



January 1, 2020

BDSI's U.S. Compliance Program Description

I. Introduction

BioDelivery Sciences International, Inc. ("BDSI") has established and maintains a Comprehensive U.S. Compliance Program concerning the marketing and sale of products in the U.S. (the "Compliance Program").

BDSI's Compliance Program has been developed in accordance with the "*Compliance Program Guidance for Pharmaceutical Manufacturers*," published by the Office of Inspector General, U.S. Department of Health and Human Services (the "OIG Guidance") and reflects BDSI's commitment to the highest standards of conduct.

As recommended in the OIG Guidance, the Compliance Program is tailored to BDSI's size, organizational structure, and available resources. While the OIG Guidance recognizes that even an effective compliance program may not completely eliminate all misconduct by individuals, BDSI's Compliance Program is reasonably designed to prevent and detect violations. The Compliance Program is dynamic, and, in order to address evolving compliance needs, BDSI assesses and updates the Compliance Program annually.

The key elements of the Compliance Program are as follows:

- A Chief Compliance Officer
- Written Standards of Conduct
- On-going compliance training
- Open lines of communication, including a Confidential Compliance Hotline
- Targeted monitoring and auditing,
- Enforcement of the Compliance Program, and
- A process for responding to compliance issues and promptly implementing corrective action.



II. Leadership and Structure

BDSI's Chief Compliance Officer ("COO") is Jim Vollins, General Counsel & Chief Compliance Officer. The COO reports directly to the Chief Executive Officer ("CEO") of BDSI and BDSI's Board of Directors.

The CCO is responsible for developing, operating, and monitoring the Compliance Program. The CCO has the authority and capability to effectuate change within BDSI and to exercise independent judgment.

III. Written Standards of Conduct

The BDSI Healthcare Compliance Policies (the "Policies") are the main compliance resource for employees of BDSI who are engaged in the sale and marketing of BDSI products in the U.S or working with U.S. healthcare professionals. Employees are required to certify at or about the time of hire and annually that they have reviewed and will comply with the Policies.

The Policies include standards of conduct that address the areas of potential risk described in the OIG Guidance. The Policies are in full accordance with the *PhRMA Code on Interactions with Healthcare Professionals*.

IV. Education and Training

BDSI educates its employees on the elements of the Compliance Program and the Policies. BDSI employees receive initial compliance training at or about the time of hire, annual training, and periodic training as may be necessary to address changes in the law, specific areas of risk, or new policies. The training materials are developed by the CCO and cover the U.S. laws that are relevant to the areas of risk identified in the OIG Guidance. BDSI regularly reviews and updates its training materials.

V. Effective Internal Lines of Communication

BDSI is committed to promoting an open dialogue between management and employees. Our goal is that all employees with questions or concerns will know who to turn to for a meaningful response, without fear of retaliation. BDSI employees are expected to report



actual or suspected violations of law or BDSI policy. Employees can report actual or suspected violations of law or policy in a number of ways, including by reporting to their managers, any manager, a member of the BDSI's Executive Leadership Team, the CCO or by using BDSI's Confidential Hotline.

VI. Auditing and Monitoring

BDSI monitors, audits, and evaluates compliance with its policies and the law. BDSI's approach includes targeted monitoring and auditing based on identified and prioritized risk areas in accordance with the OIG Guidance.

VII. Enforcing Policies

Employees that intentionally, repeated or materially violate BDSI's policies or the law are subject to appropriate disciplinary action up to termination of employment according to BDSI policy.

VIII. Investigations and Corrective Action

The CCO will promptly investigate suspected violations of BDSI policy or the law in accordance with BDSI policy. The scope and manner of the investigation will depend upon the severity, materiality and nature of the allegation. All employees are expected to comply with internal investigations as a condition of employment.

The CCO is authorized to consider whether interim compliance measures are required during the pendency of an investigation and, in consultation with management, implement appropriate interim measures to protect BDSI.

IX. Declaration under California Health & Safety Code

As part of its Compliance Program, BDSI has established an aggregate, annual dollar limit of \$5,000.00 on promotional items and/or meals provided to individual healthcare professionals who reside or practice in the State of California.

BDSI declares, to the best of its knowledge, and based on its good faith understanding of the statutory requirements, that as of January 1, 2020, it is in compliance with the



Compliance Program and the California Health & Safety Code.

Copies of the Compliance Program and this written California declaration can be obtained by calling 1-877-579-4578.

X. BDSI's Commitment to Compliance

BDSI is committed to the maintenance of an effective, comprehensive U.S. compliance program, and will update this document as necessary to reflect changes to the Compliance Program. The CCO is available to answer questions concerning the Compliance Program.