ABIOMED

Recovering hearts. Saving lives.™

# Code of Conduct and Compliance Policy

*"Your Commitment, Our Integrity"*

**(Revised March 2017)**

# GUIDELINES ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS

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# INTRODUCTION

ABIOMED's reputation as a leader in medical device technology and related scientific fields is based, to a large extent, on the excellence of its technology and products and on the skill, integrity and superior performance of its personnel. We endeavor to provide our customers with quality products, and, when we are involved in research and development work, we strive to use our best efforts to achieve the results for which we have been engaged. It is the Company's policy to comply with all federal, state and local laws and regulations pertaining to all products that we develop, manufacture or sell. We recognize that we are in the business of making medical devices and therefore human life may depend on the reliability and performance of our products. We are committed to standards of excellence in every aspect of development, manufacturing or sale of our products. We owe this to our patients, to our customers, to our shareholders and to ourselves.

The commitment of ABIOMED to legal, ethical and moral behavior is critical to our customers, our shareholders, and to all employees. As the developer and manufacturer of life-supporting equipment, our determination to do what is right in every instance should drive our behavior. We all must be completely committed to high standards for excellence, integrity and professional business conduct in everything we do. Our professional and personal reputations are our most important assets. As a result, we all personally own our actions and bear the responsibility not to tolerate any inappropriate or non-compliant actions by others.

As such, ABIOMED, Inc. ("ABIOMED" or the "Company") is committed to establishing and maintaining a high-quality compliance program consistent with the guidance published by the Office of Inspector General, U.S. Department of Health and Human Services (the "HHS-OIG Guidance"). Our comprehensive compliance program (the "Compliance Program") is one of the key components of our commitment to high standards of corporate conduct and our conformity with the laws and regulations that govern our interactions with Healthcare Professionals and others. The cornerstone of our Compliance Program is this Code of Conduct and Compliance Policy (the "Compliance Code"), which is applicable to all of our employees and directors. The Compliance Code promotes, among other ideals, honest and ethical conduct, including the proper handling of actual or apparent conflicts of interest between personal and professional relationships. The Compliance Code also provides guidance and instruction for our employees concerning the issues surrounding ABIOMED's interactions with Healthcare Professionals as well as the statutes, regulations and industry guidance that govern ABIOMED's business as a manufacturer of medical device technologies in the United States and around the globe.

Our Compliance Code is designed to seek and detect violations of both law and Company policy. As the HHS-OIG Guidance recognizes, however, the implementation of a compliance program cannot guarantee that improper employee conduct will be entirely eliminated. Nevertheless, it is ABIOMED's expectation that its employees will act in accordance with the requirements of this Compliance Code and the relevant policies and procedures referenced in it. In the event that ABIOMED becomes aware of violations of law or Company policy, we will investigate the matter and, as appropriate, take disciplinary action and implement corrective measures designed to prevent future violations.

The principles in this Compliance Code, as well as our policies and procedures, apply to all our interactions with individuals (whether clinical or non-clinical, including without limitation, physicians, physician assistants, nurses, technicians, purchasing managers, and office staff) and entities (including, without limitation, hospitals and group purchasing organizations) (referred to collectively in this document as "Healthcare Professionals") that directly or indirectly purchase, lease, use, prescribe, or recommend or arrange for the purchase, lease, use, or prescription, of any ABIOMED Product or ABIOMED Services.

In addition to the principles in this Compliance Code, many governmental entities and U.S. states have specific laws and regulations governing interactions between Healthcare Professionals and healthcare companies. When applicable, these more specific laws and regulations govern our interactions with Healthcare Professionals— regardless of the location or venue. This means that if a country or state where a Healthcare Professional practices has laws or regulations more stringent than the principles in our Compliance Code, those limitations must be followed, without exception.

ABIOMED has described below the fundamental elements of this Compliance Code. In accordance with the voluntary standards established by the HHS-OIG Guidance and as explicitly recognized in the Guidance, we have tailored our Compliance Code to fit the unique environment and size of our Company. Moreover, this document is a ***description*** of our Compliance Program. It is not a complete rulebook, or a summary of all applicable laws. A Compliance Program is dynamic, involving not only multiple policies, procedures and programmatic activities[1], but also the commitment of senior management and the support of all employees, vendors and agents to make the program effective. We are committed to regularly reviewing and enhancing our Compliance Code to meet our evolving compliance needs.

## I. OVERVIEW OF THE COMPLIANCE CODE

### A. Written Standards

The ABIOMED Compliance Code is our statement of essential ethical and compliance principles that guide our daily business operations.[2] The Compliance Code makes clear that we expect

[1] In addition to the standards described in this Compliance Code, each employee must abide by all policies set forth in ABIOMED's Employee Handbook and Company policies which are provided to each employee upon their hire by the Company. Each employee is also bound by the terms and conditions of his or her employment agreement or other agreement, if any, with the Company. Any violation or breach of any provision of the Company's Employee Handbook, Company policies or agreements may result in disciplinary and/or legal action directly by the Company.

[2] This Compliance Code is intended to facilitate ethical behavior, and is not intended to be, nor should it be construed as legal advice. The Compliance Code is not intended to define or create legal rights, standards or obligations. Any interpretation of the provisions of this Code, as well as the Company's interactions with Healthcare Professionals not specifically addressed in this Code, should be made in light of the following principle: ABIOMED encourages ethical business practices and socially responsible industry conduct and does not engage in unlawful inducements.

management, employees, vendors and agents of the Company to act in accordance with law and applicable Company policy. The Compliance Code further articulates the fundamental principles, values and framework for action within our organization. In addition to this Compliance Code, ABIOMED has formally adopted the majority of the principles set forth in the Code of Ethics on Interactions with Healthcare Professionals of the Advanced Medical Technology Association (the "AdvaMed Code").[3]

### B. Applicability, Leadership and Structure

The Compliance Code applies to all ABIOMED employees, including its Board of Directors, and other representatives engaged (directly or indirectly) to perform work for, or on behalf of, ABIOMED, including temporary agency personnel and other independent contractors, such as independent sales representatives and distributor representatives (referred to collectively in this document as "ABIOMED Representatives").

We have selected a Chief Compliance Officer who has overall responsibility for overseeing and monitoring the Company Compliance Program. Specifically, the Chief Compliance Officer is responsible for implementing this Compliance Code and related policies and procedures, certifying compliance with applicable laws and regulations, submitting all required forms to applicable government bodies, and conducting annual audits to ensure that the Company's Board of Directors, management and employees are in compliance with Company policies and procedures, rules and regulations of relevant regulatory agencies, and the laws that govern ABIOMED's business operations. In that connection, the Chief Compliance Officer will ensure that all ABIOMED Representatives, through appropriate training and education, have sufficient knowledge of applicable laws and regulations, this Compliance Code, and related policies and procedures, as well as general science, and product specific information.

The Chief Compliance Officer is assisted in this regard by the ABIOMED Compliance Committee, which is comprised of managers and other individuals from key operational areas of the Company (e.g., Marketing/Healthcare Solutions, Operations, Legal, and Regulatory Affairs).

Ultimately, the Chief Compliance Officer is responsible for reporting quarterly to the Company's President, Chairman and Chief Executive Officer, and to the Company's Board of Directors concerning the status and health of ABIOMED's compliance posture. The Chief Compliance Officer, together with the ABIOMED Compliance Committee, is empowered to implement all necessary actions to ensure achievement of the objectives of this Compliance Code.

[3] ABIOMED has not, to date, adopted AdvaMed's suggested prohibition of the occasional gifting of low-cost branded items to Healthcare Professionals (items typically valued at less than $100.00). A copy of the AdvaMed Code can be found on the ADP HR Portal under the Features section of the Company Home Page. In most instances the tenets of this Compliance Code are more restrictive than those found in the AdvaMed Code. If there is a conflict between this Code and the AdvaMed Code, the requirements of the Compliance Code will govern.

### C. Education and Training

A critical element of our Compliance Program is the education and training of our employees on their legal and ethical obligations under applicable federal health care program requirements. ABIOMED is committed to taking all necessary and appropriate steps to effectively communicate our standards and procedures to all affected personnel. Ongoing training programs include live meetings of attorneys from the ABIOMED Legal Department with Company management, sales trainees, sales and marketing employees and other personnel; regular refresher courses; and mandatory on-line training modules for employees. The Compliance Code's role in this education and training is to set and enforce minimum training requirements for employees by function and to ensure that all training received by employees is adequately documented. Moreover, ABIOMED, through its Compliance Program, will regularly review and update its training programs, as well as identify additional areas of training on an "as needed" basis.

### D. Internal Lines of Communication

ABIOMED is committed to fostering dialogue between management and employees. Not every situation which may arise can be anticipated. Our goal is that should compliance-related questions arise, all employees seek answers to those questions, and know who to turn to for a meaningful response. Additionally, employees should be able to ask questions, and to report actual and potential violations of this Code without fear of retribution. To that end, we have adopted open-door-policies, as well as confidentiality and non-retaliation policies. In order to further encourage open lines of communication regarding potential violations, we have established procedures to allow individuals who want to report anonymously to do so. Employees may report matters confidentially to the **independent compliance reporting hotline by calling 888-475-8376**[4], or directly to the Chief Compliance Officer or a member of the ABIOMED Compliance Committee.

### E. Auditing and Monitoring

ABIOMED's Compliance Program includes efforts to monitor, audit, and evaluate conformance with the Company's compliance policies and procedures, including efforts to monitor the activities of sales force personnel. We note that, in accordance with the HHS-OIG Guidance, the nature of our reviews as well as the extent and frequency of our compliance monitoring and auditing varies according to a variety of factors, including new regulatory requirements, changes in business practices and other considerations. We will utilize an ongoing assessment of our Compliance Program to identify new and emerging risk areas and address these risks.

[4] The independent compliance reporting hotline is owned, staffed, and managed by an independent company and is available to employees 24 hours per day, seven days per week.

### F. Responding to Past and Potential Violations and Corrective Action Procedures

A compliance program increases the likelihood of preventing unlawful and unethical behavior. However, HHS-OIG recognizes that even an effective compliance program may not prevent all violations. It is ABIOMED's policy to thoroughly investigate, and to respond promptly to past and potential violations of: law; the principles in this Compliance Code; and Company policies and procedures. While each situation will be considered on a case-by-case basis, the Company is committed to taking consistent and appropriate action to address inappropriate conduct and to deter future violations, including taking appropriate disciplinary action when necessary. Disciplinary action for noncompliance may include a broad range of disciplinary measures, up to and including termination of employment. Intentional and material noncompliance will be subject to the most significant sanctions. In addition, adherence to the Compliance Code and related policies and procedures will be a factor in all applicable employee performance evaluations.

ABIOMED recognizes that it is important to ultimately assess whether a past violation is in part due to gaps in our policies, practices or internal controls, and to repair such gaps, if and when they occur. In that vein, this Compliance Code outlines ABIOMED's policy on addressing, documenting and reporting compliance violations, as well as the disciplinary actions taken in response to those occurrences.

## II. RESPONSIBILITY FOR COMPLIANCE AND POLICY AGAINST RETALIATION

All ABIOMED Representatives are responsible for complying with this Compliance Code and its related policies and procedures, and for reporting any potential violations of the requirements set forth in those documents to their immediate supervisor, the Chief Compliance Officer, or the **anonymous and independent compliance reporting hotline at 888-475-8376**. Failure to make a good faith report of suspected or actual violations is itself a violation of the Compliance Code and may result in disciplinary action, including termination of an ABIOMED Representative's employment, or legal action. To the extent any investigation is necessitated by a report, ABIOMED will endeavor to keep the proceedings and the reporting individual's identity confidential to the fullest extent of applicable law.

ABIOMED will not tolerate any form of intimidation or retaliation by any ABIOMED Representative against any individual because of any good faith act taken by the individual to report a compliance concern. Retaliation against any individual for reporting a concern is prohibited, and will result in discipline, up to and including, termination. If you report in good faith a suspected violation under the Compliance Code by ABIOMED (or its agents acting on behalf of the Company) or raise issues or concerns regarding ABIOMED's business or operations to the Compliance Committee, you will not be fired, demoted, reprimanded or otherwise harmed based on your reporting of the suspected violation, issues or concerns. In addition, if you report in good faith a suspected violation under the Code which you reasonably believe constitutes a violation of a federal statute by ABIOMED, or its agents acting on behalf of ABIOMED, to a federal regulatory or law enforcement agency, you will not be reprimanded,

discharged, demoted, suspended, threatened, harassed or in any manner discriminated against in the terms and conditions of your employment based on the reporting of the suspected violation, regardless of whether the suspected violation involves you, your supervisor or the senior management of ABIOMED. Like all employees, however, an individual making a good faith complaint is expected to continue to perform his or her own job in a professional and competent manner, and to continue to comply with this Compliance Code or the policies set forth in the Company's Employee Handbook or employee agreements.

The Company requires all relevant personnel to certify annually that they have read, understood and will strictly adhere to this Compliance Code and related policies and procedures.

## III. OVERVIEW OF RELEVANT FEDERAL AND STATE LAWS AND REGULATIONS THAT GUIDE ABIOMED'S COMPLIANCE PROGRAM AND THIS COMPLIANCE CODE

ABIOMED Products are purchased and reimbursed by federal healthcare programs such as Medicare and Medicaid, as well as other federal and federally-funded programs. Internationally, the Company's products are purchased and reimbursed by various governmental entities. The sale, reimbursement and marketing of our products are regulated by a variety of laws related to these programs. These laws and regulations include, among others: the federal anti-kickback statute, dealing with fraudulent and abusive practices that promote overutilization and otherwise increase the costs of federal health care programs, or unduly influence treatment decisions by Healthcare Professionals; the Federal Food, Drug, and Cosmetic Act, governing research, development, manufacture, labeling, sale, distribution and promotion of medical devices; False claims laws, prohibiting the submission of false claims to the government or third-party payors; the United States Foreign Corrupt Practices Act, generally prohibiting U.S. entities and their agents from making or offering to make improper or corrupt payments to foreign public officials; and laws prohibiting the "off-label" marketing or promotion of Company products. In addition, the Company markets and sells its products in certain states that have adopted laws and regulations governing the interaction of medical device manufacturers with Healthcare Professionals.

The violation of these laws and regulations can have serious consequences for the Company and any ABIOMED Representative involved in the violation, including civil suits or criminal prosecutions.

ABIOMED expects each employee and representative to be familiar with, and to comply with, all laws and regulations that are applicable to his or her job or performance of services for the Company. ABIOMED has developed policies to prevent ABIOMED Representatives from running afoul of some of these laws, including the Company Insider Trading Policy, and Equal Opportunity/Harassment Policy. The ABIOMED Compliance Code is meant and designed to further address, in detail, the policies and procedures adopted by the Company to ensure it remains in compliance with federal and state laws, including those laws designed to regulate the commercialization of our products, and the manner in which we interact with Healthcare Professionals. ABIOMED is committed to full compliance with all applicable federal and state laws.

### A. The Federal Anti-Kickback Statute

The key law that governs ABIOMED's interactions and relationships with Healthcare Professionals is the U.S. federal anti-kickback statute. The anti-kickback statute and its implementing regulations provide that **anyone who knowingly and willfully offers, gives, solicits, or receives anything of value to influence or reward the ordering, purchasing or referring of federal or state healthcare program business can be charged with a felony**.

The anti-kickback statute prohibits ABIOMED from providing payments, gifts, or other things of value to Healthcare Professionals that are intended to induce someone to order, purchase, use, or refer an ABIOMED Product when that product is reimbursable by Medicare, Medicaid, or recommend or arrange for the order, purchase, use, or referral of another U.S. federal or state healthcare program. A key aspect of this law, commonly known as the "One Purpose Test," provides that even if there are other legitimate purposes for a transaction, if even one purpose of the transaction is to induce ordering, purchasing, using, or referring of an ABIOMED Product, the transaction could be construed as an illegal kickback.

In addition, there may be state laws, similar to the anti-kickback law, which apply broadly to products reimbursed by **any** healthcare program, public or private. Because it is not possible to know with certainty whether a Healthcare Professional participates in Medicare, Medicaid, or another U.S. federal or state healthcare program, ABIOMED treats all Healthcare Professionals as if they are subject to the anti-kickback statute. In other words, this Compliance Code is applicable across the board to all of our interactions with Healthcare Professionals in any country, whether the anti-kickback statute is technically applicable or not, unless a specific exception is provided in Company policies or procedures.

The Compliance Code, as well as our policies and procedures, are drafted, in part, to help ensure the Company's compliance with the U.S. anti-kickback statute (and similar state laws), and are based on the AdvaMed Code of Ethics on Interactions with Healthcare Professionals.

### B. The Stark Law

A law closely related in purpose to the federal anti-kickback statute is the Stark law. The Stark Law generally prohibits a physician from making a referral under Medicare or Medicaid for designated health services to an entity with which the physician or a member of the physician's immediate family has a financial relationship. For example, doctors cannot refer patients for certain services if the doctor would benefit financially from doing so. Notably, the Stark Law only regulates the referral of patients who are beneficiaries of federal health care programs, most notably Medicare or Medicaid. To compensate for this targeted scope, many states have passed analogous laws regulating referrals paid for by private insurance. Additionally, the Stark law is a "strict liability" statute, meaning that regardless of the violator's intent or mental state they can be held accountable for a violation.

### C. "Off-Label" Promotion or Marketing

ABIOMED is a Class III medical device company and sells and distributes its products both inside and outside the United States. The United States Food and Drug Administration ("FDA") regulates the research, development, manufacture, labeling and promotion of each of our products. Each device that ABIOMED manufacturers has a different approval and a distinct set of labeling, including indications for use, duration of use, appropriate patient groups, contraindications, warnings, and precautions and instructions for use. The approved FDA labeling for each of ABIOMED's products is attached to this Compliance Code at Appendix B.

Congress has delegated to the FDA certain regulatory powers under the Food, Drug, and Cosmetic Act ("FDCA"). Among other things, the FDCA prohibits the "misbranding" of medical devices. Under the law, a medical device can be deemed misbranded if its labeling is false or misleading, or does not bear "adequate directions for use." Because the labeling accompanying a device contains only uses that are approved or cleared by the FDA, when a device is promoted or marketed for an "off-label" use (or a use not covered by the labeling), its labeling is misleading because it does not bear adequate directions for the promoted use. Consequently, the device is deemed misbranded in such circumstances.

Violations for off-label marketing under the FDCA carry with them potential criminal and civil penalties. They can also result in additional penalties under the federal False Claims Act – a law that was first passed in 1863, in response to the widespread fraud against the government experienced during the American Civil War, and which has been greatly expanded during the last century and a half.[5] The government's legal argument under the False Claims Act, in an off-label promotion context, is that off-label promotion, rather than independent medical judgment, "causes" the prescription of unapproved medical device uses and therefore provider claims for federal reimbursement for off-label uses to be "false" under the Act. Often, in the government's

[5] Under the False Claims Act there are seven forms of misconduct that can result in civil liability. Such misconduct occurs when anyone:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
> (C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F) or (G);
> (D) has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property;
> (E) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;
> (F) knowingly buys, or receives as a pledge of an obligation of debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge property; or
> (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.

view, treble damages and an $11,000 penalty ***per claim*** can be assessed on a manufacturer for violations.

### D. The Foreign Corrupt Practices Act

ABIOMED is a medical device company with an international reach. Many of our business dealings occur in, and affect, foreign nations. The Foreign Corrupt Practices Act ("FCPA") makes it unlawful to pay, offer to pay, or cause someone else to pay anything of value, directly or indirectly, with a corrupt intent, in order to secure any improper business advantage or to obtain or retain business, to any foreign government officials. For FCPA purposes, such officials include: officials or employees of foreign government departments and agencies; foreign political parties, party officials or employees, and candidates for public office; officers or employees of government-owned entities; officers or employees of certain public international organizations; or anyone else acting in an official capacity for such foreign governments or international organizations.

In many instances, foreign health care providers work at government-owned hospitals and clinics, and are considered government officials within the meaning of the FCPA. Though physician contact, in many cases, is educational and may include sponsoring a physician's evaluation of a company's products or subsidizing presentations at medical seminars, even modest payments to foreign doctors, nurses, or hospital technicians could trigger FCPA liability, unless they are expressly permitted by the written laws of the host country. Violations of the FCPA carry with them significant criminal and civil penalties. ABIOMED is committed to acting vigilantly to ensure our foreign business dealings are in compliance with all applicable laws and regulations.

### E. Federal "Sunshine" Law

As part of the Patient Protection and Affordable Care Act, new federal reporting obligations for drug and device manufacturers were created, which require annual disclosure filings detailing their financial relationships with physicians and teaching hospitals. These federal requirements are known as the "Sunshine" provisions, as they were originally proposed as the "Physician Payments Sunshine Act" by Senators Charles Grassley and Herb Kohl.

The federal law requires drug and device manufacturers to disclose almost all payments and "transfers of value" made to physicians or to teaching hospitals. These disclosures are periodically made publically available via a searchable online database. The Sunshine Law also requires manufacturers to disclose specific payments made to individual physicians and teaching hospitals, rather than simply disclosing the aggregate payments. While the Sunshine Law does contain a limited "preemption" provision that overrides some state laws governing industry-physician disclosures, that provision does not displace state reporting requirements that are more stringent that the federal law. The Sunshine Law provides for significant financial penalties for noncompliance.

### F. Massachusetts and Other State Laws Regulating the Conduct of Medical Device Manufacturers

Massachusetts (and some other states) has adopted its own laws regarding pharmaceutical and medical device manufacturer conduct. These Massachusetts rules are intended to benefit patients, enhance the practice of medicine, and ensure that the relationship between pharmaceutical or medical device manufacturers and Healthcare Professionals does not interfere with the independent judgment of those professionals. The regulations establish a marketing code of conduct that applies to both pharmaceutical and medical device companies, with certain limited exceptions. The regulations also mandate that pharmaceutical and medical device manufacturers implement certain training and compliance programs, and provide related certifications to the Department of Public Health. Finally, the regulations require pharmaceutical and medical device manufacturers to disclose certain payments and other benefits provided to certain covered recipients, and clarify that these disclosures are limited to sales and marketing activities. The disclosures are made publicly available for review on a dedicated website. These rules require reporting of certain payments, gifts and other transfers of value to health care providers, and also limit some types of interactions between industry and providers.

## DEFINITIONS

The following terms are used extensively throughout this Compliance Code, and its associated policies and procedures. Whenever present, those terms should be afforded the following definitions:

**"ABIOMED Product"** – Any product that is developed, manufactured, sold and/or distributed by ABIOMED.

**"ABIOMED Representatives"** – Any and all employees and other representatives engaged (directly or indirectly) to perform work for ABIOMED, including temporary agency personnel and other independent contractors, such as independent sales representatives, distributor representatives, consultants, and clinical research organizations.

**"ABIOMED Services"** – Any service that is provided by ABIOMED.

**"Entertainment"** – Activities and events that are cultural or recreational in nature that do not involve business being conducted throughout the duration of the activity. This includes, but is not limited to, recreational events like golf, fishing, or hunting trips, tickets to the theater, sporting events, concerts, sporting equipment, or sightseeing or leisure trips.

**"Fair Market Value"** – The value of an item or service, as bargained for in an arms-length negotiation, consistent with the price that a well-informed buyer and seller, neither of whom is otherwise in a position to generate business for the other, would agree to purchase or sell the same item or service, at the same time of the purchase or sale, and in the same geographic region.

**"Healthcare Professional"** – Individuals (whether clinical or non-clinical, including without limitation, physicians, physician assistants, nurses, technicians, purchasing managers, and office staff) and entities (including, without limitation, hospitals and group purchasing organizations) that directly or indirectly purchase, lease, use, prescribe, or recommend or arrange for the purchase, lease, use, or prescription, of any ABIOMED Products or ABIOMED Services.

**"Modest" –** Of moderate value.

**"Occasional"** – An event that does not occur regularly, but rather, infrequently.

## Conflicts of Interest and Fair Dealing Practices

All ABIOMED employees must avoid situations in which their personal interests may conflict, or appear to conflict, with the interests of ABIOMED. All of us can recognize clear-cut cases of dishonesty. Conflicts of interest may be more difficult to detect, and sometimes it is only a matter of degree between an acceptable and an unacceptable activity. The responsibility for conduct within the letter and the spirit of this policy must rest with each individual. However, we want to stress that it is important to avoid not only any situation that is an obvious conflict of interest but also a situation that might give the appearance of being one.

In dealings with current or potential customers, suppliers, contractors, and competitors, you should act in the best interests of ABIOMED to the exclusion of your personal advantage. Because no one policy can cover all conflict of interest situations that you may encounter and judgment is involved in determining whether such a conflict exists, you should consult with a member of the Compliance Committee prior to engaging in any dealing to determine whether your personal interest may conflict with the interests of ABIOMED. Examples of situations that should be avoided include:

- Having a substantial undisclosed financial interest in a competitor or a company that seeks to do business with ABIOMED;
- Serving as a director, officer, employee or contractor of a competitor or a company that seeks to do business with ABIOMED;
- Having an undisclosed personal interest in a transaction when you know that ABIOMED is engaged in pursuing the transaction;
- Appropriating to yourself any business opportunity in which ABIOMED has an interest;
- Failing to disclose any business being conducted by you for ABIOMED with any company in which your immediate family member is a principal or officer;
- Using company property or information received in your position at ABIOMED for your own personal gain; and
- Receiving any loan or advance from ABIOMED other than customary advances or corporate credit in the ordinary course of business.

ABIOMED Representatives must never offer, give, solicit or receive any form of bribe (or any other form of economic inducement) to or from an employee of a customer, supplier or service provider to influence that employee's conduct or your conduct. Further, gifts, favors, and entertainment which are more than Modest in value may not be accepted by you or members of your immediate family from any person or organization that does or seeks to do business with, or is a competitor of, ABIOMED, except as common courtesies usually associated with customary business practices. ABIOMED has established a reporting avenue whereby ABIOMED employees can inform the ABIOMED Compliance Committee and ABIOMED management of

any gift that is received from a business partner, which valued at more than $25, or any group of gifts from the same source that total more than $100 in any 12 month period. If you are offered and accept such a gift, you are required to denote the type, amount and nature of the gift received, as well as your or the company's relationship with the other party, by sending an email to giftreports@abiomed.com.

## Protection and Proper Use of Company Assets

Proper protection and use of company assets and assets entrusted to you by others, including proprietary information, are fundamental responsibilities of each ABIOMED Representative. You must comply with security programs to safeguard such assets against unauthorized use or removal, as well as against loss by criminal act or breach of trust. These provisions also apply to property (including proprietary and confidential information) of others entrusted to ABIOMED.

***Proper Use of Company Property:***

ABIOMED's funds, products, property and services are its property and remain ABIOMED's property after an individual's employment or directorship terminates. The removal of ABIOMED's property from its facilities is prohibited without prior authorization from the appropriate departmental Vice President.

***Confidential Information:***

ABIOMED provides you with confidential information relating to ABIOMED and its business as well as the confidential information of others with whom ABIOMED does business with the understanding that such information will be held in confidence and not communicated to anyone who is not authorized to see it, except as may be required by law. You may not disclose such confidential information to an unauthorized third party or use such confidential information for your own personal benefit. Please consult ABIOMED's Information Security Program, ABIOMED's IT Security Policy, as well as ABIOMED's HIPAA Policy for additional information regarding confidential information and your related responsibilities. These policies are available for your review on the ADP HR Portal.

***Accurate Records and Reporting:***

ABIOMED is required by law to keep books, records and accounts that accurately and fairly reflect all transactions, dispositions of assets and other events that are the subject of specific regulatory record keeping requirements, including generally accepted accounting principles and other applicable rules, regulations and criteria for preparing financial statements and for preparing periodic reports filed with the SEC. Because the integrity of ABIOMED's external reports to shareholders and to the SEC depends on the integrity of ABIOMED's internal reports and record-keeping, you must adhere to the highest standards of care with respect to our internal records and reporting. ABIOMED is committed to full, fair, accurate, timely, and understandable disclosure in the periodic reports required to be filed by it with the SEC, and it expects you to work diligently towards that goal.

If you believe ABIOMED's books and records are not in accord with these requirements, you should immediately report the matter to a member of the Compliance Committee or to the **anonymous and independent compliance reporting hotline at 888-475-8376**. Employee concerns or complaints may be made anonymously. There will be no retaliation or discrimination against any employee who provides information about any conduct that the employee in good faith believes involves concerns about the accuracy of ABIOMED's books,

records and accounts.

Our Company's internal control procedures are further regulated by the Sarbanes-Oxley Act ("SOX"). SOX is a U.S. legislative response to events at public companies involving pervasive breakdowns in corporate ethics and financial reporting. It is designed to rebuild confidence in the capital markets by ensuring that public companies are operated in a transparent and honest manner. Ensuring proper and effective internal controls is among ABIOMED's highest priorities.

We take seriously the reliance our investors place on us to provide accurate and timely information about our business. In support of our disclosure obligations, it is ABIOMED's policy to always:

- Comply with generally accepted accounting principles;
- Maintain a system of internal accounting and disclosure controls and procedures that provides management with reasonable assurances that transactions are properly recorded and that material information is made known to management;
- Maintain books and records that accurately and fairly reflect transactions;
- Prohibit establishment of material undisclosed or unrecorded funds or assets; and
- Make no payment on behalf of ABIOMED with the intention or understanding that all or part of such payment will be used for any purpose other than that described by the document supporting the payment.

***Document Retention:***

Numerous federal and state statutes and regulations require the proper retention of many categories of records and documents that are commonly maintained by companies. Document retention in the context of product and regulatory requirements can be found in company SOPs. Individual departments may have their own specific document retention policies which should be consulted before destroying or discarding any material records or documents. In addition, any record, in paper or electronic format, relevant to a threatened, anticipated or actual internal or external inquiry, investigation, matter or lawsuit may not be discarded, concealed, falsified, altered, or otherwise made unavailable, once you have become aware of the existence of such threatened, anticipated or actual internal or external inquiry, investigation, matter or lawsuit.

***Corporate Advances:***

ABIOMED is prohibited by law from loaning money to you except in limited circumstances. It is a violation of the Compliance Code for you to advance company funds to any other employee or to yourself except for usual and customary business advances which are approved by a supervisor or pursuant to a corporate credit card for usual and customary business purposes. Company credit cards are to be used only for authorized business purposes. You will be responsible for any unauthorized charges to a company credit card.

# Competitive Practices

Although the free enterprise system is based upon competition, rules have been imposed stating what can and what cannot be done in a competitive environment. Certain practices can lead to liability for "unfair competition" and should be avoided, including disparagement of competitors, disrupting a competitor's business or making misrepresentations about the nature, quality or character of ABIOMED's services and products. We may describe our services and products based only in a truthful and non-misleading manner, and consistent with their documented specifications or FDA-approved labeling.

***Antitrust Concerns:***

Generally, antitrust laws enable companies to compete equally for customers. Federal and state antitrust laws preserve the free enterprise system by ensuring that competition is the primary regulator of the economy. These laws prohibit such behaviors as abuse of power, bid-rigging, price-fixing, price discrimination, tying, and boycotts. They also require scrutiny of certain mergers and acquisitions. Every corporate decision that involves customers, competitors, and business planning with respect to output, sales and pricing raises antitrust issues. Failing to recognize antitrust risk is costly. Antitrust litigation can be very expensive and time-consuming. Moreover, violations of the antitrust laws can, among other things, subject you and ABIOMED to the imposition of injunctions, treble damages, and heavy fines. Criminal penalties may also be imposed. Individual employees can receive heavy fines or even be imprisoned. For this reason, antitrust compliance should be taken very seriously at all levels within ABIOMED. Always immediately inform a member of the legal department or the Compliance Committee if local, state or federal law enforcement officials request information from you or ABIOMED concerning the Company's operations.

ABIOMED policies and business practices help us avoid anti-competitive conduct. We do not engage in conduct that may create an impression of conspiring with competitors. ABIOMED employees should not create or participate in any understanding or agreement with any competitor regarding prices, pricing policies, fees, or terms or conditions of sale of any product. You must never discuss past, present, or future prices, pricing policies, bundling, discounts or allowances, royalties, terms or conditions of sale, costs, choice of customers, territorial markets, production quotas, allocation of customers or territories, or bidding on a job with a competitor. Be careful of your conduct. An "agreement" that violates the antitrust laws may be not only a written or oral agreement, but also a "gentlemen's agreement" or a tacit understanding.

It is particularly important to be conscious of antitrust laws at trade association meetings. The following rules should be obeyed carefully:

- Attend only meetings of legitimate trade and professional organizations held for proper business, scientific or professional purposes.

- Apart from purely social affairs, never attend gatherings of representatives of competitors before, during or after the formal business sessions of a trade association. Such "rump" meetings are always suspect.

- Do not take part in, or even listen to, any discussions of price, terms of sale, boycotts or blacklists at an association meeting. However, discussions of general economic trends are proper. If the discussion at an association meeting turns to the subject of prices or other prohibited topics, leave the room and report the meeting to a member of the Compliance Committee.

- If the agenda of an upcoming association meeting includes doubtful subjects, check with your supervisor before attending.

- Advise your supervisor or a member of the Compliance Committee promptly of any activity of an association that appears to be illegal or even suspicious.

## Political Contributions and Personal Causes

Company funds, products, property or services may not be contributed to any political party or committee, or to any candidate for, or holder of, any office of any government. Exceptions to this rule are activities and solicitations related to ABIOMED's Political Action Committee ("PAC"). You should be careful to keep your personal political activities clearly separate from your position at ABIOMED and avoid any situation from which it might be inferred that you have undertaken such activities on behalf of ABIOMED.

Employees also may not use their position at ABIOMED to solicit, promote or enhance any personal activity or cause; that is, you are not to request or induce any individual or entity to contribute to or support a cause based on your status as an ABIOMED employee.

ABIOMED participates in the political process through our Government Affairs office and our PAC to promote issues that are important to our company, our stockholders and the community we serve. Through our participation we ethically and constructively promote legislative and regulatory actions that further medical technology innovation and the business objectives of ABIOMED at all levels of government. We are subject to regulation at both the federal and state levels.

There are extensive statutory and regulatory restrictions governing interaction with federal government officials and Members of Congress and their staff. In connection with federal reporting requirements, ABIOMED is required to disclose and make semi-annual certifications regarding our compliance with federal rules related to activities and contributions to covered U.S. Congressional officials and employees. Accordingly, and as described above, ABIOMED employees may not provide a gift, meal, entertainment, travel or anything else of value to a Member or staff of the U.S. Congress and to officials and employees of the federal Executive Branch.

In addition to this semi-annual certification, ABIOMED must report on a semi-annual basis any contributions that were made to an event that honors or recognizes a Federal official, or, to entities established, financed, or controlled by a Federal official. While there are minor exceptions to these rules, nothing of value should be ever provided to or in honor of a congressional or executive branch official or staff member without first consulting with Government Affairs or Legal.

By review of these procedures you are certifying that you have not made any such contributions in the capacity as an ABIOMED employee. If you have a question or have made a contribution, please reach out to ABIOMED Government Affairs or Legal for guidance.

## Insider Trading

ABIOMED expressly forbids you from trading on material non-public information or communicating material non-public information to others. Such conduct, which is illegal, is frequently referred to as "insider trading." This policy applies to every associate of ABIOMED and extends to activities both within and outside their duties to ABIOMED, including trading for a personal account.

For further guidance, please review carefully ***ABIOMED's Policy on Securities Trades by Company Personnel in the Employee Handbook***.

## Equal Employment Opportunity and Workplace Harassment

ABIOMED is committed to a work environment free from all forms of discrimination and unlawful harassment, including sexual harassment. ABIOMED will not tolerate unlawful discrimination or harassment in the working relationships between ABIOMED employees and applicants, customers, vendors, and others with whom contact is necessary to perform company business. For more information, please see ***ABIOMED's Non-Discrimination and Non-Harassment Policy in the Employee Handbook***.

## Health, Safety and Environmental Laws

Health, safety, and environmental responsibilities are fundamental to ABIOMED's values. Employees are responsible for ensuring that ABIOMED complies with all applicable provisions of the health, safety, and environmental laws of the United States, any states and of other countries where ABIOMED does business. The penalties that can be imposed against ABIOMED and its associates for failure to comply with health, safety, and environmental laws can be substantial, and include imprisonment and fines.

## Lawful Promotion

The FDA oversees the public health by assuring the safety and effectiveness of drugs and medical devices marketed in the United States. In fulfilling this responsibility, the FDA regulates how these products are labeled and promoted.

ABIOMED is bound by federal law to secure the approval or clearance of its products by the FDA. Prior to marketing or promoting a product, ABIOMED provides the FDA with evidence of the safety and effectiveness of the product for a specific use or uses. The product then receives FDA approval or clearance on the basis of this evidence, and the approved uses or indications are listed in the product labeling.

For example, in March 2015, the Impella 2.5™ heart pump received Premarket Approval ("PMA") from the FDA for its use in treating patients undergoing high-risk percutaneous coronary intervention procedures. Subsequently, the Impella CP® heart pump received Pre-Market Approval for the same indication in December 2016. That PMA approval reads as follows:

> The Impella 2.5 and Impella CP Systems are temporary (≤ 6 hours) ventricular support devices indicated for use during high risk percutaneous coronary interventions (PCI) performed in elective or urgent, hemodynamically stable patients with severe coronary artery disease and depressed left ventricular ejection fraction, when a heart team, including a cardiac surgeon, has determined high risk PCI is the appropriate therapeutic option. Use of the Impella 2.5 and Impella CP in these patients may prevent hemodynamic instability which can result from repeat episodes of reversible myocardial ischemia that occur during planned temporary coronary occlusions and may reduce peri- and post-procedural adverse events.

Similarly, in April 2016, the Impella 2.5, Impella CP®, Impella 5.0™, and Impella LD™ devices received PMA approval from the FDA for use in treating patients experiencing the emergent condition of cardiogenic shock following a heart attack or heart surgery. That additional PMA reads as follows:

> The Impella 2.5™, Impella CP®, Impella 5.0™ and Impella LD™ catheters, in conjunction with the Automated Impella Controller, are temporary ventricular support devices intended for short term use (≤ 4 days for the Impella 2.5 and Impella CP, and ≤ 6 days for the Impella 5.0 and LD) and indicated for the treatment of ongoing cardiogenic shock that occurs immediately (< 48 hours) following acute myocardial infarction or open heart surgery as a result of isolated left ventricular failure that is not responsive to optimal medical management and conventional treatment measures.* The intent of the Impella system therapy is to reduce ventricular work and to provide the circulatory support necessary to allow heart recovery and early assessment of residual myocardial function.

* Optimal medical management and convention treatment measures include volume loading and use of pressors and inotropes, with or without IABP.

Although physicians can lawfully prescribe or use ABIOMED's products for unapproved or "off-label" indications, ABIOMED is prohibited from promoting its products for "off-label" indications and uses and is restricted in how it communicates with Healthcare Professionals and other customers about these uses.

All labeling, advertising, and promotional materials for ABIOMED Products must comply with the FDCA, FDA regulations and policies, and other applicable federal and state regulations and ABIOMED policies and procedures.

***Promotional Activities***

All ABIOMED Representatives, including but not limited to members of the Marketing and Commercial teams, Healthcare Solutions and medical and clinical staff, and third-party distribution providers must ensure appropriate and accurate promotion of all Company products. For purposes of this Policy, promotion may include any written, electronic, verbal or broadcast material that describes an ABIOMED Product and is distributed by, on behalf of, or at the request of, the Company – whether from the corporate office or from field-based personnel. This includes both general correspondence between individuals and corporate communications.

All promotional communications should be:

- *On-label* – For ABIOMED Products that are 510(k) and PMA devices, communications should be consistent with the device's cleared/approved indications for use and supported by the product's labeling ("on-label"). For 510(k)-exempt devices, communications should be consistent with claims permissible to maintain the device's 510(k)-exempt status.

- *Fair and Balanced* – Promotional communications that present product/device benefits should reveal material risk information to enable the recipient of the information to appropriately assess the product information presented. Accordingly, in promoting ABIOMED Products, ABIOMED Representatives should:

    - Not omit, dismiss, limit, diminish or minimize the importance of safety or risk information;
    - Match the effectiveness data from a particular study, patient population, or data set with the corresponding safety and risk information;
    - Neither pick and choose data (whether on product benefits, effectiveness, safety or risks) selectively ("cherry picking"), nor

lift partial statements from their original context in a manner that may distort their intended meaning.

- *Truthful and not misleading* – A "false or misleading" claim is a communication (whether express or implied) about an ABIOMED Product that is not supported by substantial evidence (generally, adequate and well-controlled clinical studies or FDA-approved data) or that fails to present all relevant data and context. For example, false or misleading claims can be self-evident exaggerations or overstatements (e.g, the "best" of a class) or conclusory statements that result from an over-interpretation of the data. Superiority and "best" claims are rarely permissible since such claims would require head-to-head clinical trials against most, if not all, competitors.

  In the context of publicly discussing "real-world" data, such as clinical data derived from ABIOMED's IQ Assurance Database, the Company must be careful to accurately characterize what the data is – and what it is not. When discussing such information, ABIOMED must clearly state that it is "observational" in nature, and that while it is useful in demonstrating clinical trends, it is not statistically powered or pre-specified, and is hypothesis-generating only.

- *Targeted to appropriate audience* – ABIOMED Representatives are to target all promotional communications only to Healthcare Professionals who are reasonably likely to use the ABIOMED Product for an FDA-cleared or approved (or other appropriate regulatory authority-approved, if outside the U.S.) use or to patients or caregivers interested in the FDA-cleared or approved use.

***Statements about Competitors' Products***

ABIOMED Representatives may not make false or misleading statements about a competitor's product(s). If an ABIOMED Representative is making a direct comparison of safety and/or efficacy between products or is asked a question about a competitor's product, the ABIOMED Representative should make such direct comparison using only information that is approved by the relevant approval team and that is supported by valid scientific evidence (generally head-to-head clinical studies or other FDA-approved scientific data).

ABIOMED Representatives are prohibited from making the following types of statements:

- Stating or suggesting that the absence of a particular hazard, contraindication, side effect or precaution on an ABIOMED Product's labeling or package in comparison to a competitor product has any clinical significance.

- Stating or suggesting that a lower price means that the device is more cost-effective, because cost effectiveness claims encompass more information than just price.

- Making general superiority claims about overall health benefits, improved quality of life, or comparative customer preferences.

***Activities Prior to FDA Clearance or Approval***

Commercialization and promotion of an investigational device prior to FDA clearance or approval is prohibited.

ABIOMED may publish press releases regarding uncleared products and uses for purposes of keeping the investment community informed, provided that such releases do not include conclusions or characterizations regarding the safety or effectiveness of the product and are not promotional in tone. Press releases regarding uncleared products should not be distributed with promotional materials, in a promotional context, or by ABIOMED Sales or Marketing personnel.

***Promotional Materials***

All labeling, advertising promotional or educational material, including but not limited to reprints, slides, computer presentations, audiovisual materials, reimbursement materials, materials for distribution at externally-focused training and programs, websites and branded press materials must be submitted for review and approval by the appropriate approval team before they may be distributed or utilized in any fashion. This includes materials that describe, refer to, or promote any ABIOMED Product created and/or intended to be distributed by Sales and Marketing personnel outside of ABIOMED. Consistent with this, during promotional activities, ABIOMED Representatives may not reference or show any materials not expressly approved for promotional use. When promotional materials are replaced or become out-of-date, ABIOMED Representatives should dispose of all expired items. As set forth more fully in ABIOMED's Standard Operating Procedures concerning the review and approval of company communicative materials, the requirement of review and approval before distribution does not apply to (1) corporate materials (such as press releases, securities filings, and investor-focused information) and (2) materials designed solely for internal use, and which do not contain any claims regarding ABIOMED devices and which do not instruct the ABIOMED commercial team on how to perform their sales function.

***Homemade Materials***

ABIOMED Representatives may not create their own "homemade" promotional materials, mention or make claims about ABIOMED Products in emails or other written communications with Healthcare Professionals, or alter ABIOMED-approved promotional materials (including highlighting or excerpting selected portions of approved materials).

***Use of Medical Literature / Reprints***

Certain peer-reviewed scientific articles that have been published in medical journals may be distributed to Healthcare Professionals by ABIOMED Representatives, provided they are approved for distribution by the appropriate approval team. Medical literature/reprints provided by ABIOMED should not be abridged, marked, highlighted, summarized, characterized or altered in any way. Additionally, medical literature/reprints provided by ABIOMED Representatives should be distributed separately from information that is promotional in nature.

***Prohibition on Off-Label Promotion***

ABIOMED sales force personnel and other commercial employees may not engage in discussions with customers or potential customers on unapproved or uncleared products, or unapproved or uncleared uses of currently marketed ABIOMED Products.

Sales representatives and marketing personnel also may not distribute articles or other materials discussing off-label uses, unless such articles were approved for distribution by the appropriate approval team and meet the requirements of the FDA's Draft Guidance, "Distributing Scientific and Medical Publications on Unapproved New Uses, Recommended Practices." Similarly, ABIOMED Representatives may not "encourage" discussions of off-label uses of its products at events or "plant" questions that are likely to lead to off-label conversations or information requests.

A sales representative who receives a request for off-label information must refer the inquiry to ABIOMED's Medical Affairs staff. If a Healthcare Professional raises an off-label question concerning one or more of the devices within the Impella® line of heart pumps, an ABIOMED Representative should:

- Inform the Healthcare Professional of the relevant device's approved indication for use, as well as the device's contraindications and safety information. A complete recitation of the labeling for all of ABIOMED's commercially saleable products is listed in Appendix B.

- Inform the Healthcare Professional that the requested use is considered off-label and that he or she cannot discuss Impella's use in that particular setting.

- In response, to a request for off-label information regarding one of ABIOMED's commercially saleable products, ABIOMED Representatives are permitted to provide the requestor with a copy of an approved, peer-reviewed scientific journal article that discusses the use, provided that the article is accompanied by the appropriate FDA disclaimer cover sheet and the Representative acts in accordance with this Code's requirements concerning the distribution of medical literature and reprints (See pages 26 and 34-37).

- Provide the Healthcare Professional with information on how to submit his/her question regarding the off-label use for a response to the appropriate ABIOMED party (normally the Chief Medical Officer, the Senior Medical Director, or a member of ABIOMED's medical/scientific staff).

# Use of Social Media
## Executive Summary

ABIOMED Representatives are permitted to share approved, branded content with colleagues who may wish to share such content within their own social networks. Such activity is voluntary and not required. In general, ABIOMED employees, contractors and interns are welcome to use social media while following simple but important guidelines. The purpose of this social media policy is to protect our employees and our company brand. These guidelines apply to all ABIOMED employees, interns, and contractors who use social media including, but not limited to, Twitter, Yelp, Wikipedia, Facebook, Snapchat, Instagram, etc. We encourage you to read the policy thoroughly.

- ABIOMED is responsible for all ABIOMED-sponsored social media communications. This includes (1) any presence, channel, platform, handle, or site that is hosted, created, organized, sponsored, controlled or otherwise influenced by or on behalf of ABIOMED ("ABIOMED social media sites").

- Profiles must disclose your affiliation, but express that your opinions are personal and are not attributable to ABIOMED. ***For example: "I work for ABIOMED. All opinions expressed are my own."***

- Be advised that it is permissible to share any content that is posted by ABIOMED on Protected PCI.com, the Impella App, @ProtectedPCI, @AbiomedImpella, @HeartRecoveryAdvocates or @MikeMinogueABMD. In liking or sharing, you may add brief, appropriate personal comments that are general in nature and conform to this policy (e.g., "Check out this post…"), but must not elaborate or opine on the topic of the communication.

- If you come across information at any time (including at times when acting in a personal capacity) that appears to be an adverse event or product complaint related to an ABIOMED product, you must immediately report such information within 24 hours to ABIOMED's Medical Affairs Department, by sending a message to medicalaffairs@abiomed.com or by calling the CSC at 1-800-422-8666.

- If you are contacted by a third party requesting comments on ABIOMED's business or products (e.g., inquiry from media, journalist, investor, blogger), direct all inquiries to the ABIOMED Senior Director, Corporate Communications, by emailing mediarelations@abiomed.com. Do not respond without written approval from ABIOMED.

If you have any questions at any time, please contact Adrienne Smith, ABIOMED Senior Director, Corporate Communications at adsmith@abiomed.com.

# Use of Social Media – Full Policy

Social media encompasses all means of communicating information or content on the Internet, including through digital/electronic media tools, platforms, forums, channels, and apps that are designed to encourage users to communicate, interact, and share content with other users ("social media"). Social media communications can take a variety of formats (e.g., text, photo, video, icon, audio) and functions (e.g., share, email, feeds, "like"). Examples of social media include, but are not limited to, Facebook, Twitter, LinkedIn, Instagram, Wikipedia, YouTube, Pinterest, blogs, personal websites, apps, bulletin boards, and customer review sites (e.g., Yelp).

Social media has become increasingly widespread and can play a vital role, not only in business communications, but educating Healthcare Professionals, patients and others about important health-related issues. As a general matter, social media communications made by ABIOMED Representatives about ABIOMED or its products may be subject to strict federal and state laws regarding medical device promotion. To help ensure that ABIOMED complies with applicable laws and regulations, ***ABIOMED Representatives must comply with the following principles and related policies and procedures in this Compliance Code.***

***ABIOMED Social Media Communications***

ABIOMED is responsible for all ABIOMED-sponsored social media communications. This includes any presence, channel, platform, handle, or site that is hosted, created, organized, sponsored, controlled or otherwise influenced by or on behalf of ABIOMED ("ABIOMED social media sites"). Such sites include, but are not limited to, Protected PCI.com and, cardiogenic shock.com, as well as the Impella "App". Additionally, ABIOMED sponsored social media communications include any communications made by or on behalf of ABIOMED for use on third-party social media sites, such as the ABIOMED and Protected PCI twitter sites (collectively, "ABIOMED-sponsored social media communications"). To be clear, social media communications include content and information made in various formats and functions, which include original communications and extend to making comments, responding to third party comments or questions, "liking" and "sharing" third party content, and "endorsing" individuals or entities.

All proposed ABIOMED-sponsored social media communications are subject to the Lawful Promotion policy in this Compliance Code, including but not limited to the requirements for Promotional Activities, Promotional Materials, and the Prohibition on Off-Label Promotion. Any comments or responses to comments on any social media site may be made in real-time using previously approved content and information, or at a later time using content and information that is specifically and separately approved. As set forth more fully in ABIOMED's Standard Operating Procedures concerning the review and approval of Company communications, the requirement of review and approval before distribution does not apply to ABIOMED-sponsored social media communications that consist of corporate materials (such as press releases and investor-

focused information), provided that the ABIOMED-sponsored social media communications are limited to ABIOMED social media sites.

All ABIOMED-sponsored social media communications ***must be accompanied by ABIOMED's name or corporate logo*** to clearly disclose the Company's involvement in the communication.

ABIOMED has designated certain ABIOMED Representatives to manage and engage in ABIOMED-sponsored social media communications. Such designated ABIOMED Representatives are the only individuals permitted to manage and engage in ABIOMED social media sites and ABIOMED-sponsored social media communications on behalf of ABIOMED.

***Personal Social Media Communications***

ABIOMED Representatives are permitted to use social media for personal purposes. However, in doing so ABIOMED Representatives should not create social media accounts or otherwise engage in social media communications that could appear to be sponsored by or made "on behalf of" ABIOMED, its products, or its business partners, unless authorized to do so.

Nothing in this policy is intended to interfere with, discourage, restrain, restrict or prevent communications or actions protected or required by any federal, state or local law, such as the U.S. National Labor Relations Act or similar laws in other countries. This includes, for example, employee communications regarding wages, hours or other terms and conditions of employment.

When a social media ***interaction includes or may include discussions or comments relating to an ABIOMED product or a competitor's product***, ABIOMED Representatives must comply with the following rules:

- Do not communicate about any ABIOMED marketed product, ABIOMED investigational product, or competitor product, including written or audiovisual content, unless such communication is approved by ABIOMED or otherwise permitted by this policy. This includes "liking," sharing, or posting links to third-party communications about any ABIOMED product or competitor product. Such communications may be considered product promotion by the government, meaning they are subject to all applicable rules and regulations regarding product promotion. Remember that there is no separation for others between your personal and business roles and keep in mind that colleagues, customers, Healthcare Professionals, competitors, patients, and consumers may have access to your social media communications and that such communications can easily be forwarded to and shared with a larger audience than originally intended.

- Audio or visual content, such as photos, images, videos, or audio recordings, from Company-sponsored, internal only events or activities should not be posted or shared in social media. This includes, for example, Company town halls, medical event booths, clinical investigator meetings, advisory board meetings, product training and education, and meetings in clinical settings. The exception is if such content is shared by ABIOMED owned channels (e.g. @AbiomedImpella) and therefore becomes approved, branded content suitable for sharing.

- ABIOMED Representatives are generally permitted to "like" or share ABIOMED-sponsored social media communications except for communications that focus on investigational products or unapproved uses of marketed products (e.g., press release announcing results of investigational product or use). Be advised that it is permissible to share any content that is posted by ABIOMED on Protected PCI.com, the Impella App, @ProtectedPCI, @AbiomedImpella, @MikeMinogeABMD or @HeartRecoveryAdvocates. In liking or sharing, you may add brief, appropriate personal comments that are general in nature and conform to this policy (e.g., "Check out this post…"), but must not elaborate or opine on the topic of the communication.

- If you receive an unsolicited request for off-label information on social media, you must follow the guidelines for public responses via electronic media outlets in the Responding to Request for Off-Label Information policy in this Compliance Code.

- Disclose your Company affiliation appropriately. If you communicate or otherwise share content on social media that relates to ABIOMED, or content that relates to your expertise in subject matters that are within the scope of your job responsibilities, you must clearly identify yourself as an ABIOMED Representative. ABIOMED Representatives should not anonymously post, share, edit, or endorse (e.g., Facebook "like") social media communications that relate to the Company or its products. Your profile must express that your opinions are personal and are not attributable to ABIOMED. For example: "I work for ABIOMED. All opinions expressed are my own."

- If you come across information at any time (including at times when acting in a personal capacity) that appears to be an adverse event or product complaint related to an ABIOMED product, you must immediately report such information within 24 hours to ABIOMED's Medical Affairs Department, by sending a message to medicalaffairs@abiomed.com or by calling the Customer Service Center at 1-800-422-8666.

- If you are contacted by a third party requesting comments on ABIOMED's business or products (e.g., inquiry from media, journalist, investor, blogger), direct all inquiries to the ABIOMED Senior Director, Corporate Communications, by emailing mediarelations@abiomed.com. Do not respond without written approval from ABIOMED.

When engaging in social media, ABIOMED Representatives must comply with the following general principles, regardless of whether communications are related to ABIOMED or its products:

- Do not engage with competitors.

- Do not post any images, or content that is taken from inside the hospital setting.

- Do not disclose confidential, proprietary, or private information of ABIOMED or any related entity, including but not limited to: trade secrets; financial information; performance metrics; strategies; or any other internal business-related confidential information.

- Do not infringe the privacy or business confidentiality of customers, employees, business partners, patients, or consumers, including but not limited to their names, contact information, medical information, or any other information that could be used, whether by itself or in conjunction with other information, to identify a particular individual or entity.

- Act in a professional manner at all times and do not transmit any material (by uploading, posting, emailing, or otherwise) that is unlawful, disruptive, threatening, profane, abusive, harassing, embarrassing, tortiuous, defamatory, obscene, libelous, or is an invasion of another's privacy, violates ABIOMED's policies against harassment and discrimination, or otherwise violates any ABIOMED policy or applicable law, as determined in ABIOMED's sole discretion. Examples of such conduct might include offensive posts meant to intentionally harm someone's reputation or posts that could contribute to a hostile work environment on the basis of race, sex, disability, religion or any other status protected by law or ABIOMED policy.

- Do not use social media to conduct or report ABIOMED personnel matters (e.g., references, referrals, or performance reviews concerning current or former employees, contractors, or vendors of ABIOMED), unethical or unlawful conduct related to ABIOMED, or violations of this policy or other Company policies.

- Recognize that any content you post on social media that damages ABIOMED's business or reputation will ultimately be your responsibility.

***Monitoring***

ABIOMED may authorize specific ABIOMED Representatives and/or third parties to monitor social media for content relating to the Company and its products. All monitoring will be reported to a designated ABIOMED Representative for evaluation for adverse events, product complaints, and other issues as they relate to an ABIOMED product.

If third party content posted on social media is found to contain inaccuracies, misstatements, or falsities about ABIOMED or its products, ABIOMED may, at its discretion, take reasonable steps to inform the applicable third party of such inaccuracies, misstatements, or falsities, request correction, and provide such third party with ABIOMED-approved information.

ABIOMED reserves the right to monitor, prohibit, restrict, block, suspend, terminate, delete, or discontinue your access to any social media using ABIOMED equipment or networks at any time, without notice and for any reason and in its sole discretion. As such, when using ABIOMED's equipment or networks, you should have no expectation of privacy with regard to time, frequency, content or other aspect of your use, including the sites you visit and other Internet/Intranet activity. ABIOMED also reserves the right to review your public online activity performed using the Company's equipment or networks.

***Reporting***

If you believe that you or any other ABIOMED Representative has made a social media communication, or used any social media site, in violation of this policy or any other Company policy, you must notify your supervisor, the Chief Compliance Officer, or the General Counsel immediately.

# Scientific Exchange

Medical and scientific communications play an important role in the education of Healthcare Professionals and the scientific and clinical community. These communications include communications concerning approved or cleared uses of our devices, clinical presentations, scientific publications, and information regarding unapproved or uncleared ABIOMED Products or Product uses. In certain limited, non-promotional activities and circumstances, ABIOMED may provide scientific information that is outside the scope of approved product labeling and cleared product indications under the principle of free and open scientific exchange.

***Conferences / Scientific Booths***

The exchange of scientific information by clinical investigators regarding investigational products should be limited to peer-review settings allowing for the balanced presentation of scientific information. A balanced presentation must also fully disclose the unapproved status of the product.

An uncleared 510(k) ABIOMED Product may be displayed or depicted at a conference or trade show booth, but orders may not be taken. Any display or depiction should be accompanied by a statement noting that the device is investigational, pending FDA clearance, and is not available for sale in the United States. Any discussion of the uncleared device with U.S. persons should be limited to a description of the device and how it operates, and should be fairly balanced. Discussions may not include statements or claims that the device is safe or effective and should not include comparisons to other devices. Display or depiction of PMA-pending devices is **not** permitted.

ABIOMED Representatives working at ABIOMED-sponsored booths at medical or scientific conferences or trade shows are **not** permitted to engage in the following activities:

- *Take Orders*. With respect to unapproved or uncleared products, ABIOMED Representatives may not take orders or be prepared to take orders.

- *Training/Demonstration*. ABIOMED and ABIOMED Representatives may not provide demonstration of hands-on training relating to uncleared or unapproved devices or uses.

- *ABIOMED-Commissioned Special Supplements / Publications*. ABIOMED Representatives are not permitted to provide copies of articles that are not purely independent or peer-reviewed, such as those commissioned by ABIOMED.

***Medical Literature and Reprints***

ABIOMED Representatives are permitted to disseminate certain peer-reviewed scientific articles regarding uncleared devices or uncleared uses of cleared devices that have been published in

medical journals. Scientific articles distributed by ABIOMED must be reviewed and approved in advance and must adhere to the guidelines set forth in FDA's Draft Guidance, "Distributing Scientific and Medical Publications on Unapproved New Uses – Recommended Practices."

In the normal course, approved medical articles and literature should be disseminated by ABIOMED Medical Affairs, however, ABIOMED sales force personnel ***are permitted*** to physically deliver such publications to Healthcare Professionals at a hospital, in the Professional's office, or at a medical or scientific conference in a setting appropriate for scientific exchange. To the extent approved medical articles and literature are distributed by ABIOMED sales force personnel, such personnel are permitted to introduce the medical article/literature to the Healthcare Professional, which necessarily may include explaining: the context of the article, the topic of the article, and the findings/conclusions that the article's authors ultimately reach in the publication. ABIOMED sales and marketing personnel, however, should not engage in a "discussion" of the article with the recipient. Accordingly, if there are questions from the physician about the article or publication, sales force personnel should direct those inquiries to the appropriate personnel in ABIOMED's Medical Affairs department.

When delivering a medical or scientific article to a Healthcare Professional, ABIOMED Representatives must always explain any significant adverse events or safety risks identified in the article and also draw attention to any known information that reaches a contrary conclusion. Much of that information is contained in the disclaimer page that accompanies every externally approved medical journal article.

Medical and scientific literature and reprints may never be attached to any promotional materials.

***Press Releases***

ABIOMED may publish press releases regarding uncleared products and uses for purposes of keeping the investment community informed, provided that such releases do not include conclusions or characterizations regarding the safety or effectiveness of the product and are not promotional in tone. Press releases should be directed to the relevant investment community and not to potential customers or mass media generally.

***Study Recruitment***

In certain limited, non-promotional activities and circumstances, ABIOMED may make known the availability of an investigational device (or unapproved/uncleared use of a marketed device) for the purpose of obtaining clinical investigators and/or patients to participate in a clinical study involving the device. Recruitment advertising may not include direct or implied claims or characterizations regarding the reliability, durability, dependability, safety, or effectiveness of the device for the use under investigation, and must include a prominent statement indicating that the device or use is investigational or unapproved. ABIOMED Representatives may not engage in any study recruitment without specific direction from the Compliance Committee.

## Responding to Requests for Off-Label Information

Within certain parameters, ABIOMED may respond to unsolicited requests for information regarding uncleared or unapproved devices or uncleared or unapproved uses for cleared devices.

***Unsolicited Requests vs. Solicited Requests***

Unsolicited requests and questions are those initiated by persons or entities that are completely independent from ABIOMED, and are not prompted or facilitated, in any way, by ABIOMED or an ABIOMED Representative. Examples of ***unsolicited requests*** include, but are not limited to the following:

- An individual calls or emails an ABIOMED Representative seeking information regarding an off-label use, and the request was not prompted by any promotional activities;
- An individual asks a question regarding an off-label use during a live presentation or event with other individuals in attendance;
- An individual asks a question regarding an off-label use at an exhibit during a trade convention.

ABIOMED Representatives, including ABIOMED consultants, may **not** solicit questions or requests for information regarding off-label uses. Solicited requests and questions are those prompted or facilitated in any way by ABIOMED or an ABIOMED Representative. Examples of impermissible ***solicited requests*** include, but are not limited to:

- An ABIOMED Representative mentioning an off-label use and inviting a Healthcare Professional to request more information;
- An ABIOMED Representative, including a paid speaker, presenting off-label use data at an ABIOMED promotional or educational event and attendees asking or submitting requests for more information;
- Inviting Healthcare Professionals or others to contact ABIOMED for more information regarding an off-label use or a "coming soon" use (e.g., a use or indication that is currently under a clinical investigation or in the FDA approval process or that of a similar regulatory authority);
- Encouraging product users to post videos regarding their own uses of an ABIOMED Product on a video-sharing website (such as YouTube.com);
- Sending out packets of information to known bloggers or online consumer reviewers and encouraging them to write about off-label uses; or

- Announcing results of a study on a social media site (e.g., Twitter, Facebook, etc.) and suggesting that the off-label use is safe and effective.

***Responding to Requests***

Requests for off-label information should be documented and directed to the appropriate Medical Affairs expert for fulfillment. Sales and Marketing personnel should not respond directly to requests for information regarding uncleared or unapproved ABIOMED Products, but are permitted to discuss, generally, the Product's cleared or approved capabilities and operational parameters.

Specifically, if a Healthcare Professional raises an off-label question concerning one or more of the devices within the Impella® line of heart pumps, an ABIOMED Representative should:

- Inform the Healthcare Professional of the relevant device's approved indication for use, as well as the device's contraindications and safety information. A complete recitation of the labeling for all of Abiomed's commercially saleable products is listed in Appendix B.

- Inform the Healthcare Professional that the requested use is considered off-label and that he or she cannot discuss Impella's use in that particular setting.

- In response, to a request for off-label information regarding one of Abiomed's commercially saleable products, Abiomed Representatives are permitted to provide the requestor with a copy of an approved, peer-reviewed scientific journal article that discusses the use, provided that the article is accompanied by the appropriate FDA disclaimer cover sheet and the Representative acts in accordance with this Code's requirements concerning the distribution of medical literature and reprints (See pages 26 and 34-37).

- Provide the Healthcare Professional with information on how to submit his/her question regarding the off-label use for a response to the appropriate ABIOMED party (normally the Chief Medical Officer, the Senior Medical Director, or a member of ABIOMED's medical/scientific staff).

Public responses via electronic media outlets should be limited to providing specific contact information (e.g., email, address, telephone) for ABIOMED Medical Affairs so individuals can follow up independently to obtain specific information about the off-label use. The public response should convey that the question pertains to an unapproved/uncleared use and should not include any off-label information. Representatives who provide public responses should disclose their title/position at ABIOMED. Public responses should not be promotional in nature or tone and should include a link or other mechanism for access to FDA-approved product labeling (package insert or patient labeling) but not links to promotional websites.

# Conduct of ABIOMED Representatives in Clinical Settings

It is generally appropriate for ABIOMED Representatives, if adequately trained, to be present in an operating room or other clinical setting where a procedure is being performed as a technical advisor on the use of ABIOMED Products during clinical procedures involving the use of such product.

All ABIOMED Representatives shall follow applicable regulations, restrictions or guidelines promulgated by the specific facilities where patient care is provided. In the event of a conflict between facility policies and requirements and this Policy, the more restrictive of the two shall apply.

***Training***

Prior to participating in any way in a clinical setting during a clinical procedure involving an ABIOMED Product with a live, human patient, the ABIOMED Representatives must undergo ABIOMED training regarding appropriate and inappropriate actions and statements in a clinical setting. At a minimum, for ABIOMED Representatives whose job duties and services require them to be in an operating room environment, such training will include guidance regarding: (1) the unauthorized practice of medicine; (2) providing clear identification of the ABIOMED Representatives to the clinical setting staff, the patient, and the patient's family; (3) maintenance of the sterile field; (4) permissible purposes and actions in the operating room; and (5) the confidentiality of Protected Health Information.

***No Unauthorized Practice of Medicine***

ABIOMED Representatives who will be present in a clinical setting during a clinical procedure involving the use of an ABIOMED Product with a live, human patient must do so in accordance with the relevant national and/or state provisions relating to the licensing or authorization to practice medicine. ABIOMED Representatives are prohibited from: (1) holding themselves out to a patient or the public generally as a physician or a medical professional; and (2) taking any actions that could reasonably constitute the practice of medicine. At no time should an ABIOMED Representative in the clinical setting physically touch a patient or manipulate or "reposition" an in vitro catheter. Physical manipulation of the AIC should always be done at the explicit direction of hospital staff. Accordingly, the actions and statements of ABIOMED Representatives in the clinical setting during a procedure should be limited to facilitating the use of the ABIOMED Product by:

- Assisting in ensuring that the ABIOMED Products are being used by a Healthcare Professional in a safe and appropriate manner. All decisions regarding the treatment of the patients ultimately rest with the treating physician;

- Providing guidance to hospital staff about proper sterilization and reprocessing of products and instruments as per ABIOMED Instructions for Use;

- Assisting a physician, physician's assistant, and/or nurses and technicians with identifying the appropriate ABIOMED instrumentation or disposable supplies that are required for a particular procedure; and

- Providing technical information pertaining to ABIOMED Products.

***No Off-Label Promotion***

ABIOMED Representatives are prohibited from encouraging or recommending off-label uses of ABIOMED Products with physicians. An off-label use is one that is not specifically indicated on the ABIOMED Product's FDA-cleared or FDA-approved (or other appropriate regulatory authority-approved, if outside the U.S.) labeling or packaging. However, if a physician has made the independent determination that he or she will use an ABIOMED Product in an off-label manner, and requests the technical assistance of an ABIOMED Representative during that procedure, the ***ABIOMED Representative is permitted to provide such technical assistance in the clinical setting to ensure the device performs as intended.*** Such technical assistance may necessarily include discussing and even demonstrating the use of the ABIOMED Product in that setting.

When an ABIOMED Representative is present in a clinical setting where an ABIOMED Product (i.e., Impella 2.5™, Impella 5.0™, Impella CP®) is to be used in an "off-label" manner, the Representative should:

- Inform the Healthcare Professional of the relevant device's approved indication for use, as well as the device's contraindications and safety information. A complete recitation of the labeling for all of Abiomed's commercially saleable products is listed in Appendix B

- Inform the Healthcare Professional that although the use in the intended procedure is off-label, that he or she is willing to provide technical and advisory assistance in the clinical setting to ensure the device performs as intended.

- Provide safety and risk information regarding the relevant ABIOMED Product.

***Assistance of Hospital Personnel***

ABIOMED Representatives must not, unless permitted by applicable law, custom and hospital policy:

- Perform or assist in any duty of a member of the hospital staff or a Healthcare Professional;

- Other than ensuring that the ABIOMED Product is being used appropriately and safely, make suggestions regarding the manner in which a physician or other Healthcare Professional performs or should not perform any particular aspect of a clinical procedure; or

- Offer an opinion as to how a physician or other Healthcare Professional assisting the physician should carry out any particular aspect of the procedure.

***Confidentiality of Health Information – HIPAA Compliance***

If present in a clinical setting during the use of an ABIOMED Product with a live, human patient, ABIOMED Representatives must adhere to applicable national, state and local laws and regulations relating to the confidentiality of Protected Health Information of the patient. ABIOMED Representatives should not use or disclose Protected Health Information for any other purpose.

***Notifications***

ABIOMED Representatives should provide notification and receive approval in accordance with clinical setting requirements, as appropriate, to the hospital or other health care facility where a procedure will take place regarding their presence in the clinical setting as a technical advisor on the use of ABIOMED Products during a procedure involving the use of an ABIOMED Product. Such notification should be made in conformance with hospital requirements and all applicable local laws and regulations.

## Prohibition on Entertainment

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

Accordingly, ABIOMED Representatives are prohibited from providing, paying for, or reimbursing, either from his or her own funds or from ABIOMED's funds, any Entertainment for any Healthcare Professional, regardless of value, or whether the Company has engaged the Healthcare Professional as a speaker or other consultant, or whether the Entertainment is secondary to an educational purpose.

Such prohibited activities include, but are not limited to, theater, sporting events, golf, skiing, hunting, and leisure and vacation trips.

## Providing Educational Items of Value

As a preliminary matter, certain U.S. states, such as Massachusetts and Vermont, have limitations or outright bans on providing any items of value to Healthcare Professionals licensed in those states. If you have a specific inquiry regarding interactions with Healthcare Professionals licensed in certain U.S. states, contact Associate General Counsel and Chief Compliance Officer Sean C. Flynn at **978-646-1701**, or a member of the ABIOMED legal department for further information.

***Permissible Gifts***

Generally, for Healthcare Professionals not licensed in states with specific limitations, ABIOMED may occasionally provide items to Healthcare Professionals that benefit patients or serve a genuine educational function for Healthcare Professionals. Such permitted items include, but are not limited to, educational brochures, journal reprints, textbooks, and anatomical models. Other than medical textbooks or anatomical models used for educational purposes, any such item should have a Fair Market Value of less than $100.00.

ABIOMED Representatives are also permitted to occasionally provide a Healthcare Professional with low cost branded promotional items (items typically with a value significantly less than $100) such as pens, notebooks, mugs or other similar, branded material.

***Prohibited Gifts***

Prohibited gifts include, but are not limited to:

- Items that are capable of use by a Healthcare Professional (or his or her family members, office staff or friends) for non-educational or non-patient related purposes.

  Examples of such prohibited items include, but are not limited to, DVD players, MP3 players, iPods, cameras and computers.

- ABIOMED Product, equipment, or product accessories or other non-educational items

  ABIOMED Representatives may not provide equipment, ABIOMED Products, or product accessories, such as the Automated Impella® Controller, to be used with ABIOMED Products and intended to facilitate or aid the Healthcare Professional's work free of charge.

- Personal gifts

  ABIOMED Representatives also may not provide any gift or item of value to a Healthcare Professional to acknowledge "life events" such as

weddings, births, anniversaries, or deaths. Examples of prohibited gift items include, but are not limited to, cookies, chocolates, wine, flowers, gourmet food items, gifts baskets, holiday gifts, or cash equivalents.

Unless approved in advance by the Compliance Officer or Compliance Committee, ABIOMED Representatives may not provide gifts or items of value to Healthcare Professionals, regardless of whether the gift is paid for or reimbursed using ABIOMED's funds or the personal funds of ABIOMED Representatives.

***No item must ever be offered to a Healthcare Professional with the intent to encourage referrals, purchases, orders, use, or recommendations of ABIOMED Products or ABIOMED Services.***

## Business Meals with Healthcare Professionals and the Payment of Travel Expenses for Healthcare Professionals

***Meals with Healthcare Professionals***

The principles provided in this section are meant to address any situation in which a Healthcare Professional is present at a meal with ABIOMED Representatives. Such events may include, but are not limited to, investigator meetings, one-on-one or small group dinners with a Healthcare Professional, meetings to discuss product features, contract negotiation meetings, consultant meetings, speakers' bureau programs, or business meals or events held in conjunction with third-party educational conferences and programs.

Business meals provided to Healthcare Professionals must be Modest and Occasional in nature. In addition, meals must comply with the following standards:

- *Informational Presentation*: The meal should be incidental to a *bona fide* presentation or discussion of scientific, educational or business information, and/or supporting medical research and education, and conducted in a manner conducive to the presentation of such information.

- *Value*: Business meals should be Modest in value. The cost for such meals (including any, taxes, gratuity, etc.) should not exceed the following:

  Breakfast: $50.00 USD per person
  Lunch: $50.00 USD per person
  Dinner: $150.00 USD per person

  If ABIOMED training and special event personnel with job responsibilities for coordinating events believe they are unable to comply with these limitations, a waiver must be obtained in advance from the appropriate ABIOMED departmental Vice President and Compliance Officer that provides justification for exceeding these limitations in advance of the event. Such exceptions will be available only in **limited** circumstances.

- *Venue*: The meal should be provided in a setting that is conducive to *bona fide* scientific, educational, or business discussions, such as the Healthcare Professional's place of business or a hospital setting. In some cases, however, the place of business or a hospital setting may not be available for, or conducive to, such scientific, educational or business discussions. ABIOMED recognizes that in other cases, it may be impractical or inappropriate to provide meals at the Healthcare Professional's place of business or in a hospital setting, including when it is necessary to discuss confidential product development or improvement information or where a

private space cannot be obtained on-site. In these circumstances, ABIOMED Representatives may provide meals to Healthcare Professionals at an out-of-office location conducive to informational exchange, such as in a restaurant or hotel.

- *Attendance*: ABIOMED may provide meals only to Healthcare Professionals who actually attend a business meeting. ABIOMED Representatives may not provide a meal for an entire office staff where everyone is not invited to attend the business meeting. Furthermore, ABIOMED may not provide a meal where ABIOMED Representatives are not present for the duration of the meal.

- *Guests*: ABIOMED Representatives may not pay for meals for guests or spouses of Healthcare Professionals or for any other person who does not have a *bona fide* professional interest in the information being shared at the meeting.

It bears note that certain states, including Massachusetts and Vermont, have enacted restrictions on the provision of meals to Healthcare Professionals licensed in those states that are more limiting than otherwise permitted by these principles. In states that are more restrictive, state requirements must be followed.

***Travel for Healthcare Professionals***

ABIOMED may pay for or reimburse Healthcare Professionals for necessary and reasonable travel-related expenses incurred by a Healthcare Professional, which are related to his/her performance of services for ABIOMED or for ABIOMED business at the Company's request, including travel to events such as Company-conducted product training and education; sales, promotional and other business meetings; consultant meetings; and third-party educational conferences. Payment for, or reimbursement of, travel-related expenses to individuals or entities must be limited to those individuals for whom there is a *bona fide* documented, reasonable business purpose for such travel.

Travel expenses are **not** allowed for:

- Potential customers for purely promotional purposes, other than for product demonstrations or plant tours;

- Attendance at educational conferences or professional society meetings, unless serving as an ABIOMED consultant or speaker at such event; or

- Spouses or guests of a consultant or other Healthcare Professional or any other person without a *bona fide* professional interest in the information being shared.

***Air Travel***

ABIOMED may provide Coach/Economy class airfare for Healthcare Professionals who are traveling domestically for a reasonable ABIOMED business purpose and in accordance with ABIOMED policies and procedures, such as attending an ABIOMED Product training event, factory tour, installation, or meeting at ABIOMED Headquarters, or in association with providing services to ABIOMED pursuant to a written agreement, such as attending an advisory board meeting. If the length of the domestic flight is three hours or more, ABIOMED may provide Premium Coach/Economy (if available), but not First Class or Business Class, airfare. ABIOMED may provide Business Class airfare for those Healthcare Professionals who are required to travel internationally or if the duration of the flight is five hours or more.

Healthcare Professionals who choose to extend travel dates before or after an ABIOMED training course or consulting engagement to allow for personal travel must do so at their own expense.

***Ground Transportation***

Reimbursement for ground transportation costs (such as taxi, bus, train, subway fare, parking and mileage) incurred by Healthcare Professionals is generally appropriate and must be reasonable and necessary for the conduct of ABIOMED business. A receipt is required for reimbursement of expenses.

***Lodging***

Any meeting facility or hotel where Healthcare Professionals will be lodged at ABIOMED's expense must be reasonable and appropriate to the business purpose.

Lodging reservations may be made for the night prior to a morning meeting to accommodate the Healthcare Professional's reasonable and timely travel to the program. An additional night of lodging after the conclusion of the program may also be reimbursed, if the additional night is required due to flight and other travel constraints.

***Spouses/Guests***

ABIOMED will only pay for or reimburse the travel-related expense for individuals who are performing services on behalf of ABIOMED or have a *bona fide* business purpose for such travel. ABIOMED will not pay travel-related expenses for a spouse or other guest of a Healthcare Professional.

For more information regarding the provision of meals and travel for Healthcare Professionals please consult the *"Meal Scenarios Chart"* included herein.

ABIOMED Representatives who are unsure whether they may provide or pay for a certain item/event/travel arrangement for a Healthcare Professional in accordance with this Policy

should contact a member of the ABIOMED Compliance Committee or the Chief Compliance Officer **prior to** offering or furnishing such items to Healthcare Professionals.

## ABIOMED Product Training and Education

ABIOMED recognizes that it has a weighty responsibility to make quality training and detailed education on its products and medical technologies available to Healthcare Professionals who may use those products. Indeed, the FDA mandates training and education to facilitate the safe and effective use of certain medical technologies. Accordingly, ABIOMED may provide to Healthcare Professionals training on the safe and effective use of ABIOMED Products (e.g., hands-on training sessions), and educational programs providing information concerning or associated with ABIOMED Products (e.g., disease state presentations, cadaver workshops, lectures and presentations and grand rounds, etc.). ABIOMED product training and education programs must comply with the following standards:

- *Appropriate business purpose and documentation*: The *bona fide* commercial business, clinical purposes, goals and objectives, and agenda of each product training or educational program must be clearly established and documented in writing before any attendee is invited to participate and before any location is selected for the program. The documentation should explain how the program will satisfy a legitimate business need that was identified through the annual needs assessment (including any duly executed amendment or supplement thereto).

- *"On-Label"*: All training and education programs must be intended to train or educate Healthcare Professionals in a manner consistent with the approved or cleared product labeling. In addition, if another manufacturer's product is discussed during a training or education program, any discussion of such product, including its use during a particular procedure in which an ABIOMED Product is also used, must be consistent with its product labeling.

- *Venue*: Training and education activities should be conducted in settings that are conducive to the effective transmission of information. These may include clinical, educational, conference or other settings, such as hotels or other commercially available meeting facilities. In some situations, it will be appropriate for ABIOMED Representatives to provide training and education at a Healthcare Professional's location. Generally, venues should be located in cities that are (1) reasonable in proximity to the places of business of the Healthcare Professionals attending; (2) centrally located with easy travel access and reasonable travel and Modest lodging available or other reasonable location convenient to a large number of the attending Healthcare Professionals; or (3) ABIOMED's place of business.

  ABIOMED will not take into account the value of referrals or other business generated by a particular facility when selecting venues for ABIOMED Product training and education programs. ABIOMED will maintain written agreements with all training facilities that have been

provided ABIOMED Products for the purposes of conducting ABIOMED training programs, if such products will be stored at the facility. The written agreement should clearly articulate the basis for the faculty's use of any such products that will be stored at the facility, including that such products may be used solely for the purpose of conducting ABIOMED training programs.

In addition, even if the Company is not providing ABIOMED Products to a training facility (because the facility will use its own products during training programs), ABIOMED should obtain express permission to conduct the training at the facility, which permission may be granted through written agreement or other form of documentation.

- *Hands-on Training and Faculty*: Programs providing "hands-on" training on ABIOMED Products should be held at training facilities, medical institutions, laboratories or other appropriate facilities. Any training staff used by ABIOMED should have the proper qualifications and expertise to conduct such training. Training staff may include qualified field sales or clinical employees who have the technical expertise to perform the training. Training staff and faculty must not be selected based on the actual or potential volume or value of ABIOMED Products used, ordered, or recommended by the proposed trainer or faculty member.

  When using consultants, ABIOMED may compensate faculty (including trainers and speakers), except in limited circumstances. Compensation should only be at rates that do not exceed Fair Market Value of any such commercially reasonable services furnished to ABIOMED. ABIOMED will negotiate any such arrangements at arms-length and maintain written agreements with all service providers (including speakers, faculty, and trainers). Such agreements generally should adhere to the provisions of the ABIOMED Policy concerning Healthcare Professional Consulting Arrangements.

- *Selection of Invitees*: Selection and invitation of Healthcare Professionals to attend an ABIOMED Product training or education program must be limited to individuals for whom there is a *bona fide* business or scientific purpose for attendance, consistent with the written goals and purpose of the training program. ABIOMED Representatives are prohibited from inviting Healthcare Professionals if there is not a *bona fide* business or scientific purpose for having such individuals attend the ABIOMED Product training or education program.

- *Meals, Refreshments, and Expenses*: ABIOMED may provide Healthcare Professionals attending a training or education program with Modest meals and refreshments, so long as such meals and refreshments are subordinate in time and focus to the educational purpose of the program,

and comply with applicable state law requirements. In addition, as necessary, ABIOMED may cover and/or reimburse reasonable and necessary travel and lodging costs of Healthcare Professionals attending an off-site product training program. For overnight stays, a substantial amount of the business day must be allocated to training and education, and/or round-trip travel must not be practical within a single day.

- *Vermont* requires that any reasonable meals, travel, or lodging costs provided to Healthcare Professionals licensed in that state in connection with device training programs be described in a ***written agreement***.

  For more information regarding the provision of meals and the rules applicable to various situations in which ABIOMED may provide meals to Healthcare Professionals, please consult the *"Meal Scenarios Chart."*

- *Prohibited Compensation and Reimbursement*: Under no circumstances should a Healthcare Professional be provided compensation for their time required to attend a training or education event (with the exception of a consultant providing services to the Company in connection with the event and as specified in a written agreement).

- *Guests*: It is not appropriate for ABIOMED to pay for meals, refreshments, travel or other expenses of guests of Healthcare Professionals or for any other person who does not have a *bona fide* professional interest in the information being shared at the program.

- *No Entertainment*: Training and education activities must not include Entertainment of any kind.

- *Involvement of Sales and Marketing Personnel*: ABIOMED Sales and Marketing personnel may assist in planning ABIOMED Product training and education programs, including identifying Healthcare Professionals that have a *bona fide* business or scientific purpose for attending a program and working with those individuals to make necessary travel arrangements, and assisting with preparing a facility and administering a program.

  In the event Sales and Marketing personnel necessary for a program are traveling with a Healthcare Professional to an out-of-town training program, they must strictly comply with all ABIOMED policies and procedures that govern interactions with Healthcare Professionals, including policies and procedures on the provision of meals and prohibitions on Entertainment and the provision of items or services that do not serve a genuine educational function.

## Educational Grants and Support for Third-Party Educational Conferences, including CME

ABIOMED may elect to support *bona fide* independent, educational projects, including scientific and policymaking conferences that promote scientific knowledge, medical advancement and the delivery of effective healthcare. These typically include conferences sponsored by national, regional, or specialty medical associations and conferences sponsored by accredited continuing medical education providers.

Some examples of third-party training and medical education events organized by Healthcare Professionals or medical education providers that, if approved, may be financially supported by ABIOMED through grants, generally include:

- Congresses, conferences and professional meetings organized by national, regional or specialty medical associations or conferences;

- Fellowship programs organized by academic medical centers or medical schools that enable Healthcare Professionals in training to train in clinical settings or work on special projects;

- Continuing medical education programs including programs provided in accordance with the ACCME Standards for Commercial Support (or other similar commercial support standards of an appropriate accrediting body), that are organized by academic medical centers, medical schools, and hospitals that are accredited educational providers;

- Training programs for qualified attendees, such as workshops and in-services, that are organized by academic medical centers, medical schools, or other training institutions; and

- Roundtables or discussion groups, such as grand rounds events, that advance medical education and/or understanding of disease states or technology which may be of interest to ABIOMED that are hosted by academic medical centers, medical schools, or other training institutions, and are generally open to qualified attendees.

The following standards apply to the Company's support of or participation in *bona fide* independent, educational, scientific, and policymaking conferences:

- *Funding Recipients*: ABIOMED may provide a grant only to organizations with a genuine educational function. The conference sponsor should independently control and be responsible for the selection of program content, faculty, audience, educational methods, materials, and venue. ABIOMED may not be involved in selecting these aspects of a particular conference, even if the conference sponsor requests the

assistance of ABIOMED. In addition, ABIOMED may not provide educational conference funding (1) to an individual, including a physician; (2) in a manner designed to benefit or support the education of specific individual Healthcare Professionals (such as a hospital to provide training to its own staff, or to support the travel of a particular physician to an educational program); (3) to a physician practice or group; or (4) to an organization on the HHS OIG List of Excluded Individuals and Entities, the U.S. General Services Administration (GSA) Excluded Parties List System or the U.S. Food and Drug Administration (FDA) Debarment List. All grant funding must come from an approved ABIOMED budget**.**

- *Amount of Funding*: ABIOMED should establish and maintain an educational grant budget on an annual basis. The amount of any particular grant should be limited to a reasonable estimate of the costs of the grant-funded activities. ABIOMED will not make any educational grant that would cause ABIOMED to exceed its annual budget for such grants, as it may be amended, unless it is approved in writing by the appropriate departmental approver. The amount of any funding provided by ABIOMED to any particular recipient may not be based on, or related to, the past, present or future volume or value of business generated for ABIOMED by that recipient or the anticipated volume or value of business to be generated by the medical resident, intern, fellow, or other individual who may benefit from the grant.

- *Use of Funding*: Educational conference funding may be used to support only the legitimate expenses for *bona fide* educational activities and should be consistent with applicable standards established by the conference sponsor and the body accrediting the educational activity, if applicable. Under no circumstances may ABIOMED offer an educational grant/funding to induce the use, purchase, or recommendation of ABIOMED Products by a Healthcare Professional.

  Educational conference funding may be used to (1) reduce conference costs, (2) support the provision of meals and refreshments to conference attendees; (3) allow attendance by medical students, residents, fellows, and others who are Healthcare Professionals in training (so long as the conference sponsor or training institution selects the beneficiaries of the funding), and (4) for reasonable honoraria, travel, lodging, and Modest meals for Healthcare Professionals who are *bona fide* conference faculty members.

  ABIOMED may not direct a grant to an organization designated for a specific faculty member or directly pay an individual faculty member with a grant. ABIOMED funding may **not** be used to: (1) pay for or reimburse the costs of travel, lodging, or other personal expenses of *non-faculty* Healthcare Professionals attending the program; (2) compensate Healthcare Professionals for time spent attending the program; or (3) provide payment

directly to speakers, trainers and/or faculty for fees, costs, or expenses associated with the presentation at the educational event or program.

- *Independent Programming / Content*: The entity/organization that is the recipient of an ABIOMED educational grant/funding must maintain **full control** over the disposition and disbursement of financial support, including the selection of the individuals that will benefit from the grant (e.g., the fellows that will be supported by a grant, the residents that will attend the workshop, etc.), course work, content, faculty, educational methods, materials, and venue for the education program and the disbursement of financial support provided by ABIOMED. ABIOMED Representatives may **not** assist the grant recipient organization with the selection of the fellow, audience, content, faculty or venue, and may not be involved in developing materials for the program, even if the grant recipient requests or permits such ABIOMED involvement.

- *Written Agreement*: The Company's support for such activities must be documented in a written letter of agreement between ABIOMED and the funding recipient.

- *Associated Meals*: ABIOMED may provide funding to a conference sponsor to support the provision of meals and refreshments to conference attendees. In addition, ABIOMED may provide meals and refreshments for Healthcare Professional attendees if such meals and refreshments are provided: (1) to all Healthcare Professional attendees (unless the meal is provided in accordance with the principles set out in ABIOMED's Meals Policy, and its associated policies and procedures), and (2) in a manner that is consistent with applicable standards established by the conference sponsor and the body accrediting the educational activity, if applicable. Any meals and refreshments should be Modest in value, subordinate in time and focus to the purpose of the conference, clearly separate from the continuing medical education portion of the conference, and provided consistent with applicable state law.

  For more information regarding the provision of meals and the rules applicable to various situations in which ABIOMED may provide meals to Healthcare Professionals, please consult the *"Meal Scenarios Chart."*

- *Compliance with Rules of the Accrediting Body*: ABIOMED professional education programs for which continuing education credit is available must be conducted strictly in compliance with the rules and guidelines of the accrediting body.

- *No Return on Investment Analysis*: All educational funding is solely for beneficent purposes. ABIOMED may not conduct a return on investment (ROI) or similar analysis of educational grant programs, or assess the

impact of such programs on the prescribing or recommending practices of attendees or faculty.

- *Other Conference Support*: ABIOMED may purchase advertisements and lease booth space for ABIOMED displays at third-party educational conferences in accordance with the principles set forth in the ABIOMED Policy on Convention/Conference Sponsorships and Promotional Booths.

***Approvals***

All educational grants and support for third party educational activities must be approved in advance, in writing, by the ABIOMED Grants Committee. Requests for approval must identify the requesting grant recipient, the proposed amount of the educational grant, the specific type of education or training to be provided to the recipient, how the grant is applied, and the stated purpose or benefit of the educational opportunity. Neither the eligibility for, nor the approval of, any educational grant provided by ABIOMED to any particular recipient will be based on the past, present or future volume or value of business generated for ABIOMED by that recipient. Approved requests must be within the ABIOMED annual budget, as it may be amended, for educational grants.

The ABIOMED Grants Committee will not approve any educational or fellowship grant that is designed or specifically intended to: (1) reward a Healthcare Professional for using, ordering or recommending ABIOMED Products; (2) induce a Healthcare Professional to generate business for ABIOMED; or (3) induce a medical resident, intern or fellow to use or recommend ABIOMED Products.

Prior to entering into any arrangement to provide an educational grant to a recipient, the recipient must have received any necessary approvals or authorizations from the appropriate national, regional or state authorities (if any), as may be required.

***Roles of Sales and Marketing Personnel***

Upon request by the Grants Committee, ABIOMED Sales and Marketing personnel may provide input about the suitability of a proposed grant recipient or grant-funded fellowship program, but Sales and Marketing personnel should neither control nor unduly influence the decision of whether a particular entity or organization will receive a grant, or the amount of such grant. All inquiries and decisions will be made solely by the ABIOMED Grants Committee.

## Advertising and Booth Space at Conferences

ABIOMED may purchase advertisements or lease booth space for ABIOMED displays at third-party educational conferences and other third-party programs attended by potential customers or prescribers of ABIOMED Products or ABIOMED Services who are independent of the third-party program host/sponsor/organizer, provided that such advertisements and booths serve a legitimate business purpose of ABIOMED and that ABIOMED pays no more than Fair Market Value for the advertising or booth space. ABIOMED may not purchase booth or display space from a customer or Healthcare Professional for an event where the event is not open to attendees who are not employees or contractors of that same customer or Healthcare Professional.

***Documentation***

ABIOMED's commercially reasonable business purpose, goals and objectives, including what will be obtained by ABIOMED through the promotional opportunity (e.g, booth space with access to 5,000 Healthcare Professionals or advertising rights in an event publication with a circulation of 10,000) should be clearly documented in advance and approved by the appropriate ABIOMED management before any commitments are made or expenses are incurred.

Additionally, payments for booth space should be made in accordance with the terms of a written agreement.

***Travel, Hospitality and Entertainment***

ABIOMED may only seek marketing and promotional opportunities with Healthcare Professionals at conventions and other promotional events (such as purchasing certain naming rights, advertising rights and/or booth space in association with such events) in order to further the Company's commercially reasonable business purposes, goals and objectives. As noted above, any expenditures for such opportunities must be based solely on the Fair Market Value of the booth, advertising space, naming rights or other opportunity, and not take into account the costs of any meals, hospitality, or other benefits that may be provided to attendees as part of the convention or promotional event. Securing sales or potential sales of ABIOMED Products to the convention/conference or promotional event host is **not** a commercially reasonable business purpose. No fees paid by ABIOMED should be designated in any way for the use or deferment of expenses for particular Healthcare Professionals attending the event.

***Promotional Materials***

At ABIOMED promotional exhibits, all written materials and communications should be on-label, fair and balanced, and targeted only at Healthcare Professionals who are reasonably likely to prescribe or use ABIOMED Products for uses approved or cleared by the FDA (or other appropriate regulatory authorities, if outside the U.S.). All ABIOMED marketing and promotional activities at conventions and other promotional events must be approved in advance in accordance with ABIOMED's policy and procedure concerning promotional materials.

***Items of Value***

At promotional exhibits, ABIOMED Representatives may only Occasionally provide Healthcare Professionals with items that: (1) serve a genuine educational function; or (2) benefit patients, and are provided in strict accordance with the ABIOMED Policy on Items Provided to Healthcare Professionals.

*No such items must ever be offered to a Healthcare Professional with the intent to encourage, or modify referrals, purchases, orders, use or recommendation of ABIOMED Products or ABIOMED Services.*

***Requests for Off-Label Information***

Requests for information regarding unapproved uses of ABIOMED Products should be directed to the Medical Affairs Department, as is more fully set forth in ABIOMED's Policy Responding to Requests for Off-Label Information.

# Research Grants

It is generally appropriate for ABIOMED to provide support for scientific or medical-related research to non-profit, charitable research institutions, including hospitals, universities and medical schools, in the form of research grants to support specified legitimate independent medical research activities that have scientific or clinical merit related to ABIOMED Products or in disease state areas where ABIOMED has an interest in supporting important research. Any such research grant made by ABIOMED must be given to the non-profit charitable research institution itself (and not to a specific individual or clinical department), by providing the grant to the department or office of the institution that is authorized to accept charitable donations. No research grants may be provided directly to a Healthcare Professional that is an individual or a physician practice or may be designated to support the research of a specific individual Healthcare Professional or physician practice. Additionally, ABIOMED should ensure that the organization to receive the research grant is not on the HHS OIG List of Excluded Individuals and Entities, the U.S. General Services Administration (GSA) Excluded Parties List System or the U.S. Food and Drug Administration (FDA) Debarment List.

*Research grants may not be provided in exchange for purchasing, referring or using ABIOMED Products or ABIOMED Services or to reward the past use or purchase of ABIOMED Products or ABIOMED Services*.

***Research With Defined Goals, Objectives and Milestones, Which Has Scientific Merit Related to ABIOMED Products***

All research grants made by ABIOMED to non-profit charitable research institutions must be made solely to support specified genuine medical research with a *bona fide* medical purpose, which has defined goals, objectives and milestones. In addition, all such grants should be for research that relates in some manner to ABIOMED Products or procedures involving ABIOMED Products or products in development.

***Amount and Form of Research Grant***

ABIOMED will develop an annual budget for research grants. Absent the appropriate ABIOMED approvals, the amount of all research grants must fit within the annual research grant budget. The amount of any research grant provided by ABIOMED to any particular research institution will not be based on the past, present or future volume or value of business generated for ABIOMED by that research institution.

Research grants may be provided in monetary form, through a loan of ABIOMED Products or through free or reduced-charge ABIOMED Products.

***Approvals***

All research grants made by ABIOMED should be approved in advance, in writing, in accordance with the approval process set forth in ABIOMED's research grants procedure.

Grants may not be contingent upon factors such as past or future purchases, referrals, or recommendations of ABIOMED Products or Services. ABIOMED will not approve any research grant that is designed or specifically intended to: (1) reward a Healthcare Professional for ordering products from ABIOMED; or (2) induce a Healthcare Professional to order products from, or generate business for, ABIOMED.

Prior to providing a research grant to a research institution that is a Healthcare Professional, the Healthcare Professional and/or ABIOMED, as appropriate, must have received any necessary approvals or authorizations from the appropriate national, regional or local authorities, and/or institutions (if any), as may be required.

The Company's Research Grants must be documented in a written agreement between ABIOMED and the grant recipient.

***The Role of Sales and Marketing Personnel***

ABIOMED Sales and Marketing personnel may provide input about the suitability of a proposed grant recipient or program, but Sales and Marketing personnel should neither control nor unduly influence the decision of whether a particular Healthcare Professional or institution will receive a research grant or the amount of such grant. All inquiries and decisions will be made solely by the ABIOMED Grants Committee in accordance with policies that guide the Committee.

***In-Kind Research Grants of ABIOMED Products***

In addition to the information required for approval of all research grants, in-kind research grants of ABIOMED Product also require the potential grant recipient to certify that:

1. The grant recipient does not intend to use the provided ABIOMED Products for commercial purposes, and will not sell or trade such products for financial or commercial gain;

2. The grant recipient can and will use the provided ABIOMED Products in a safe and appropriate manner; and

3. The grant recipient will only use the provided ABIOMED Products in conjunction with the identified research activity, and not for other research activities or to supplement inventory for patient use.

# Charitable Donations

ABIOMED may provide monetary or product donations to charitable organizations for charitable purposes, such as supporting indigent care, patient education, public education or the sponsorship of events where the proceeds are intended for charitable purposes consistent with the charitable mission of the recipient organization.

Donations should be made only to organizations recognized as charitable organizations by an appropriate governmental authority, such as organizations recognized by the United States Internal Revenue Service as tax-exempt under Section 501(c)(3) of the Internal Revenue Code (as documented by the organization's Section 501(c)(3) determination letter from the Internal Revenue Service) or local or community-oriented non-profit organizations that do not have a formal status as a Charitable Organization, but are not in a position to generate or influence business for ABIOMED (such as children's sports leagues or other community activities). ABIOMED will not make charitable donations or in-kind donations to individuals or religious groups for religious purposes.

Prior to making the donation, ABIOMED should obtain documentation from the Charitable Organization that substantiates its charitable status, or from the local or community-oriented non-profit that substantiates its non-profit/community oriented status. ABIOMED also must confirm that the organization to receive the charitable donation is not on the HHS OIG List of Excluded Individuals and Entities, the U.S. General Services Administration (GSA) Excluded Parties Lists System or the U.S. Food and Drug Administration (FDA) Debarment List.

Any charitable donations or in-kind donations made by ABIOMED must be unrestricted and given to the non-profit, Charitable Organization or the local or community-oriented non-profit as a whole and not directly to a particular employee, program, department, or other individual or entity affiliated with the Charitable Organization.

***Charitable Purpose***

All charitable donations or in-kind donations made by ABIOMED must be made solely for *bona fide* charitable reasons. Under no circumstances may ABIOMED offer a charitable donation or in-kind donation in return for, or any way tied to, the receipt of some form of consideration to ABIOMED (including actual or implied agreements from the recipient or a related party to purchase, use, order or recommend ABIOMED Products). Charitable donations may not be intended as a price term or offered in place of a price concession or discount, unless required by a public request for proposal (RFP) issued by a government-run hospital or health system.

***Charitable donations must not be conditioned on or in any way tied to the use, purchase, or referral of any ABIOMED Products or ABIOMED Services.***

To avoid any appearance of impropriety, charitable donations to Charitable Organizations generally should not be made contemporaneously with contract negotiations.

Any benefit incidental to a charitable donation (e.g., a table at an event, seats at an award dinner, etc.) may not be offered or provided to a Healthcare Professional.

***Unrestricted Use***

All charitable donations made by ABIOMED should be unrestricted, meaning that ABIOMED should not determine how the donation is to be used by the Charitable Organization. For example, ABIOMED should not require that a charitable donation be used specifically to support a certain educational program or research project; however, it is appropriate for a charitable donation to be given to a Charitable Organization in recognition of specific work or charitable endeavors, such as a certain educational program or research project.

***Form of Charitable Donations***

Charitable donations may include the following:

- Cash or cash equivalents (e.g., checks and gift certificates, wire transfer or electronic funds transfer);
- Items contributed to raffles or other fundraising efforts (e.g., ABIOMED items, golf clubs, event tickets, etc.);
- A purchase of tickets or a table at a fundraiser dinner or slots at a charity golf tournament; provided, however, that event tickets may be used only by ABIOMED Representatives or returned to the Charitable Organization so it may donate the tickets to recipients of its own choosing. ABIOMED may not provide tickets to individual Healthcare Professionals to attend the event;
- In-kind donations through Patient Assistance Programs (PAPs);
- In-kind donations for emergency/natural disaster or humanitarian relief.

***Approvals***

All charitable donations made by ABIOMED should be approved in advance, in writing, in accordance with the approval process set forth in ABIOMED's charitable donations procedure. ABIOMED's Grants Committee will require any organization requesting a contribution to provide the following to ABIOMED in writing: (1) a brief description of the organization and an explanation of how the donation will be used; and (2) proof of IRS 501(c)(3) non-profit status.

ABIOMED sales personnel may provide input about the suitability of a proposed donation recipient or program, but Sales and Marketing personnel should neither control nor unduly influence the decision of whether a particular charitable organization will receive a donation or the amount of such donation. All inquiries and decisions will be made solely by the ABIOMED

Compliance Committee. All charitable funding must come from an approved ABIOMED budget.

***In-Kind Donations***

All requests for in-kind donations must meet the following criteria:

1. The Charitable Organization has been formed for humanitarian purposes, does not intend to use such donation for commercial purposes, has financial integrity and is a qualified recipient of an in-kind donation.

2. ABIOMED may require certain legal representations from the Charitable Organization, which may include, but are not limited to the following:

    a. Legal compliance with respect to the use of the in-kind donation. If the intent is to export the product to an international location, this must be included in the legal representation.

    b. Safeguarding of ABIOMED's intellectual property.

    c. Safeguarding of any and all ABIOMED confidential information that is inadvertently disclosed.

3. The recipients of in-kind donations consisting of ABIOMED Products should be able to demonstrate the safe and effective use of such products.

# Consultant and Development Arrangements

ABIOMED, through various types of arrangements, engages Healthcare Professionals to provide a range of valuable, *bona fide* consulting services, such as presentations at Company sponsored training and education events, research, product development, participation on advisory boards, development and/or transfer of intellectual property, and other services.

Examples of consulting arrangements under which the Company compensates Healthcare Professionals for their services include, but are not limited to, the following:

- Trainers for product training courses;
- Trainers for Company personnel;
- Product development and research;
- Clinical studies;
- Speakers (at a Company booth during a trade show, convention, or annual meeting);
- Advisory board meetings;
- Performance of other services at a trade show, convention, or annual meeting;
- Authoring Company-branded publications (such as marketing materials);
- Reviewing Company-developed publications (such as marketing materials).

ABIOMED is prohibited from entering into a consulting arrangement with a Healthcare Professional for services that are not necessary to fulfill a legitimate business purpose of ABIOMED, are not commercially reasonable, or for which the amount of compensation offered or provided by ABIOMED is based on, or related to, the past, present, or future volume or value of business generated directly or indirectly for ABIOMED by the Healthcare Professional. All services or work product provided by a consultant must be documented and used, or be genuinely intended for use, by the Company.

***Consultant Arrangements***

The Company's arrangements with Healthcare Professionals to provide *bona fide* services to ABIOMED must comply with the following standards:

- *Annual Needs Assessment*: Every fiscal year, as part of the budgetary process, based on forecast requirements and budgets, ABIOMED will carry out a needs assessment as part of a good faith effort to establish the commercially reasonable business purpose for retaining consulting and other services from Healthcare Professionals, the scope of consulting services reasonably required to achieve that identified commercially reasonable business purpose, and an associated budget for such services. The annual needs assessment should be conducted and documented, in writing, prior to identifying a Healthcare Professional capable of providing consulting

services, whether for a new engagement, or a renewal or extension of an existing engagement. The annual needs assessment may be amended or supplemented in certain circumstances to account for services to satisfy a business need that could not have been identified during the normal process.

- *Legitimate Business Need*: Consulting agreements should be entered into only where a legitimate need for the services is identified in advance of the service being engaged. Once the legitimate need is identified, ABIOMED may select Healthcare Professionals to fill that need.

- *Number of Consultants Retained*: The number of consultants retained for a particular activity must be limited to that which is reasonably necessary to achieve the stated business need. Engaging unnecessary numbers of Healthcare Professionals to provide services is prohibited.

- *Selection of Consultants*: Selection of a consultant must be made based on the totality of the consultant's qualifications and expertise to meet the defined need, and never be based on the value of past or future referrals, purchases, or recommendations of ABIOMED Products or ABIOMED Services. In particular, in selection HCPs to serve as speakers for the Company and its products, ABIOMED will consider: the Healthcare Professional's experience using the Impella platform of devices; the credibility and degree of influence, which the Healthcare Professional enjoys in the cardiovascular field; whether the Healthcare Professional is a published author; whether the Healthcare Professional is an effective public speaker; and whether the Healthcare Professional is affiliated with an academic medical center or teaching hospital. No one factor is to be given more importance than any other and the totality of the physician's qualifications should be considered in each instance.

  ABIOMED Sales and Marketing personnel may provide input about the suitability of a consultant, but Sales and Marketing personnel should neither control nor unduly influence the decision to engage a particular Healthcare Professional as a consultant.

- *Written Agreement*: Each consulting arrangement must be documented in a written contract signed by both the Healthcare Professional and the Company. Each consulting agreement must satisfy the following criteria:

  - *Term*. The agreement should have a term of <u>at least one year</u>.

  - *Services.* The contracted services must have been identified in the annual needs assessment (including any duly executed amendment or supplement thereto) and the aggregate services contracted for must not exceed those that are reasonably necessary to accomplish the commercially reasonable business purpose of the services. The

services performed under the agreement must not involve the counseling or promotion of a business arrangement or other activity that violates state or federal law.

- *Compensation*. The agreement must specify that the compensation to be paid over the term of the arrangement is set in advance, does not exceed Fair Market Value for the contracted services, and is not determined in a manner that takes into account the volume or value or any referrals or other business generated between the parties. In addition, the agreement should provide that compensation will only be paid upon the provision of documentation supporting the completion of the contracted services.

- *Reimbursement*. The written agreement should set forth the terms relating to the Company's reimbursement, if any, for documented, reasonable and actual expenses incurred by the consultant that are necessary to carry out the consulting services. In addition, the agreement should provide that the Company will only provide reimbursement after receiving an itemized expense report and related receipts for the consultant.

- *Representations*. The written agreement should include representations by the consultant that: (i) the consultant is authorized to enter into the consulting agreement, and has made all disclosures and obtained all approvals necessary to do so, and (ii) provision of the services by the consultant is not inconsistent with any obligation of the consultant to an employer or other third-party.

- *Documentation of Services Rendered*: The Company will not make any payment for consultant services without documentation that reasonably details the services that were actually provided in accordance with the terms of the consulting agreement.

- *Fair Market Value Compensation*: Compensation paid to a consultant should be consistent with Fair Market Value in an arm's length transaction for the services actually provided (including participation in consultant meetings) and should not be based on the volume or value of the consultant's past, present or anticipated business. To determine Fair Market Value, factors such as experience, expertise, reputation in the relevant medical field, and time commitment should be considered. Generally, compensation should be in the form of a check or wire transfer; however, in limited circumstances, the Company will compensate Healthcare Professional consultants in the form of products or the use of products.

- *Coverage/Reimbursement of Expenses*: ABIOMED may pay for documented, reasonable and actual expenses incurred by a consultant that are necessary to

carry out services under a consulting arrangement (including participation in consultant meetings), such as costs for reasonable travel and Modest meals and lodging. Prior to reimbursement by the Company for any such expenses, the consultant must submit an itemized expense report and related receipts. Neither ABIOMED nor ABIOMED Representatives may pay any expense, including meals or refreshments, of a consultant's spouse or guest that does not have a *bona fide* professional interest in the services.

***Consultant Meetings***

Occasionally, it may be necessary to gather a number of consultants in one location for a meeting, such as for an advisory board meeting or speaker training. Consultant meetings must comply with the following standards:

- *Legitimate Need*: There must be a legitimate purpose and need to hold a consultant meeting, such as to gain valuable feedback about the use or clinical development of ABIOMED Products, or the effectiveness of particular ABIOMED marketing programs. The business need must be identified in advance of the meeting. In addition, the number of consultant meetings must be dictated by business need.

- *Number of Attendees*: The number of consultants proposed to attend the meetings must be limited to that which is reasonably necessary to achieve the stated business need.

- *Venue and Circumstances*: The venue and circumstances for consultant meetings should be appropriate to the subject matter of the consultation and in a location that is convenient and easily and cost effectively reached by the majority of the attendees. In addition, consultant meetings should be conducted in clinical, educational, conference or other settings, including hotel or other commercially available meeting facilities, conducive to the effective exchange of information.

- *No Entertainment*: Entertainment of any kind in conjunction with consultant meetings is prohibited.

- *Meals and Refreshments*: Meals and refreshments provided in conjunction with a consultant meeting must be Modest in value (in accordance with these guidelines) and should be subordinate in time and focus to the primary purpose of the meeting.

  For more information regarding the provision of meals and the rules applicable to various situations in which ABIOMED may provide meals to Healthcare Professionals, please consult the "*Meal Scenarios Chart.*"

- *Active Participation*: The purpose of consultant meetings is to obtain valuable feedback from participants regarding a specific business need. Consultants are expected to actively engage while attending such meetings.

- *Speaker Presentations*: All presentations made by Healthcare Professionals on behalf of ABIOMED must be on-label.

- *Coverage/Reimbursement of Expenses*: ABIOMED may pay for documented, reasonable and actual expenses incurred by a consultant that are necessary to participating in consultant meetings, such as costs for reasonable travel and Modest meals and lodging. Neither ABIOMED nor ABIOMED Representatives may pay any expense, including meals or refreshments, of a consultant's spouse or guest.

***Impermissible Arrangements***

The Company may not enter into a consulting arrangement with a Healthcare Professional for any of the following purposes:

- To influence or reward the generation of business directly from the Healthcare Professional or a health care provider affiliated with the Healthcare Professional;

- To promote off-label use of the Company's products; or

- As a token arrangement where there is no legitimate need for a *bona fide* intended use of the information or service provided by the consultant.

Additionally, ABIOMED may not enter into a consulting arrangement with a Healthcare Professional that is on the HHS OIG List of Excluded Individuals and Entities, the U.S. General Services Administration (GSA) Excluded Parties List System or the U.S. Food and Drug Administration (FDA) Debarment List.

***Clinical Research Services***

Arrangements that involve the provision of clinical research services by a Healthcare Professional, as part of a clinical trial or otherwise, in return for compensation, are a type of consulting arrangement and, therefore, must satisfy the requirements applicable to consulting arrangements. In addition, the agreement with a consultant performing clinical research services must be associated with a written research protocol that includes specific milestones expected of the research.

***Provisions on Payment of Royalties***

ABIOMED recognizes that Healthcare Professionals often make valuable contributions that improve and enhance ABIOMED Products and Services. Healthcare Professionals

also develop intellectual property, for example, patents, trade secrets and know-how, under a product or technology development or intellectual property licensing agreement. ABIOMED is permitted to make certain royalty payments to Healthcare Professionals in consideration of these contributions.

- Arrangements involving the payment of royalties to a Healthcare Professional should meet the contractual standards set forth in these guidelines.

    - ABIOMED may enter into a royalty arrangement with a Healthcare Professional only where the Healthcare Professional is expected to make or has made a novel, significant, or innovative contribution to the development of a product, technology, process or method. A significant contribution, if it is the basis for compensation, should be appropriately documented.

    - The calculation of Fair Market Value royalties payable to a Healthcare Professional in exchange for intellectual property will be based on factors that preserve the objectivity of medical decision-making and avoid the potential for improper influence.

    - Royalties paid in exchange for intellectual property will not be conditioned on:

        1. a requirement that the Healthcare Professional purchase, order or refer any existing ABIOMED Product or ABIOMED Service or any product or technology produced as a result of the development project;

        2. the number of units purchased, used or ordered by the Healthcare Professional and/or members of the Healthcare Professional's practice; or

        3. a requirement to market the product or medical technology upon commercialization (ABIOMED may, however, enter into separate consulting agreements with Healthcare Professionals for marketing services, if such services meet the requirements set forth in these guidelines).

## Provision of Coverage, Reimbursement, and Health Economics Information

As medical technologies have become increasingly complex, so have payor coverage and reimbursement policies. Patient access to necessary medical technology may be dependent on Healthcare Professionals and/or patients having timely and complete coverage, reimbursement and health economic information. As such, ABIOMED may provide Coverage, Reimbursement and Health Economics information ("CRHE Information") regarding its products that is *accurate and objective*.

In addition, ABIOMED may collaborate with Healthcare Professionals, patients and organizations representing their interests, to achieve government and commercial payor coverage decisions, guidelines, policies and adequate reimbursement levels that allow patients to access ABIOMED Products.

Permissible activities involving the provision of CRHE Information may include, but are not limited to the following, where such activities are also permissible under the anti-kickback law:

- *Identifying Clinical Value*: Identifying the clinical value of the ABIOMED Products and the services and procedures in which they are used when providing CRHE Information and materials to Healthcare Professionals, professional organizations, patient organizations and payors.

- *Joint Advocacy*: Collaborating with Healthcare Professionals, their professional organizations and patient groups to conduct joint advocacy on CRHE issues.

- *Developing Materials*: Supporting Healthcare Professionals and their professional organizations in developing publicly available materials and otherwise providing direct or indirect input into payor coverage and reimbursement policies.

- *Promoting Accurate Claims*: Promoting accurate Medicare and other payor claims by providing accurate and objective information and materials to Healthcare Professionals regarding ABIOMED Products, including identifying coverage, codes and billing options that may apply to ABIOMED Products or the services and procedures in which they are used.

- *Efficient Use of Products*: Providing *accurate and objective* information about the economically efficient use of ABIOMED Products, including on-label information about where and how they can be used within the continuum of care.

- *Reimbursement Revenues and Costs*: Providing information related to ABIOMED Products regarding available reimbursement revenues and associated costs.

- *Changes in Coverage and Reimbursement*: Providing information relating to changes in coverage or reimbursement amounts, methodologies and policies and the effects of such changes.

- *Technical Support*: Providing accurate and objective information designed to offer technical or other support intended to aid in the appropriate and efficient use or installation of ABIOMED Products.

- Patient Coverage Decisions Assistance: Facilitating patient access to ABIOMED Products by providing Healthcare Professionals with assistance in obtaining patient coverage decisions from payors. This assistance may include providing information and/or training on payor policies and procedures for obtaining prior authorization, and providing sample letters and information on medical necessity and appeals of denied claims. No such information may be customized for a particular Healthcare Professional or patient. In addition, at the request of a Healthcare Professional to facilitate patient access to ABIOMED Products, and subject to appropriate privacy safeguards, ABIOMED may assist the patient by furnishing non-customized materials or information to facilitate the preparation and/or submission of requests for coverage determinations, prior authorizations, pre-certifications and appeals of denied claims, relating to ABIOMED Products; however, such assistance must not be provided as an unlawful inducement.

ABIOMED may not interfere with a Healthcare Professional's independent clinical decision making or provide CRHE Information support as an unlawful inducement. Furthermore, ABIOMED Representatives must not suggest mechanisms for billing services that are not medically necessary, or for engaging in unlawful practices to achieve inappropriate payment.

CRHE Information must be provided and available to all Healthcare Professionals on equal terms and conditions. ABIOMED may not offer or provide any items or services to a Healthcare Professional on the basis of the volume or value of business generated for ABIOMED. In addition, ABIOMED must ensure that the Company does not provide general practice management advice to Healthcare Professionals. It is **inappropriate** for ABIOMED to provide personnel or services to a Healthcare Professional in situations that relieve the Healthcare Professional of hiring such personnel or purchasing such services. It is also not appropriate for ABIOMED to provide customized advice to Healthcare Professionals that is not ABIOMED Product-focused. Coding or third-party reimbursement information programs must not take the place of work normally performed by the Healthcare Professional and should not include, without a Fair Market Value charge, the use of systems, functions or duties that would normally be provided by, or purchased at the expense of, the Healthcare Professional.

ABIOMED must not condition the sale of any ABIOMED Product on coverage or reimbursement by an insurer. The Company must not provide any assurances to a Healthcare Professional that any coding or coverage determination is correct, that an ABIOMED Product will be reimbursed by an insurer, or that the product will be reimbursed at any particular amount.

# Evaluation and Demonstration Products

Providing products to Healthcare Professionals at no charge for evaluation and demonstration purposes can benefit patients in many ways. These benefits include improving patient care, facilitating the safe and effective use of products, and educating Healthcare Professionals regarding the use of products. ABIOMED Representatives may provide Healthcare Professionals with the use of Demonstration Products and Evaluation Products only in accordance with the terms of this Policy.

***Standards Applicable to Providing Evaluation Products to Healthcare Professionals***

ABIOMED Products may be provided at no charge to allow Healthcare Professionals to evaluate, for a limited time period, the appropriate use and functionality of the product and determine whether and when to use, order, purchase, lease or recommend the product in the future. ABIOMED Products provided for evaluation may be used in patient care in accordance with the terms contained in a written agreement with a Healthcare Professional.

ABIOMED Representatives must also adhere to the following standards when providing Evaluation Products to Healthcare Professionals:

- *No Inducement or Reward.* Evaluation Products must never be provided with the intent to induce or reward, or otherwise be conditioned upon, a Healthcare Professional's future or continued purchase, lease, order, use, prescription, recommendation or arrangement for the purchase, lease, use, prescription, or order of that product or **another** ABIOMED Product or Service, or as a reward for such activity.

- *Quantity and Duration*. ABIOMED Representatives may provide Evaluation Products for the use of Healthcare Professionals for a period of **no more than 60 days** (the "Evaluation Period"). In addition, the number of single-use Evaluation Products provided at no charge may not exceed the amount reasonably necessary for the adequate evaluation of the products under the circumstances. A multiple-use Evaluation Product may be used by a Healthcare Professional without charge only for a period of time that is reasonable under the circumstances to allow an adequate evaluation and, under no circumstances, for more than 60 days. ABIOMED Representatives may not provide Evaluation Products without charge on a repeated basis for the use of the same Healthcare Professional; once a Healthcare Professional has received a particular Evaluation Product that Healthcare Professional is ineligible to receive that Evaluation Product without charge again without appropriate approvals set forth in corresponding procedures.

- *Documentation*. Prior to provision of an Evaluation Product for use by a Healthcare Professional, the ABIOMED Representative shall adhere to documentation requirements set forth in corresponding procedures. Such documentation shall set forth the terms and conditions of the use of the product, including the express prohibition on resale or inappropriate billing of patients or third-party payors for use of the Evaluation Product, and the charge the Healthcare Professional will incur if the Healthcare Professional fails to return the Evaluation Product at the end of the Evaluation Period.

- *Return of Evaluation Product.* The Healthcare Professional must return the Evaluation Product to the Company in accordance with the terms of the documented arrangement upon expiration of the Evaluation Period. ABIOMED Representatives shall abide by the equipment removal and tracking requirements set forth in advance by the Company.

- *Fees for Use After the Evaluation Period.* ABIOMED Representatives should remind Healthcare Professionals that they must return Evaluation Products at the end of the Evaluation Period in order to avoid being charged for use of Evaluation Products that are not returned at the end of the Evaluation Period, as specified in an applicable Demonstration & Evaluation Agreement. ABIOMED Representatives are not authorized to, and shall not, represent to any Healthcare Professional that the Company will waive any fee attributable to use of Evaluation Products after expiration of the Evaluation Period.

***Standards Applicable to Providing Demonstration Products to Healthcare Professionals***

ABIOMED Products may be provided at no charge for Healthcare Professional and patient awareness, education, and training.

ABIOMED Representatives must adhere to the following standards when providing Demonstration Products to Healthcare Professionals:

- *No Inducement or Reward*. Demonstration Products must never be provided conditioned upon a Healthcare Professional's purchase, lease, order, use, prescription, recommendation, or arrangement for the purchase, lease, use, prescription, or order of, **another** ABIOMED Product or Service, or as a reward for any such activity.

- *Quantity*. The number of Demonstration Products provided at no charge may not exceed the amount reasonably necessary for the adequate demonstration of the products under the circumstances. ABIOMED Representatives may not provide Demonstration Products without charge on a repeated basis for the use of the same Healthcare Professional; once a

Healthcare Professional has received a particular Demonstration Product that Healthcare Professional is ineligible to receive that Demonstration Product without charge again without appropriate approvals set forth in corresponding Standard Operating Procedures.

- *Special Designation*. Demonstration Products must bear a designation of "Sample," "Not for Human Use," or another suitable designation on the product, the product packaging or documentation that accompanies the product.

- *Documentation*. Prior to provision of a Demonstration Product for use by a Healthcare Professional, the ABIOMED Representative shall adhere to documentation requirements set forth in corresponding procedures. Such documentation shall set forth the terms and conditions of the use of the product, including the express prohibition on resale or inappropriate billing of patients or third-party payors for use of the Demonstration Product.

# Discount Programs

ABIOMED may develop discount and rebate programs for use in negotiations with potential or existing customers for the sale or lease of ABIOMED Products or ABIOMED Services. Such discounts or rebates may apply to a single ABIOMED Product or ABIOMED Service, or in some cases, to a group of ABIOMED Products or ABIOMED Services sold together as a package. All such discount and rebate programs must be approved by the Finance and Legal Departments and the Compliance Committee. ABIOMED Representatives are prohibited from offering unapproved discounts to potential or existing customers.

Any discount that ABIOMED might provide to a Healthcare Professional must be properly documented to ensure compliance with the U.S. anti-kickback law and implementing regulations. Importantly, discount program brochures, agreements, terms and conditions, invoices, or other relevant paperwork may contain certain disclaimers and language, as well as information regarding the value of the discount and how it applies to the product(s) purchased. ABIOMED Representatives are prohibited from altering, in any form, any materials related to an ABIOMED discount program.

Approved discounts or rebates generally must meet the following requirements:

- The discount or rebate must be disclosed to the customer in writing at, or before, the time of sale.
- The net sale or lease price must be accurately reported to the purchaser.
- The net sale or lease price for each ABIOMED Product or ABIOMED Service must be at or above ABIOMED's cost.
- The purchaser must be informed of his/her/its obligations to report the discount or rebate as applicable.
- A rebate may only be furnished based upon ABIOMED Products actually sold and purchased. Rebates may not be paid in cash or paid before the full purchase price has been rendered.
- Discounts or rebates on one ABIOMED Product or ABIOMED Service should not be tied to purchase of different ABIOMED Products or ABIOMED Services, unless the discount or rebate applies equally to all such purchases of a customer.

***Prohibited Discounts, Rebates and Price Concessions***

Some discounts, rebates, and price concessions are not approved under any circumstance, including:

- Up-front payments for using ABIOMED Products (e.g., "prebates," signing or conversion "bonuses");

- Rebates paid in cash rather than by check or credit memorandum;

- Discounts, rebates or price concessions earned on products or services covered by a federal healthcare program, but applied to products or services not covered by the program;

- Discounts, rebates, or price concessions available when a product is covered by private payors, but not available when it is covered by a federal healthcare program;

- Credits earned on trade-ins in excess of the Fair Market Value of the product that is traded; and

- Provision of ABIOMED Products to a purchaser without charge or below ABIOMED's cost for the product, except in accordance with the approval processes required by this Policy.

- Discounts or rebates on ABIOMED Products or ABIOMED Services made conditional upon the purchase of different ABIOMED Products or ABIOMED Services, unless the ABIOMED Products or ABIOMED Services are reimbursed by the same federal healthcare program using the same payment methodology, and the reduced charge is fully and accurately reflected and reported, or the program is reviewed and approved by the Legal Department.

# Conducting Business Internationally

ABIOMED is a global medical device company. Many of our business dealings occur in, and affect, foreign nations. Under the Foreign Corrupt Practices Act ("FCPA"), we may not directly or indirectly pay, give, offer, or promise money or anything of value to any officer, employee or representative of a government outside the United States or of a public international organization, or to any political party, party official, or candidate for political office outside the United States in order to (1) secure an improper advantage in obtaining, retaining, or directing business, (2) influence any act or decision of the recipient in an official capacity, or (3) induce the recipient to do or omit to do an act in violation of such person's lawful duty.

For FCPA purposes, such foreign officials include: officials or employees of foreign government departments and agencies; foreign political parties, party officials or employees, and candidates for public office; officers or employees of government-owned entities; officers or employees of certain public international organizations; or anyone else acting in an official capacity for such foreign governments or international organizations.

***In many instances, foreign health care providers work at government-owned hospitals and clinics, and are considered government officials within the meaning of the FCPA***. Though physician contact, in many cases, is educational and may include sponsoring a physician's evaluation of a company's products, or subsidizing presentations at medical seminars, even Modest payments to foreign doctors, nurses, or hospital technicians could trigger FCPA liability, unless they are expressly permitted by the written laws of the host country.

The United Kingdom (UK) Bribery Act prohibits bribery by UK companies, companies doing business in the UK, UK citizens/nationals, and any other person who commits a prohibited act in the UK. The law extends further, however, to include acts of bribery outside the UK. It also imposes strict liability on companies that fail to prevent anyone performing services on their behalf from a providing a bribe.

ABIOMED is committed to acting vigilantly to ensure our foreign business dealings are in compliance with all applicable laws and regulations.

# Complaint Investigation Procedures and Employee Discipline

Each ABIOMED Representative will be held accountable for his or her adherence to this Compliance Code. It is also the responsibility of every ABIOMED Representative to promptly bring violations and suspected violations of the Compliance Code, Company policy or the law to the attention of the Company as described below. Information transmitted to the Company through the Chief Compliance Officer, the Compliance Committee or the independent compliance hotline, as described below, will be investigated thoroughly and the identity of the source, if provided, will be maintained in confidence, unless otherwise required by law. Employees will not be subject to any disciplinary or retaliatory action for reporting a violation or potential violations of the Compliance Code, Company policy or the law in good faith, unless it is the employee's own violation. However, making known false or malicious reports will not be tolerated, and any ABIOMED Representative who files such a report will be subject to appropriate disciplinary action.

The following procedures apply to the receipt of complaints or questions related to the Compliance Program, the investigation of reported violations, and the potential discipline of ABIOMED employees for breach of the Program's requirements.

## I. Reporting Potential Compliance Violations

Violations or potential violations of this Compliance Code, Company policy or applicable law should either be reported directly to the Chief Compliance Officer at the Company's headquarters located at 22 Cherry Hill Drive, Danvers, Massachusetts 01923, or through the anonymous and independent compliance reporting hotline – **((888)-475-8376).**

- In instances where the Chief Compliance Officer is a concerned party in the report, the report may be directed to ABIOMED's General Counsel or to the Vice President of Human Resources, or if all such parties are also concerned, then to a member of the Company Compliance Committee.

- The Chief Compliance Officer will check the independent compliance hotline regularly.

- Employees providing anonymous information must provide enough information for the Chief Compliance Officer to reasonably investigate the alleged violation.

- All reports shall be evaluated by the Chief Compliance Officer. Based on initial evaluation, the Chief Compliance Officer may determine the corrective actions required, or may determine that no additional action is necessary.

## II. Investigation of Potential Compliance Violations

The Chief Compliance Officer shall have the authority to determine if the violation report merits further investigation. The Chief Compliance Officer may conduct such further investigation. When necessary in the Chief Compliance Officer's determination, the Chief Compliance Officer may empanel a Compliance Task Force, which will be comprised of the Chief Compliance Officer and any other appropriate parties as determined by the Chief Compliance Officer.

- During any stage of the investigation, the Chief Compliance Officer or the Compliance Task Force may, in his/her or its discretion and at the Company's expense, seek the advice and guidance of independent legal counsel.
- The Compliance Task Force will investigate the report of a violation or potential violation of the Compliance Code, and shall transmit its findings to the ABIOMED Compliance Committee, which will determine the appropriate disciplinary or corrective actions required. All employee disciplinary actions will be approved by the Vice President of Human Resources.
- If the Chief Compliance Officer or the Compliance Task Force receives credible evidence of misconduct and, after a reasonable inquiry, believes that the misconduct may violate criminal, civil or administrative law, the Chief Compliance Officer will consult with the Company's outside legal counsel and the ABIOMED Compliance Committee regarding the misconduct. If so advised by outside legal counsel, and upon notice to the Compliance Committee, the Chief Compliance Officer will promptly report the existence of the misconduct to the appropriate federal and state authorities within a reasonable period, but not more than 60 days, after determining that there is credible evidence of a violation.

## III. Disciplinary Action as a Result of Compliance Program Violations

Any ABIOMED Representative guilty of a compliance violation will be subject to disciplinary consequences because of the violation of his or her contractual duties, regardless of any sanctions stipulated by law.

The Compliance Committee will consider each situation on a case-by-case basis, taking into account all relevant factors, to determine the appropriate response. Depending on the severity of the compliance violation and the local legal solution, the following disciplinary measures are available:

- informal warning
- formal warning
- forfeiture of voluntary remuneration elements/stock awards
- forfeiture of variable pay
- transfer to another position

- dismissal

The following requirements define a process of cooperation between the Compliance Committee and Human Resources to deal with compliance violations on the corporate level.

### A. General Process

Compliance violations will be handled as follows:

- The Chief Compliance Officer will inform the Vice President, Human Resources and the Chief Executive Officer immediately with a written report summarizing provable facts of any alleged breaches of the Compliance Program and the severity of the compliance violation.

- The Vice President, Human Resources, together with the employee's manager, will be responsible for ensuring that the necessary and appropriate disciplinary measures are implemented to deal with the breach of the Compliance Program.

- The Vice President, Human Resources and the employee's manager will also decide whether the employee will be suspended. If there is reason to believe that the employee's manager may also be subject to disciplinary measures, that manager's supervisor will decide together with the Vice President, Human Resources.

- The Vice President, Human Resources will inform the Chief Compliance Officer, as applicable, about the outcome of any employment law conflict arising from the measures adopted.

### B. Disciplinary Measures in Cases of Compliance Violations

Depending on the severity of the compliance violation and the local legal situation, the following disciplinary measures are to be taken.

#### 1. Informal warning

An informal warning is appropriate in cases of slight compliance violations. An informal warning consists of (1) an objection to the employee's behavior and (2) the demand to change his/her behavior in a certain way. It does not, however, include the announcement of further measures (particularly the termination of employment) in case the employee does not change his/her behavior.

#### 2. Formal warning

A formal warning is appropriate for compliance violations beyond slight offenses but not of a severity that justifies more severe sanctions up to the termination of employment. A formal

warning consists of (1) an objection to the employee's behavior, (2) the demand to change his/her behavior in a certain way, and (3) the announcement of further measures (particularly the termination of employment) if the employee does not change his/her behavior.

### 3. Forfeiture of voluntary remuneration elements/stock awards

If the employee is guilty of a compliance violation warranting more than a formal warning, the forfeiture of voluntary remuneration elements may be appropriate, in addition to a formal warning.

If such disciplinary measure is imposed, the employee will not be granted some or all of the new stock awards to which he or she would have otherwise been entitled during the relevant grant period following a compliance violation. The same applies analogously to other voluntary remuneration elements.

### 4. Forfeiture of variable pay

If the employee is guilty of a compliance violation warranting more than a formal warning, he/she may also be required to forfeit all or part of his/her variable pay for a defined period of time in addition to receiving a formal warning, as far as legally possible under the relevant conditions of employment.

### 5. Transfer to another position

The employee will be transferred to another position if the compliance violation makes a job change necessary. This measure may be taken in addition to or in combination with the measures set out above.

### 6. Dismissal

#### a) Compliance training

Every employee who commits a compliance violation warranting more than an informal warning must complete a compliance training, which provides instruction in the specific subject matter area involved in the violation. The Chief Compliance Officer is responsible for implementing adequate training. The employee's direct supervisor is responsible for ensuring that the compliance training is completed.

#### b) Contractual notice of dismissal

A contractual notice of dismissal is appropriate in cases of compliance violations that do not legally justify a summary dismissal but require a termination of employment and are too severe to be sanctioned solely with – exclusively or cumulatively – a formal warning, the forfeiture of voluntary remuneration elements, the forfeiture of variable pay, and a transfer to another position.

### c) Summary dismissal

An employee will be dismissed with immediate effect if he/she has violated his/her contractual duties in a manner that warrants summary dismissal and ABIOMED reasonably concludes that employment should not be continued through the next contractual termination date.

## C. Consequences of Compliance Program Violations Within the Comprehensive Performance Management System

An employee's compliance violation warranting more than a formal warning will have an impact on the employee's evaluation, income, and development actions in the ABIOMED Comprehensive Performance Management System.

### 1. Impact on evaluation criteria of "Compliance"

Compliance violations warranting more than a formal warning have an impact on the employee's "Efforts and Attitudes" evaluation in the Comprehensive Performance Management System. Specifically, a compliance violation warranting more than a formal warning will result in the employee receiving a "1" in the "Commitment to ABIOMED Code of Conduct and Compliance Policy" block of the Efforts and Attitude section of the evaluation. Such a rating will automatically result in the employee being rated as an overall "1" (below the target level expectation) for the fiscal year in which the violation occurred.

### 2. Impact on income actions and statements of potential

An employee who receives more than a formal warning due to a compliance violation will be excluded from a salary increase during the following management review meeting.

## Chief Compliance Officer Duties

In connection with the Chief Compliance Officer's role as the focal point for compliance activities related to the Compliance Code and the Company Compliance Program, the Chief Compliance Officer shall:

- oversee and monitor implementation of the Compliance Program, including the development of written policies and procedures;
- chair the ABIOMED Management-level Compliance Committee, and hold periodic meetings amongst the committee members to review and gauge the state of compliance readiness in the Company;
- review, independently investigate and act in response to reports of violations of the Compliance Program, including empanelling a Compliance Task Force;
- maintain a written log of all reports and consistently document each report, the investigation of the report and the disposition of the matter;
- report on a regular basis to the Company's Board of Directors and President, Chairman and Chief Executive Officer on compliance matters and assist these individuals and groups to establish methods to reduce the Company's vulnerability to fraud and abuse, both actual and perceived;
- develop, coordinate and implement an educational and training program for ABIOMED Representatives on the elements of the Compliance Program;
- assist other Company personnel in coordinating internal compliance review and monitoring activities; and
- periodically review and, as appropriate, revise and amend the Compliance Code and its related policies and procedures to address any changes in the Company's business and the legal and regulatory environment.

## Training and Education of ABIOMED Representatives

Within 120 days of being hired, an employee must complete new hire compliance training. This could be live training or web-based training depending on the individual's job title and level.

Employees must receive training each year that covers:

- The ABIOMED Compliance Code of Conduct, and all relevant policies and procedures;
- All new state regulations and reporting requirements related to aggregate spend with U.S.-based Healthcare Professionals;
- Proper methods of marketing and selling products that are reimbursed by government programs;
- The employee's personal obligation to ensure that government-reimbursed products are marketed and sold in accordance with all applicable requirements of the government programs; and
- The legal rules and sanctions for violations that relate to products reimbursed by those programs.

In addition, all ABIOMED employees will receive a copy of the ABIOMED Compliance Code of Conduct, its supporting policies and procedures, and the AdvaMed Code within 120 days of joining ABIOMED. Every two years, ABIOMED employees are required to retake the new hire compliance training course and certification.

All employees will be required to complete a certification, which may be in electronic form, confirming they have completed the applicable training.

Additional training regarding the Compliance Program may be required, in the discretion of the Chief Compliance Officer, for each ABIOMED Representative who is primarily affected by the Compliance Program, including, specifically, sales and marketing personnel and medical and clinical staff. The Chief Compliance Officer also may develop other training and information to distribute to employees and representatives in order to address the content of and any changes in the Compliance Program, applicable law and regulations, or any issues that may be important to the Company's business.

## Monitoring and Auditing

The Company will take reasonable steps to ensure that all ABIOMED Representatives are acting in accordance with the strictures of the Compliance Code and the Compliance Program. To that end, the Company has established monitoring and auditing priorities based on relevant factors including identified risk factors, industry trends, government enforcement actions, or changes in statues, regulations, and case law. As appropriate, the Company has also established state-specific compliance procedures for compliance with related state law compliance.

## Reference Documents

AdvaMed Code of Ethics on Interactions with Healthcare Professionals

FDA Draft Guidance for Industry: Presenting Risk Information in Prescription Drug and Medical Device Promotion

FDA's Draft Guidance for Industry, Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices

FDA's Draft Guidance Distributing Scientific and Medical Publications on Unapproved New Uses, Recommended Practices

FDA's January 17, 2017 Guidance document "Medical Product Communications That Are Consistent with FDA-Required Labeling – Questions and Answers."

# Meal Scenarios Chart

| Context | Scenario | Rules |
|---|---|---|
| **Business Meals** | Scenario 1: Business meals in the ordinary course of business (e.g., detailing visit) | ▪ ABIOMED Representatives must attend for the duration of the meal<br>▪ Meal must be incidental to an informational presentation<br>▪ Healthcare Professional must be present and actually attend the informational presentation<br>▪ Value of the meal must be in accordance with the per person dollar limits ($50 for breakfast, $50 for lunch; and $150 for dinner)<br>▪ Meal setting must be conducive to informational exchange (office or hospital, or a restaurant or hotel in some circumstances)<br>▪ May not provide meals to individuals with no *bona fide* professional interest (e.g., friends, spouses) |
| **Consultants** | Scenario 2: Meals provided *during consultant meetings* | ▪ Follow rules from Scenario 1<br>▪ In addition, meals must be subordinate in time and focus to the primary purpose of the meeting |
| | Scenario 3: Reimbursing cost of meals for consultants who are traveling to provide services to ABIOMED | ▪ Must be reasonable, documented (e.g., receipts), and actual meal expenses incurred by the consultant |
| **Product Training** | Scenario 4: Meals provided *during medical device training programs* | ▪ Follow rules from Scenario 1<br>▪ In addition, meals must be subordinate in time and focus to the primary purpose of the meeting |
| | Scenario 5: Reimbursing cost of meals for Healthcare Professionals who are traveling to attend medical device training programs | *Not Permitted* (ABIOMED is only permitted to reimburse reasonable travel and lodging costs associated with attendance at *bona fide* product trainings) |
| **Conferences** | Scenario 6: Providing meals and refreshments to *all* conference attendees | ▪ Meal/refreshments must actually be provided, or available to, all conference attendees<br>▪ Must be provided consistent with standards established by the conference sponsor and the body accrediting the educational activity<br>▪ ABIOMED may not select the conference attendees |
| | Scenario 7: Providing meals to a select group of conference attendees | ▪ *Not permitted*, unless it is part of a business meeting separate and apart from the conference<br>o If provided as part of a business meeting, this is treated as a business meal and ABIOMED must follow all rules from Scenario 1 |
| | Scenario 8: Providing funding for meals to a conference sponsor | ▪ Funding may be provided to third-party educational conference sponsors to reduce overall conference costs, including the provision of meals and refreshments to conference attendees<br>▪ Must be provided consistent with standards established by the conference sponsor and the body accrediting the educational activity<br>▪ ABIOMED may not select the conference attendees |

ABIOMED

Recovering hearts. Saving lives.™

# Code of Conduct and Compliance Policy:

## State Disclosure, Code of Conduct and Lobbyist Law

## Appendix A

*"Your Commitment, Our Integrity"*

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# California (CA)

**CODE OF CONDUCT:** Pursuant to the California Health and Safety Code *(Cal. Health & Safety Code § 119400 – 119402)*, pharmaceutical and medical device manufacturers are required to adopt a Comprehensive Compliance Program ("CCP") in accordance with OIG Compliance Program Guidance for Pharmaceutical Manufacturers ("CPGPM") and, for medical device companies, the Advanced Medical Technology Association Code of Ethics on Interactions with Health Care Professionals ("AdvaMed Code"). The law requires ABIOMED to implement changes or updates to its CCP within six (6) months of any update or revision to the CPGPM or AdvaMed Code.

ABIOMED's CCP must explicitly establish a specific dollar limit on gifts, promotional materials, items or activities that ABIOMED may give or otherwise provide to an individual medical or health professional in California. Additionally, ABIOMED's CCP should contain policies enforcing compliance with the CPGPM and AdvaMed Code.

### Who is a medical or health professional?

- Licensed Prescriber, including
    - Doctor (MO, DO, Dentist)
    - Resident
    - Naturopathic Doctor
    - Optometrist with therapeutic pharmaceutical agents (TPA) certification
    - Podiatrist
    - Advanced Practice Registered Nurse (APRN), including:
        - Nurse Practitioner with furnishing number
        - Certified Nurse Midwife with furnishing number
    - Physician Assistant
- Medical Student
- Member of Drug Formulary Committee

### What is the spending limit?

As required by the California statute, ABIOMED must determine and include in its CCP a specific annual dollar limit for gifts, promotional materials, and items or activities that ABIOMED may give or provide to a medical or health professional. Approved expenditures that count toward the annual medical or health professional dollar limit include:

- Gifts
- Meals
- Promotional materials
- Textbooks and other educational items

ABIOMED's annual spending limit per applicable California medical or healthcare professional is $3,500.

### What are the exemptions to the limitations requirement?

The following items are exempt from any limits so long as the support is provided in a manner that conforms with the CPGPM and AdvaMed Code:

- Samples
- Financial support for continuing medical forums ("CME") and health education scholarships that comply with the CPGPM and AdvaMed Code
- Fair market value compensation for bona fide professional services that comply with the CPGPM and AdvaMed Code (e.g., advisory boards, speaker programs).

### Declaration

ABIOMED shall annually declare its CCP and written certification of compliance with the program on ABIOMED's website and shall also provide a toll-free telephone number where a copy or copies of the CCP and written certification of compliance may be obtained. California does not set forth a specific reporting deadline for the annual declaration statement. ABIOMED is expected to maintain this information for auditing purposes and to conduct annually an audit of its compliance with its policies and spending limits.

# Colorado (CO)

**LOBBYIST REGISTRATION AND GIFT PROHIBITION/LIMITATION:** The Colorado Lobbyist Disclosure Act (COLO. REV. STAT. ANN. § 24-6-301 - 303) requires all lobbyists who direct lobbying[1] activities toward a covered official[2] to register with the Colorado Secretary of State and submit monthly disclosure statements of all contributions made to covered officials. Covered officials include members of the Pharmaceutical and Therapeutics Committee and public officials. The law also requires any person who makes expenditures for the benefit of covered officials in the aggregate amount of $200 per calendar year to submit monthly disclosure statements to the secretary.

Additionally, Colorado's Constitution Article XXIX Ethics in Government prohibits a lobbyist from giving "any gift or thing of value, of any kind or nature" and from providing meals or beverages to public officers, members of the general assembly, or government employees. The article also broadly prohibits public officers, members of the general assembly, local government officials, and government employees from (1) accepting or receiving any money, forbearance, or forgiveness from any person, without such person receiving lawful consideration of equal or greater value in return; and (2) from accepting anything of value having either a fair market value or aggregate actual cost greater than $53, including but not limited to, gifts, loans, rewards, promises or negotiations of future employment, favors or services, honoraria, travel, entertainment or special discounts without the person receiving lawful consideration (e.g., a service) of equal or greater value in return from the public officer, member of the general assembly, local government official, or government employee who solicited, accepted or received the gift or other thing of value.[3]

### Lobbyist Registration Procedure

All lobbyists must register and file lobbyist disclosure reports electronically, utilizing the Online Lobbyist System. Prior to engaging in lobbying activities, individuals are required to register with the Colorado Office of the Secretary of State. Each lobbyist is required to submit an updated registration by July 15th of each year. The fee for lobbyist registration is $40 and covers a one-year period.

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[1] This law defines "lobbying" as directly communicating or soliciting a state agency in order to effect the drafting or adoption of a rule or standard.

[2] A "covered official" is defined as a member of a rulemaking board or commission, or rulemaking official of a state agency.

[3] On April 8, 2011, the Independent Ethics Commission issued Position Statement 11-01 which increased the gift limit amount from $50 to $53. According to the Position Statement, the gift limit will be $53 "until the first quarter of 2015 when it shall be recalculated."

### What must be included in the monthly disclosure report?

Each monthly disclosure statement must include, among other things, the following:

- The name and address of each person who made a contribution of $100 or more to or for a person lobbying during the calendar year, as well as the total amount paid to the lobbyist during the calendar year
- The names of covered officials who were given gifts or items of value equaling $53 or more
- The total of all expenditures in connection with lobbying since the last disclosure statement as well as the cumulative total for the calendar year
- The names of recipients and amounts of payments given to papers, periodicals, magazines, radio, or television stations printing or broadcasting advertisements, articles or editorials related to lobbying

### What are the exemptions to the disclosure requirement?

This law does not require a lobbyist to disclose expenses for the lobbyist's personal needs, including meals, travel, lodging, and parking.

### When is the report due?

By the 15$^{th}$ day of each month; a cumulative disclosure statement must be filed for the fiscal year on July 15th and include the total gross income received for lobbying that year.

# Connecticut (CT)

**CODE OF CONDUCT:** Pursuant to the Connecticut Comprehensive Compliance Program/Code of Conduct Law (Connecticut General Statutes Sec. 21a-70d-e), ABIOMED is required to adopt and implement a Code that is consistent with the Advanced Medical Technology Association Code of Ethics on Interactions with Health Care Professionals ("AdvaMed Code"). Additionally, the law requires ABIOMED to adopt a Comprehensive Compliance Program ("CCP") in accordance with OIG Compliance Program Guidance for Pharmaceutical Manufacturers ("CPGPM").

**MARKETING DISCLOSURE:** Connecticut Public Act 14-12 requires pharmaceutical and medical device companies that provide payments or other transfers of value to advanced practice registered nurses ("APRNs") to submit quarterly reports to state.[4]

### Who is a covered person/entity?

- APRN, which includes:
  - Nurse Practitioner
  - Certified Registered Nurse Anesthetist
  - Clinical Nurse Specialist
  - Certified Nurse Midwife

### What is the spending limit?

To date, there is no spending limit in Connecticut that is specific to APRNs.

### What is reportable?

- All payment(s) or other transfer(s) of value, including, but not limited:
  - Consulting fees
  - Compensation for services other than consulting
  - Honoraria
  - Gifts
  - Entertainment
  - Food and beverage
  - Travel and lodging (including the specified destinations)

[4] Connecticut Public Act 14-217 was signed on June 13, 2014, which changes the date by which applicable manufacturers will be required to submit reports from January 1, 2015 to July 1, 2015 and requires reports to be submitted to the Commissioner of Consumer Protection. CT PA 14-217 will become effective October 1, 2014 and will replace PA 14-12.

- Education
- Charitable contribution
- Royalty or license
- Compensation for serving as faculty or as a speaker for an accredited and certified continuing education program
- Compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program
- Grant

### What are the exemptions to the disclosure law?

- Samples distributed free of charge
- Certain indirect payments to APRNs where ABIOMED does not know or intend that the payment or transfer of value will be made to an APRN.

### When is the report due?

Reports are due quarterly: January 1st, April 1st, July 1st, and October 1st

## Massachusetts (MA)

**CODE OF CONDUCT:** Pursuant to the Massachusetts Pharmaceutical and Medical Device Manufacturer Conduct Law (Mass. Gen. Laws ch. 111N; 105 MASS. CODE REGS. 970.000), ABIOMED is required to annually register and certify that it:

- Has a marketing Code of Conduct in compliance with the MA Pharmaceutical and Medical Device Manufacturer Conduct Law.
- Adopted a training program to routinely train appropriate employees.
- Has policies and procedures in place for conducting investigations into any and all non-compliance with the Massachusetts Marketing Code of Conduct.
- Completed an annual audit to ensure compliance with the Massachusetts Marketing Code of Conduct.
- Submitted an electronic disclosure report file, via email.

An annual $2,000 fee must be included with its certification form.

### What is prohibited by the Code of Conduct Law?

- Meals that are part of an entertainment or recreational event, are offered without an informational presentation made by a pharmaceutical marketing agent, or are provided to a healthcare practitioner's spouse or other guest. The company may provide modest meals outside of the health care practitioner's office or hospital setting for non-CME, informational/educational purposes, as long as it is in a venue and manner conducive to informational communication.
- Certain financial support for CMEs, third-party scientific or educational conferences, and professional meetings, compensation for health care practitioners' time at these events, payment directly for meals at these events, and sponsorship for CME that does not meet ACCME standards or equivalent commercial support standards of the relevant continuing education accrediting body. The regulations also require a separation of grant-making functions from sales and marketing and prohibit any guidance to the CME provider regarding content.
- Entertainment, cash or cash equivalents or complimentary items that are not for services, payments or transfers of value in exchange for prescribing, disbursing, and using prescription products, or any other kind of kickback.
- Entertainment or recreational items of any value to any health care practitioner who is not a salaried employee of the pharmaceutical or medical device manufacturing company (i.e., theater or sporting event tickets, concerts, sporting equipment, or leisure or vacation trips).

- Payments of any kind, such as cash or cash equivalents, equity in kind, or tangible items, including complimentary items (e.g., pens, coffee mugs, gift cards, etc.), except as compensation for bona fide services.
- Grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items in exchange for prescribing, disbursing, or using prescription drugs, biological or medical devices or for a commitment to continue prescribing, disbursing, or using prescription drugs, biologics or medical devices.
- Rebates or kickbacks prohibited under applicable federal or state fraud and abuse laws, or regulations including the federal anti-kickback statutes and equivalent Massachusetts laws.

**MARKETING DISCLOSURE:** Under the same Massachusetts law, ABIOMED is also required to report and disclose certain expenditures and transfers of value. The law requires ABIOMED to disclose the value, nature, purpose and particular recipient of any fee, payment, subsidy or other economic benefit with a value of at least $50, either directly or through its agents, to any covered recipient in connection with the company's sales and marketing activities.

### Who is a covered recipient?

- Doctor (excluding employee of ABIOMED)
- Employee of doctor or other licensed prescriber
- Resident
- Registered Nurse
- Physician Assistant
- Pharmacist
- Other Prescriber, including:
    - Advanced Practice Registered Nurse, which includes:
        - Nurse Practitioner
        - Psychiatric Nurse Mental Health Clinical Specialist
        - Certified Nurse Midwife
- Other Healthcare Provider, including:
    - Psychologist
    - Physical Therapist
    - Occupational Therapist
    - Respiratory Therapist
    - Perfusionist
- Buyer/Purchaser
- Benefits Manager
- Health Plan Administrator
- Hospital
- Nursing Home

- Clinic
- University

### What is the spending limit?

There is no annual limit on expenditures to covered recipients. ABIOMED must, however, disclose all payments related to sales and marketing activities made to covered recipients that exceed $50 per expense.

### What is reportable?

- Meals
- Textbooks and other educational items
- Fair market value compensation for bona fide services (e.g., advisory boards, speaker programs, etc.)
- Payments for CME, third-party conferences, and meetings made directly to organizer, not health care providers
- Other payments related to education and training
- Research (other than clinical trials and other genuine research)
- Charitable donations
- Grants or educational gifts
- Any other payment of $50 or more not expressly excluded

### What are the exemptions to the disclosure requirement?

- Expenditures that do not exceed $50
- Payment related to clinical trials and genuine research
- Samples
- Evaluation units
- In-kind items used for the provision of charity care
- Confidential price concessions
- Double-blinded market research organized by and paid through independent research entity

### When is the report due?

The report is due July 1st annually, however, Massachusetts may require quarterly reports[5] for all or a portion of the aforementioned reportable items.

[5] As of September 2014, Massachusetts has not promulgated final regulations or provided guidance for reporting meals.

# Miami-Dade County, Florida (MDFL)

**LOBBYIST REGISTRATION:** Pursuant to the Code of Miami-Dade County (Code of Miami-Dade County, Florida § 2-11.1.(s)) any individual who seeks to encourage the actions, decisions, or recommendations of the County Commission, County Manager, County Personnel or any county board or committee must annually register as a lobbyist with the Miami-Dade Board of County Commissions. This includes pharmaceutical and medical device representatives who interact with University of Miami[6] and Jackson Health System physicians who serve on a procurement review or selection committee.

This law also requires each registered lobbyists to file an annual lobbyist expenditure report with the Board. The disclosure statement must include a list of all expenditures in excess of $25 for the preceding calendar year.

### What is reportable?

Lobbyists must submit to the Clerk of the Board of County Commissioners a signed statement under oath listing in detail expenses in excess of $25 by the following categories:

- Food and beverage
- Entertainment
- Research
- Communication
- Media Advertising
- Publications
- Travel
- Lodging
- Special events

### What are the exemptions to the disclosure requirement?

- Expenditures that do not exceed $25
- Political contributions and expenditures reported under election laws
- Campaign-related personal services provided without compensation

[6] According to an Advisory Opinion issued by the Commission on Ethics and Public Trust ("Commission"), any vendor that approaches a University of Miami ("UM") doctor for a physician preference is required to register as a lobbyist if the: (1) physician serves on a procurement review or selection committee; or (2) the vendor is seeking to influence the action, recommendations, or decision of County personnel (UM physicians are considered country personnel when they make decisions regarding particular products and services for use in Jackson Health System facilities). The Advisory Opinion also states that a pharmaceutical/medical device representative is required to register as a lobbyist if he or she approaches UM doctors regarding the purchase of products or services that "foreseeably" will be reviewed by the Public Health Trust ("PHT") Board of Trustees or a PHT board or committee.

- The lobbyist's or principal's salary, office expenses, and personal expenses for lodging, meals, and travel

## Lobbyist Registration

Any individual who engages in lobbying must register as a lobbyist within five (5) business days of being retained as lobbyist. Each new registrant must complete and file an Annual Lobbyist Registration form for lobbyist registration and renewal. Each registered lobbyist is required to renew his or her registration by January 15th of each year. The annual lobbyist registration and renewal fee is $490.

## Lobbyist Training

Lobbyists are required to complete an Ethics course and submit a certificate of completion to the Clerk of the Board of County Commissioners within sixty (60) days of registering as a lobbyist. A refresher course is required to be completed every two years. The Ethics course will include a review of Miami-Dade's Conflict of Interest and Code of Ethics Ordinance and other related state laws. The fee for the Ethics course is $100.

## Lobbyist Reporting Deadlines

Each lobbyist must submit a Lobbyist Expenditure report to the Clerk by July 1st of each year for expenditures incurred during the preceding calendar year (January 1st- December 31st).

# Nevada (NV)

**CODE OF CONDUCT:** The Nevada Pharmaceutical Code of Conduct Law (Nev. Rev. Stat. Ch. 639) requires wholesalers and manufacturers who employ a person to sell or market a drug, medicine, chemical, device, or appliance in Nevada to adopt a written marketing Code of Conduct establishing the practices and standards that govern the marketing and sale of their products.

Pursuant to the Nevada Pharmaceutical Code of Conduct Law, ABIOMED is required to:

- Adopt a written marketing Code of Conduct that establishes the practices and standards that govern the market and sale of its product(s).
- Adopt a written training program to provide regular training to appropriate employees on the marketing Code of Conduct. This includes, but is not limited to, all sales and marketing staff.
- Conduct annual audits to monitor compliance with the marketing Code of Conduct.
- Adopt policies and procedures for investigating instances of non-compliance.
- Identify a compliance officer.

A wholesaler or manufacturer who employs a person to sell or market a device or appliance in the state may adopt, without modification, the AdvaMed Code as its marketing Code of Conduct to fulfill the requirements of this law. If a company chooses to create and follow its own marketing Code of Conduct that meets the requirements of the Nevada Pharmaceutical Code of Conduct Law, then it must submit a copy to the Board of Pharmacy.

### What must be included in the Code of Conduct?

If ABIOMED develops its own marketing Code of Conduct, the Code must address the following subjects:

- Basis of interactions
- Informational presentations by or on behalf of a manufacturer or wholesaler
- Third-party educational or professional meetings
- The use of consultants
- Speaker training meetings
- Scholarships and educational funds
- Educational and practice-related items
- Independence of decision marking
- Adherence to the marketing Code of Conduct

### What must be submitted?

ABIOMED must annually submit to the Nevada State Board of Pharmacy:

- A copy of its marketing Code of Conduct

- A description of its training program
- A description of its investigation policies
- The name, title, address, telephone number and electronic mail address of its compliance officer
- Certification that it has conducted its annual audit and is in compliance with its marketing Code of Conduct

### When is the compliance certification due?

ABIOMED is required to submit the compliance package and the annual audit certification forms to the Board by June 1st annually by 5:00 p.m. PST. Mail postmarked by June 1 will be deemed to be compliant even if it is received later than June 1.

# Vermont (VT)

**MARKETING DISCLOSURE**: Pursuant to the Vermont Prescribed Products Gift Ban and Disclosure Law (VT. STAT. ANN. Tit. 18, § 4631a; VT. STAT. ANN. Tit. 18, § 4632) ABIOMED is required to annually disclose the value, nature, purpose and recipient of any allowable expenditure or permitted gift.

### Who is a health care provider?

- Doctor (excluding employees of ABIOMED), including:
  - MD
  - DO
  - Dentist
  - Optometrist
  - Podiatrist
  - Veterinarian
- Resident
- Registered Nurse
- Physician Assistant
- Pharmacist
- Other Prescriber, including:
  - Advanced Practice Registered Nurse, which includes:
    - Nurse Practitioner
    - Certified Registered Nurse Anesthetist
    - Psychiatric Mental Health Clinical Specialist
    - Certified Nurse Midwife
- Other Healthcare Provider, including:
  - Social Worker
  - Psychologist
- Employee of doctor, medical practice, or other healthcare provider
- Buyer/Purchaser
- Benefits Manager
- Health Plan Administrator
- Member of Green Mountain Care Board
- Hospital
- Nursing Home
- Clinic
- Clinical Trial/Research Organization
- University/Academic Institution
- Nonprofit Hospital Foundation

- Professional Organization
- Patient Organization

### What is the spending limit?

There is no spending limit in Vermont, subject to the prohibitions below.

### What permissible expenditures/transfers are reportable?

- Payments to sponsor or organizer of educational or scientific conference
- Fair market value compensation for bona fide services (e.g., advisory boards, speaker programs, etc.)
- Expenses for medical device training
- Clinical trial and research project expenses,[7] including:
    - Gross compensation for the Vermont location
    - Direct salary support per principal investigator and other health care professionals
    - Expenses paid on behalf of investigators and other professionals
- Textbooks, reprints, and other educational items
- Financial and product donations to free clinics
- Grants and scholarships
- Discount program allowances and redemptions (e.g., coupons, vouchers, etc.)
- Samples
- Sponsorship of an educational program offered by a medical device manufacturer at a national or regional professional society meeting at which programs accredited by the ACCME are also offered

### What is prohibited?

- ABIOMED representatives and agents are prohibited from offering or giving any gift to a health care provider licensed in Vermont. A gift is defined as anything of value provided for free, and anything else of value given to a health care provider or to a member of the Green Mountain Care Board, including food, entertainment, travel, subscription or service, unless it is otherwise exempted as an allowable expenditure.
- Meals may not be provided to covered persons in Vermont, except meals associated with advisory boards, provided the cost of the meal is subtracted from the health care provider's honorarium.

### Which permissible expenditures/transfers are exempt from the disclosure requirement?

- Royalties and licensing fees
- Rebates and discounts in the normal course of business (other than coupons, vouchers, etc.)

[7] Allowable expenditures for bona fide clinical trials must be disclosed after the earlier of FDA approval or clearance of the prescribed product or four calendar years after the date the payment was made.

- Prescribed products distributed free of charge or at a discounted price pursuant to a manufacturer-sponsored or manufacturer-funded patient assistance program
- Reasonable expenses related to an individual's interview for a bona fide employment opportunity
- Snacks or coffee provided at a seminar or conference booth
- Loans of medical devices for short-term trial (120 days) periods

**When is the report due?**

April 1st, annually

ABIOMED

Recovering hearts. Saving lives.™

# Code of Conduct and Compliance Policy:

## FDA Approvals
## Appendix B

*"Your Commitment, Our Integrity"*

2832368

# Abiomed Products – FDA Labeling

## Impella® Device Indication and Safety Information

### INDICATIONS FOR USE

***Protected PCI***

The Impella 2.5® and Impella CP® Systems are temporary (≤ 6 hours) ventricular support devices indicated for use during high-risk percutaneous coronary interventions (PCI) performed in elective or urgent, hemodynamically stable patients with severe coronary artery disease and depressed left ventricular ejection fraction, when a heart team, including a cardiac surgeon, has determined high-risk PCI is the appropriate therapeutic option. Use of the Impella 2.5 and Impella CP Systems in these patients may prevent hemodynamic instability, which can result from repeat episodes of reversible myocardial ischemia that occur during planned temporary coronary occlusions and may reduce peri- and post-procedural adverse events.

***Cardiogenic Shock***

The Impella 2.5®, Impella CP®, Impella 5.0®, and Impella LD® Catheters, in conjunction with the Automated Impella Controller (collectively, "Impella® System Therapy"), are temporary ventricular support devices intended for short term use (≤ 4 days for the Impella 2.5 and Impella CP, and ≤ 6 days for the Impella 5.0, and Impella LD) and indicated for the treatment of ongoing cardiogenic shock that occurs immediately (< 48 hours) following acute myocardial infarction or open heart surgery as a result of isolated left ventricular failure that is not responsive to optimal medical management and conventional treatment measures (including volume loading and use of pressors and inotropes, with or without IABP). The intent of Impella System Therapy is to reduce ventricular work and to provide the circulatory support necessary to allow heart recovery and early assessment of residual myocardial function.

***Important Risk Information for Impella devices***

### CONTRAINDICATIONS

The Impella 2.5, Impella CP, Impella 5.0 and Impella LD are contraindicated for use with patients experiencing any of the following conditions: Mural thrombus in the left ventricle; Presence of a mechanical aortic valve or heart constrictive device; Aortic valve

stenosis/calcification (equivalent to an orifice area of 0.6 cm2 or less); Moderate to severe aortic insufficiency (echocardiographic assessment graded as ≥ +2); Severe peripheral arterial disease precluding placement of the Impella System; Significant right heart failure*; Combined cardiorespiratory failure*; Presence of an Atrial or Ventricular Septal Defect (including post-infarct VSD)*; Left ventricular rupture*; Cardiac tamponade*

* This condition is a contraindication for the cardiogenic shock indication only.

**POTENTIAL ADVERSE EVENTS**

Acute renal dysfunction, Aortic valve injury, Bleeding, Cardiogenic shock, Cerebral vascular accident/Stroke, Death, Hemolysis, Limb ischemia, Myocardial infarction, Renal failure, Thrombocytopenia and Vascular injury

In addition to the risks above, there are other WARNINGS and PRECAUTIONS associated with Impella devices.

Visit www.protectedpci.com/hcp/information/isi and
www.cardiogenicshock.com/hcp/information/isi to learn more.

# Right Side Support – Indication and Safety Information

## INDICATIONS FOR USE

The Impella RP® is indicated for providing circulatory assistance for up to 14 days in pediatric or adult patients with a body surface area ≥ 1.5 m2 who develop acute right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery.

***Important Risk Information for Impella RP***

## CONTRAINDICATIONS

The Impella RP is contraindicated for use with patients experiencing any of the following conditions: Pulmonary artery wall disorders precluding placement or correct positioning of the Impella RP device; Anatomic conditions precluding insertion of the pump; Tricuspid or pulmonic valve abnormalities including: mechanical valves, severe stenosis or regurgitation; Mural thrombus of the right atrium or vena cava; Other illnesses or therapy requirements precluding use of the pump; Presence of a vena cava filter or caval interruption device, unless there is clear access from the femoral vein to the right atrium that is large enough to accommodate a 22 Fr catheter.

## POTENTIAL ADVERSE EVENTS

Arrhythmia, Atrial fibrillation, Bleeding, Cardiac tamponade, Cardiogenic shock, Death, Device Malfunction, Hemolysis, Hepatic failure, Insertion site infection, Perforation, Phlegmasia cerulea dolens (a severe form of deep venous thrombosis), Pulmonary valve insufficiency, Respiratory dysfunction, Sepsis, Thrombocytopenia, Thrombotic vascular (non-central nervous system) complication, Tricuspid valve injury, Vascular injury, Venous thrombosis, Ventricular fibrillation and/or tachycardia.

In addition to the risks above, there are other WARNINGS and PRECAUTIONS associated with Impella RP.

Visit www.abiomed.com/impella/impella-rp to learn more.