, the provision of free goods, and other items and services of value provided to purchasers as part of a pricing negotiation, should be taken into account in determining the prices reported to CMS and DVA.

2. *Compliance with Internal Standard Operating Procedures*

Reports to CMS under the Medicaid Drug Rebate Program and for Medicare Part B will be made in compliance with United Therapeutics’ standard operating procedures with respect to the preparation of such reports.

Reports to DVA under the DVA drug discount program will be made in compliance with United Therapeutics’ standard operating procedures with respect to the preparation of Public Law 102-585 Submissions to the Department of Veterans Affairs.

XVI. POLICY ON PAYMENTS TO PHARMACIES FOR COMMUNICATIONS TO PATIENTS

A. Scope and Purpose

This Policy applies to programs in which United Therapeutics compensates pharmacies for sending “refill reminder” and other communications to patients under the conditions below. United Therapeutics may also enter into service agreements with pharmacy customers designed to provide information about Company products to physicians or to patients having certain conditions (e.g., by having the pharmacy send letters to patients identified in their claims or dispensing databases as having certain conditions or using certain types of therapies). All such arrangements must be approved by the General Counsel’s office.

B. Policy

United Therapeutics may enter into agreements with pharmacies compensating the pharmacies for sending refill reminder letters or communications containing information about disease states and United Therapeutics products, provided the following conditions are met:

1. *No patient identifying information disclosed*

United Therapeutics may not obtain individually identifiable patient information from pharmacies.

2. *Clinically appropriate maintenance medication refills*

Refill reminder programs must be based on appropriate medical data demonstrating that compliance with a prescribed medication regimen will reduce overall health care costs and improve patient outcomes. Patient education communications that contain information regarding United Therapeutics products and that are sent to patients filling prescriptions for competitors’ products, may only be provided with respect to United Therapeutics products that are clinically appropriate alternative therapies.

3. *Compensation structure*

Payment for sending the letters must be made on an aggregate flat fee or “per letter” basis that is consistent with fair market value. Payment may not be based on the pharmacy’s success at generating refills or new prescriptions. Payment may not be made as an inducement to the pharmacy to purchase or stock United Therapeutics products, or in lieu of a discount.

4. *Review of letters*

The specific content of refill reminder letters and patient informational letters must be approved through the process set forth in Policy XII, “Policy on Advertising and Promotional Materials and Activities” to ensure compliance with FDA requirements.

5. *No payment for required services*

No payments may be made for services that a pharmacist or other health care professional is already required to provide to patients as part of professional dispensing practices (e.g., patient counseling at the time of dispensing).

6. *Disclosures*

Letters sent to patients must disclose United Therapeutics’ payment to the pharmacy for the communication (e.g., “[Pharmacy] is being paid by United Therapeutics Corporation, the manufacturer of [Drug], for this communication.”) and must state that United Therapeutics will not receive any individually identifiable patient information. If United Therapeutics personnel authored the communication, the communication must disclose United Therapeutics’ authorship.

7. *“Opt-out” mechanism*

Letters sent to patients must offer the patient the alternative not to receive similar letters in the future and describe the mechanism for “opting out” of the pharmacy’s program.

8. *Accompanying patient incentives*

If the letter encloses patient coupons or other incentives to use United Therapeutics products, those incentives must comply with other applicable Policies and be approved by the General Counsel's office.

9. *Written Agreement*

Prior to paying any compensation, the pharmacy must sign an agreement specifying the services to be provided and the compensation to be paid by United Therapeutics. The agreement shall specify that (1) United Therapeutics shall have the right to review and approve all communications prior to transmission to any patient; (2) the pharmacy shall include all disclosure statements required by United Therapeutics; and (3) the pharmacy shall comply with all federal and state laws and regulations relating to the privacy of health information, and shall obtain all required consents or authorizations.

10. *"Carve-outs"*

Where letters about United Therapeutics products are sent to patients filling prescriptions for competing products, United Therapeutics should not pay for any such communications made to patients covered under federal or state health care programs, including Medicare or Medicaid.

XVII. POLICY ON PRECEPTORSHIPS

A. General

United Therapeutics is committed to having an educated sales force with relevant and current clinical insight pertaining to the therapeutic practice areas in which our products are marketed. In particular therapeutic areas, this education can be enhanced by pairing United Therapeutics sales representatives with physicians and other clinicians to observe first-hand the clinical practice issues that face practitioners and patients, and gain insight into the role United Therapeutics' products may play in the clinical practice setting. Thus, United Therapeutics periodically may contract for the services of a practitioner to provide our sales representatives with this "preceptorship" training. However, such preceptorship arrangements raise significant legal and regulatory issues that must be carefully addressed by United Therapeutics in order to ensure our continued compliance with the law. Thus, preceptorships may only be arranged pursuant to the policy and procedures set forth herein.

B. Responsibility

The head of a United Therapeutics office proposing to enter into a preceptorship is responsible for qualifying their employees for participation in a preceptorship, based on the eligibility criteria set forth below. The Compliance Officer is responsible for reviewing all preceptorship arrangements.

C. Criteria

1. New United Therapeutics sales representatives may participate in one preceptorship during their first year of employment in this capacity. Ideally, the preceptorship will occur within 180 days of employment as a sales representative.

2. Preceptors shall be compensated at fair market value. Compensation shall be paid only upon completion of the actual preceptorship, and shall only be paid to the institution employing the preceptor. Neither preceptors nor institutions shall be selected based on their

history or potential for purchasing, prescribing, or arranging for favorable formulary treatment for United Therapeutics products.

3. All preceptorships will be conducted under an agreement approved by the General Counsel's office. The agreements shall be entered into with the institution that employs the preceptor, shall last for a period of at least one year, shall specify the number of preceptorship sessions to be provided, and shall state United Therapeutics' legitimate business need for such training. All Preceptor agreements shall be signed by the head of the office requesting the preceptorship and initialed by the Chief Compliance Officer and the General Counsel's office.

4. The preceptor will be required to obtain signed HIPAA-compliant authorization forms from each patient for whom the United Therapeutics sales representative will be present during the preceptorship. The preceptorship agreement will affirmatively state this requirement. The authorization form shall: state the name of the United Therapeutics representative; disclose his or her affiliation with United Therapeutics; describe the purpose of the representative's presence; notify the patient of his or her right to withdraw the authorization at any time; and contain an assurance that the sales representative and United Therapeutics will maintain strict confidentiality regarding the patient's identity and health care information.

5. Other United Therapeutics employees (i.e., Marketing) may participate in preceptorships if the Compliance Officer approves the preceptorship on the basis of educational needs justification.

D. Failure to Comply

Any sales representative or other United Therapeutics employee who is determined to have engaged in preceptorships which have not been established as set forth in this policy or who are determined to have violated a patient confidence learned in the course of a preceptorship, will be subject to immediate disciplinary action, up to and including termination.

E. Recordkeeping

Records pertaining to preceptorships, including executed preceptorship agreements, will be maintained by the Compliance Officer in accordance with United Therapeutics' record retention policy.

XVIII. POLICY ON ADVISORY BOARDS

A. General

An Advisory Board is a meeting with a select group of healthcare professionals who prescribe or administer United Therapeutics' marketed products invited by United Therapeutics to participate in a consulting/advisory role. Advisory Boards are a means to receive feedback and guidance on clinical, medical or marketing issues for United Therapeutics' marketed products. Advisory Boards must comply with this Policy and also with Policy VIII, "Consulting and Service Agreements with Customers."

The appropriate use of Advisory Boards is to gain an understanding of the clinical landscape and marketplace relative to United Therapeutics' products and services. United Therapeutics' policy is that Advisory Boards may never be used as a forum to promote United Therapeutics' products, nor as a vehicle to remunerate healthcare practitioners in order to induce them to purchase, prescribe, or provide favorable formulary status for United Therapeutics' products.

B. Processing Requests

1. A United Therapeutics employee who wishes to convene an Advisory Board meeting or a series of Advisory Board meetings for any sales and marketing purposes must submit a proposal memorandum to the Compliance Committee for review and approval. The memorandum should provide the following information:

- An explanation of why the advisors' advice is needed and the objectives that the advisory board meeting(s) will serve.
- A rationale for the number of meetings and number of advisors per meeting.
- The proposed agenda, which must reflect the objectives of the meeting.
- The proposed honoraria, if any.

- The proposed date and location.
 - Who will be attending from United Therapeutics (name, title and department).
 - How the advice will be recorded.
 - Whether a vendor is involved.
 - The individual who will prepare the final report on the Board's advice.
 - The individuals or components within United Therapeutics that will evaluate and use the advice provided.
2. The Compliance Committee will review the proposal memorandum to ensure that the purpose of the meeting, as articulated by the proponent, is to provide advice and feedback that is useful to United Therapeutics, and not to provide information to healthcare practitioners or facilitate communication among attendees. All decisions to approve or reject proposals will be documented.
 3. A United Therapeutics employee who wishes to convene an Advisory Board meeting or a series of Advisory Board meetings to address clinical or medical issues surrounding a United Therapeutics marketed product must submit a completed Committee Checklist including a summary of what will be discussed during the Advisory Board meeting and consulting agreements for all attendees. The Compliance Committee will review the checklist and consulting agreements to ensure that the purpose of the meeting, as articulated by the proponent, is to provide clinical advice and feedback that is useful to United Therapeutics, and not to provide information to healthcare practitioners or facilitate communication among attendees. All decisions to approve or reject proposals will be documented.

C. Selection of Advisory Board Members

Attendees must be selected on the basis of their relevant expertise and experience. A practitioners' prescribing history or potential is not taken into account. The number of attendees must be appropriate for the intended purpose of obtaining feedback and advice.

D. Written Agreement

All Advisory Board members must enter into a written agreement that complies with Policy VIII on "Consulting and Service Agreements with Customers," which will specify the purpose of the meeting and the services expected from the advisors; where and when the meeting will occur; the reimbursable expenses, the honorarium, and that payment of the honorarium is contingent upon their participation and completion of the listed services.

E. Compensation

The honorarium paid to each Advisory Board member must be reasonable and may not exceed the fair market value of the services.

F. Hospitality

1. United Therapeutics may pay the reasonable documented travel and lodging expenses of Advisory Board members. Modest gifts are permitted, consistent with Policy VII on "Gifts, Meals and Entertainment for Physicians and Other Healthcare Professionals."

2. The venue selected for the meeting must be conducive to the consulting and may not be a resort location. Entertainment and recreation are not permitted .

G. Guests

Advisory Board members' spouses and guests should not be invited to Advisory Board meetings and should be discouraged from attending. If, despite United Therapeutics' request that guests not attend, an advisor brings a guest, the advisor will be solely responsible for the guest's expenses and the guest may not attend any Advisory Board events or related events.

H. Ensure Use of Information Collected

The opinions and information provided by the advisors must be systematically recorded at the meeting and subsequently summarized in usable form. The information from the advisors will be provided to the appropriate United Therapeutics departments and used for its intended purpose. A final report summarizing the advice obtained will be prepared by the individual identified in the Advisory Board proposal memorandum.

I. Documentation

Documents relating to Advisory Boards, including the proposal memorandum, approval, and final report will be retained by the Marketing Coordinator in accordance with United Therapeutics' record retention policy.

**XIX. POLICY ON PRESENCE OF UNITED THERAPEUTICS' EMPLOYEES
IN PHYSICIANS' OFFICES WHILE A UNITED THERAPEUTICS
PRODUCT IS ADMINISTERED TO A PATIENT**

A. General

United Therapeutics' employees may be present in physicians' offices, provided that the physician or his or her designee requests such a visit in advance in writing, and provided that the employee adheres to this policy as well as all other applicable Company policies governing employees' interactions with healthcare providers and any applicable institutional policies.

B. Purpose

United Therapeutics' employees may be present in the office to provide to physicians and other healthcare practitioners technical support on the use of Company products and to learn about customer requirements associated with Company products.

C. Procedure

1. General requirements.

- United Therapeutics' employees may be present in a physician's office with a patient present only upon the unsolicited request of the physician, his or her designee or another healthcare practitioner in the physician's office. The employee shall document the request, for example by noting it in his or her call notes, including the name of the healthcare practitioner, the date of the request, the date of the procedure, the location of the procedure, and a brief description of the planned procedure.
- The employee must have the physician or his or her designee complete a request form provided by the Company requesting that the United Therapeutics employee be present for the procedure.

- The employee should ensure that, before starting the procedure, the physician or healthcare practitioner introduces the employee to the patient as an employee of United Therapeutics and asks the patient to consent to the employee being present for the procedure. Upon obtaining the patient's verbal consent, the employee shall document such consent, for example by noting it in his or her call notes. The employee shall not include the patient's name or other protected health information in such documentation. If the patient does not consent, the employee must leave the room immediately.
- United Therapeutics' employees are prohibited from seeking access to or review of any patient medical records, or from retaining any health information obtained in the course of the procedure.
- United Therapeutics' employees may not engage in promotional discussions with the physician immediately before, during, or immediately after the procedure. This precludes promotional discussions of the device or products used for the particular United Therapeutics' employees must adhere to all applicable Company policies and procedures on interactions with healthcare providers.
- If a question on off-label use of a United Therapeutics product arises during the procedure, employees must refer all such questions to the Company's medical affairs department. United Therapeutics' employees are prohibited from promoting any off-label or unapproved use of a Company product at any time.
- In all situations, the physician shall make the decision as to the appropriate device, product and procedure to be used. At a physician's request, technically trained United Therapeutics' employees may provide support, advice and information to the physician in the operation and use of Company products.

2. Prior to the procedure, United Therapeutics' employees must:
 - When taking equipment into the physician's office, ensure compliance with all office or hospital policies and procedures, such as obtaining approval from the appropriate personnel, autoclaving, etc.
 - Observe all office or hospital policies and procedures for being present during a patient procedure.
 - If requested, familiarize the physician with the use of the product well in advance of his or her scheduled first use, and if requested, provide in-service training to office personnel prior to the procedure. Such training may be provided only for the approved product use or uses.
 - Ensure that the physician has a copy of the applicable product labeling.

3. During the procedure United Therapeutics' employees must:
 - Limit activities to those that are directly requested by the physician during the course of the procedure.
 - To the extent that he or she provides any information to the physician, limit such information to the product itself - i.e., the technical operation, physical characteristics, and performance or use of an associated device. United Therapeutics' employees should never initiate discussions about off-label clinical uses.
 - Refrain from providing information that would require the exercise of clinical or medical judgment or the diagnosis of a disease or disorder.
 - Refrain from engaging in any conduct that might be construed as "practicing medicine," such as touching the patient or administering Company products. United Therapeutics' employees should never hand Company products to the physician or assist the physician by taking any action that might be construed as participating in the procedure.

- If consistent with hospital or office policies and procedures, wear a visible nametag with his or her name and the Company's name visible during the procedure.
- Observe appropriate office decorum at all times. United Therapeutics' employees should be aware that the physician's full attention should be devoted to the patient and should not engage in any activity or conversation that would disrupt the physician's attention or concentration.
- Never disparage another company's product or service while visiting a physician's office.