

# OTSUKA AMERICA PHARMACEUTICAL, INC. COMPREHENSIVE COMPLIANCE PROGRAM

## 1. Introduction

Otsuka America Pharmaceutical, Inc. (“OAPI” or the “Company”) is committed to conducting our business with a high degree of ethics and integrity and in compliance with all applicable legal and regulatory requirements. We have established a system of internal policies and procedures that promote adherence to the laws, regulations and requirements applicable to our business activities.

The purpose of our Comprehensive Compliance Program (the “Compliance Program”) is to promote compliance with the laws, rules and regulations that govern our interactions with healthcare professionals and communications about our products. Our Compliance Program has been developed in accordance with the elements of the U.S. Federal Sentencing Guidelines, U.S. Department of Health and Human Services *Office of Inspector General (OIG) Compliance Program Guidance for Pharmaceutical Manufacturers* dated May 5, 2003 (the “OIG Compliance Guidance”), and the standards set forth in the *Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals* (the “PhRMA Code”), and other relevant industry guidances.

The Company shall review and update this Compliance Program from time to time as it reasonably deems appropriate.

## 2. Written Standards

The OAPI Code of Conduct and Business Ethics (“Code of Conduct”) describes our fundamental principles and values and summarizes the policies and legal requirements that apply to our business. In addition, the Code of Conduct provides standards for conducting our business, summarizes expectations of employee conduct, informs employees of their compliance obligations, sets out specific procedures for reporting possible noncompliance and describes OAPI’s disciplinary policy.

The OAPI Code of Conduct is supported by written policies and procedures governing our general business activities as well as those activities related to the marketing and sales of our products and interactions with healthcare professionals. Our policies and procedures are designed to ensure compliance with the provisions of the OIG Compliance Guidance and PhRMA Code and address areas including the following: meals, venues, and educational items to facilitate interactions with healthcare professionals; grant support for third-party education, investigator-sponsored studies, and charitable organizations; fee-for-service arrangements with healthcare professionals; provision of prescription drug samples; use of prescriber data; review of promotional materials; conducting internal investigations, and addressing non-employment or retention of individuals and entities excluded from participation in any federal health care program.

3. Chief Compliance Officer

The Chief Compliance Officer is charged with monitoring the Compliance Program and serves as a contact person for issues relating to the Program. The Chief Compliance Officer has overall responsibility for developing and implementing policies, procedures, and practices designed to ensure compliance with applicable healthcare program requirements. The Chief Compliance Officer provides periodic reports regarding compliance matters to the Board of Directors of OAPI and chairs the Compliance Committee of OAPI.

4. Compliance Committee

The Compliance Committee is made up of senior management personnel and provides oversight and guidance for compliance activities. The Compliance Committee assists the Chief Compliance Officer in the analysis of the Company's risk areas and oversees the monitoring of internal and external audits and investigations, as needed.

5. Training

The Company provides Compliance Program training for all of our employees at least annually. Our Compliance Program training includes key areas of compliance related to integrity of data used for payments under government healthcare programs, anti-kickback and other fraud and abuse laws, laws and regulations governing samples, the PhRMA Code, and related policies and procedures.

6. Auditing and Monitoring

The Company adopts an annual auditing and monitoring plan based upon an analysis of various inputs. The Company uses audits and/or monitoring procedures to review certain programs and activities including, but not limited to, those involving sales and marketing to determine whether such programs were carried out in accordance with the relevant OAPI policies and procedures and applicable laws, rules and regulations. The results of such reviews may be used as a basis for improving upon existing policies/procedures or adopting new ones.

7. Procedures for Reporting Violations

The Company's Code of Conduct requires employees to report any known or suspected violations of law, regulations, company policies or procedures to their supervisor or to the Chief Compliance Officer. In most cases, an employee's supervisor is in the best position to address an area of concern. However, if employees are not comfortable speaking with their supervisor or employees are not satisfied with their supervisor's response, employees are encouraged to speak with someone in the Human Resources Department or anyone in management whom employees are comfortable approaching. Supervisors and managers are required to report suspected violations of the

Code of Conduct to the Chief Compliance Officer, who has specific responsibility to investigate all reported violations. Additionally, our policies strictly prohibit retaliation against any person who, in good faith, reports known or suspected compliance issues. The Company has established a toll-free telephone number, 1-800-363-5670, for reporting of such violations or possible violations.

8. Investigations, Corrective Actions and Sanctions

In the event that the Company becomes aware of any suspected violations of law, regulation, policy or procedure, the Company investigates the circumstances surrounding the suspected noncompliance to determine whether a violation has occurred. If a violation is found, the Company takes appropriate corrective action, which may involve disciplinary action up to and including termination of employment.

9. Annual Dollar Limit on Gifts or Incentives Provided to Medical or Health Professionals in California

As required by, and in accordance with the definitions set forth in, California SB 1765, the Company has established an annual dollar limit on gifts, promotional materials, or items or activities that the Company may give or otherwise provide to an individual medical or healthcare professional in California. This annual dollar limit is \$1,400 per such individual and may be revised by OAPI from time to time. As of January 1, 2007, OAPI implemented a calendar year reporting cycle for purposes of making its annual declarations under California Health and Safety Code Sections 119400 - 119402. Beginning in 2008, the annual declaration shall be made by July 1 each year for covered activities occurring in the preceding calendar year.

10. Obtaining Copies of the OAPI Comprehensive Compliance Program for Sales and Marketing Activities and Annual Declaration of Compliance

Copies of OAPI's Comprehensive Compliance Program and annual Declaration of Compliance can be obtained by calling our toll-free number, 1-800-363-5670 or from our corporate website at [www.otsuka-us.com](http://www.otsuka-us.com).

**Dated: July 1, 2005 (Revised July 1, 2011)**