

# BDSI's Culture of Compliance

BioDelivery Sciences International, Inc. (BDSI), is committed to conducting business ethically and in compliance with the laws and regulations that govern our industry. Furthermore, BDSI's executive leadership, including its Board of Directors, is committed to promoting a compliant and ethical corporate culture for the benefit of its patients, investors, customers, and employees.

There are a number of resources available that guide our employees' decisions and are designed to ensure that they do the right thing, including:

## BDSI's Code of Ethical Conduct

BDSI's corporate policies and procedures

Compliance materials and training

Compliance Officer and compliance committee

Guidance from managers

BDSI's Ethics and Compliance Hotline

## BDSI's Comprehensive Compliance Program

BDSI has established a Comprehensive Compliance Program (Compliance Program), in accordance with the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals (PhRMA Code) and the Compliance Program Guidance for Pharmaceutical Manufacturers published by the U.S. Department of Health and Human Services Office of Inspector General in April 2003 (OIG Guidance). The Compliance Program is designed to comply with applicable federal and state laws and the above mentioned industry standards relating to the marketing and promotion of its products.

### **Overview of BDSI's Compliance Program**

#### *Written Policies and Procedures*

BDSI has written policies and procedures to assure substantial compliance with the applicable laws, regulations, and standards governing the marketing and promotion of our products. BDSI has established written policies and procedures that govern activities involving interactions with our customers regarding the appropriate use of our products including instruction, education, training, and support required for the safe and effective use. BDSI also has policies and procedures governing activities involving the advancement of scientific and educational activities supporting medical research and education.

#### *Designated Compliance Officer*

BDSI has appointed a Vice President as the Commercial Compliance officer, who has been empowered with appropriate authority to exercise independent judgment and has free and unencumbered access to senior management. In addition, a Commercial Compliance Committee has been formed. This

committee is chaired by the VP serving as the Commercial Compliance officer and appropriate members of BDSI's Management Team.

### ***Training and Communication***

BDSI has a Compliance Program training process that is mandated for all employees. New employees receive training at the time of hire and as appropriate thereafter. The training covers applicable guidelines governing our Compliance Program.

BDSI employees are encouraged to report any compliance concerns to their manager, our Human Resources team, the Legal Department or Compliance Department. BDSI employees also have the option to report potential violations by accessing BDSI's Compliance Line at 1-844-687-BDSI (1-844-687-2374); BDSI@GetInTouch.com; or [www.InTouchWebsite.com/BDSI](http://www.InTouchWebsite.com/BDSI).

### ***Auditing and Monitoring***

BDSI self-assesses, audits and monitors its Compliance Program and reviews policies and procedures periodically. Audit and monitoring observations are tracked to ensure timely closure of any identified items.

### ***Enforcement and Disciplinary Guidelines and Policies and Procedures for Violations***

BDSI will take disciplinary actions, up to and including termination, in response to a violation of BDSI's compliance policies or procedures. An investigation of any matter that is brought to BDSI's attention will occur and will be brought to closure in a timely manner in accordance with our compliance policies.

In accordance with BDSI's compliance policies, any potential violations of BDSI's Compliance Program are promptly addressed. Responses to any potential violations may include additional training, enhanced communications, refinement of policies, or possible disciplinary actions, up to and including termination.

Our Compliance Program is designed to prevent, detect and remediate violations of law, regulations and company policies, as well as to promote an ethical culture that will, among other things, guide our interactions with healthcare professionals and healthcare entities. BDSI's Compliance Program is tailored to its size, organizational structure, and resources and reasonably intended to meet the specific needs of BDSI.

Last update: October 30, 2018

# **California Declaration of Compliance**

## **Declaration**

BDSI declares that to the best of its knowledge, and based upon a good faith understanding of California Health & Safety Code Sections 119400-119402 (the California Statute), that as of this date BDSI (1) has established a Comprehensive Compliance Program that is reasonably designed to prevent or detect and address misconduct and that encompasses the compliance program requirement set forth in the California Statute, and (2) is in compliance with its Comprehensive Compliance Program and the California Statute.

Compliance is a dynamic concept and the BDSI Comprehensive Compliance Program is similarly intended to be a dynamic program designed to meet the company's evolving compliance needs. Accordingly, BDSI will at least annually review and, as needed, modify its Comprehensive Compliance Program to enhance its effectiveness.

### **Annual Aggregate Dollar Limit**

In compliance with the California laws, BDSI has established a specific annual aggregate dollar limit of **\$2,500** on gifts, promotional materials, or items or activities that BDSI and its subsidiaries may give or otherwise provide to an individual medical or healthcare professional in California. Such items or activities primarily include: items that are primarily directed to the dissemination or communication of medical and scientific information as a resource for healthcare professionals to assist in making clinical or other medical judgments; modest meals associated with a substantive discussion of a BDSI product or a disease state; and other items or activities permitted under the OIG Compliance Guidance and PhRMA Code. BDSI may revise this limit from time to time. This limit represents a spending cap, not a goal or average; in many cases, the amount spent per physician may be substantially less than the cap amount. BDSI has internal monitoring mechanisms designed to measure compliance with the spending limits as set by BDSI for California medical and healthcare professionals.

The annual limits do not include the following: financial support for continuing medical education forums; financial support for health educational scholarships; payments for legitimate healthcare professional services, and any meals or expenses associated with the provision of such services; items of nominal value with a retail value of less than \$10 (e.g., visual aids, reprints of medical journal articles); or patient educational materials provided to patients by their physician with the purpose of educating the patient or enhancing the patient's understanding or management of the condition.

Questions regarding BDSI's Code of Business Conduct or this Compliance Disclosure may be addressed to BDSI's Corporate Compliance Department at: [compliance@bdsi.com](mailto:compliance@bdsi.com)

Last update: October 30, 2018