

**OTSUKA AMERICA PHARMACEUTICAL, INC. AND
OTSUKA PHARMACEUTICAL DEVELOPMENT &
COMMERCIALIZATION, INC.
COMPREHENSIVE COMPLIANCE PROGRAM**

1. Introduction

Otsuka America Pharmaceutical, Inc. (“OAPI”) and Otsuka Pharmaceutical Development & Commercialization, Inc. (“OPDC”) (collectively, “Otsuka”) are 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.

Otsuka shall review and update its Compliance Program from time to time as it reasonably deems appropriate.

2. Written Standards

Otsuka’s Code of Ethics and Professional Conduct (“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 Otsuka’s disciplinary policy.

The 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 implementing the Compliance Program and serves as the primary contact for issues relating thereto. 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 Audit Committee of the Otsuka Board of Directors, the full Otsuka Board of Directors, and chairs Otsuka's Compliance Committee.

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 Otsuka's risk areas and oversees the monitoring of internal and external audits and investigations, as needed.

5. Training

Otsuka provides Compliance Program training for all employees and applicable suppliers 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, the Code of Conduct, and related policies and procedures. Otsuka also tailors training specifically to employees' and suppliers' responsibilities and risk levels. Consistent with the Department of Justice and the Office of Inspector General expectations, Otsuka continues to develop training programs based on regulatory agency guidance and a review of recent industry settlements and corporate integrity agreements.

6. Auditing and Monitoring

Otsuka adopts an annual auditing and monitoring plan based upon an analysis of various inputs to test the implementation and effectiveness of compliance policies and procedures, utilizing both risk-based and random sampling techniques. Otsuka 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 Otsuka 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 to allow Otsuka to take actions to mitigate the risk of future non-compliance.

7. Procedures for Reporting Violations

Otsuka's Code of Conduct requires employees to report any known or suspected

violations of law, regulations, or Otsuka 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 Ethics & Compliance, Human Resources, Legal Affairs, 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 any retaliation against any person who, in good faith, reports known or suspected compliance issues. Otsuka has established a toll-free telephone number, 1-800-363-5670, and online web portal for reporting of such violations or possible violations.

8. Investigations, Corrective Actions and Sanctions

In the event that Otsuka becomes aware of any suspected violations of law, regulation, policy, or procedure, Otsuka investigates the circumstances surrounding the suspected noncompliance to determine whether a violation has occurred. If a violation is found, Otsuka 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 Health and Safety Code Sections 119400 et. seq., Otsuka has established an annual dollar limit on gifts, promotional materials, or items or activities that Otsuka 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 Otsuka from time to time. As of January 1, 2007, Otsuka 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 Otsuka Comprehensive Compliance Program for Sales and Marketing Activities and Annual Declaration of Compliance

Copies of Otsuka'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.

Dated: July 1, 2005 (Last Revised July 1, 2025)