

# Mallinckrodt's Corporate Compliance Program US

Mallinckrodt Pharmaceuticals ("Mallinckrodt") is committed to establishing and maintaining an effective Compliance Program in accordance with the California Health and Safety Code sections 119400 and 119402 and the "Compliance Program Guidance for Pharmaceutical Manufactures," published by the Office of Inspector General, U.S. Department of Health and Human Services (the "HHS-OIG Guidance"). Our Compliance Program is one of the key components of our commitment to the highest standards of corporate conduct.

The purpose of our Compliance Program is to prevent and detect violations of law or company policy. As the HHS-OIG Guidance recognizes, however, the implementation of such a program cannot guarantee that improper employee conduct will be entirely eliminated. Nonetheless, it is Mallinckrodt's expectation that employees will comply with Mallinckrodt's Guide to Business Conduct, the Mallinckrodt Comprehensive Compliance Program (U.S.) document and the Mallinckrodt Third Party Intermediary Code of Conduct (for third-party agents working on Mallinckrodt's behalf).

In the event that Mallinckrodt becomes aware of violations of law or company policy, we will investigate the matter and, where appropriate, take disciplinary action and implement corrective measures to prevent future violations. Mallinckrodt has described below the fundamental elements of Mallinckrodt's Compliance Program. As HHS-OIG calls for in its Guidance, we have tailored our Compliance Program to fit the unique environment of our company. Moreover, our Compliance Program is dynamic; we regularly review and enhance our Compliance Program to meet our evolving compliance needs.

## Overview of Our Compliance Program

### Chief Compliance Officer and Compliance Committee

Mallinckrodt has designated a Chief Compliance Officer. Our Chief Compliance Officer has the ability to effectuate change within the organization as necessary and to exercise independent judgment. The Chief Compliance Officer is charged with the responsibility for developing, operating and monitoring the Mallinckrodt Compliance Program. Mallinckrodt has a Compliance Committee at the Board level, as well as a Management Compliance Committee as the senior leadership level.

### Written Standards

Mallinckrodt's Guide to Business Conduct is an expression of the company's expected standards of behavior for everyone who conducts business on behalf of the Company. The Guide establishes compliance responsibilities, supports applicable laws and regulations, and reinforces corporate policies and procedures. The Guide articulates our fundamental principles, values and framework for action within our organization. Both Mallinckrodt's Conduct Guide for Field Professionals and its Comprehensive Compliance Program (U.S.) document provide principles and standards for our interactions with health care professionals.

### 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 health care program requirements. Mallinckrodt is committed to taking necessary steps to effectively communicate our standards and procedures to all affected personnel. Moreover, Mallinckrodt will regularly review and update its training programs, as well as identify additional areas of training on an "as needed" basis.

### Internal Lines of Communication

Mallinckrodt is committed to encouraging dialogue between management and employees. Our goal is that all employees, when seeking answers to questions or reporting potential instances of fraud and abuse, should know to whom to turn for a meaningful response and should be able to do so without fear of retribution. To that end, we have adopted principles regarding confidentiality and policies prohibiting retaliation as outlined in the Mallinckrodt Guide to Business Conduct. Employees are expected to report suspected violations of company policy by contacting their Manager, the Legal Department, Human Resources, the Compliance Department, or via the Compliance Integrity Hotline.

### Annual Spending Limit

The Mallinckrodt Compliance Program includes an annual spending limit of \$2,000 for certain promotional activities directed toward healthcare professionals. The amount spent per healthcare professional is anticipated

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to be substantially less than this maximum amount. Any waiver in excess of this amount requires the approval of the Mallinckrodt Chief Compliance Officer.

### **Auditing and Monitoring**

Mallinckrodt's Compliance Program includes efforts to monitor, audit, and evaluate adherence to the company's compliance activities. 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.

### **Responding to Potential Violations and Corrective Actions**

Mallinckrodt's Compliance Program strives to ensure that the consequences of violating the law or company policy are clearly understood and the appropriate, consistent disciplinary action is enforced. Additional efforts are underway to create a Compliance Program that increases the likelihood that unlawful and unethical behavior is identified and prevented. However, HHS-OIG recognizes that even an effective compliance program may not prevent all violations. As such, our Compliance Program requires the company to evaluate each case and respond promptly to potential violations of law or company policy, take appropriate disciplinary action, assess whether the violation is in part due to gaps in our policies, practices, or internal controls, and take action to prevent future violations.

### **Contact Information**

For questions or comments regarding Mallinckrodt's Compliance Program email us at [Compliance.Dept@mnk.com](mailto:Compliance.Dept@mnk.com).

### **California Compliance Declaration**

As part of Mallinckrodt, Inc.'s continuing activities in the area of corporate compliance, we have implemented the Mallinckrodt Corporate Compliance Program. This program was developed with consideration given both to the goals of sections 119400- 119402 of the California Health and Safety Code and to the operations, size, and organization of our Company. Based upon our good faith understanding of these statutory requirements, we believe we are in compliance in all material respects with our Compliance Program and the requirements of the California Health and Safety Code.

### **The Mallinckrodt Compliance Integrity Hotline**

Mallinckrodt's Compliance Integrity Hotline allows colleagues or partners to report a concern or obtain information, or seek advice. You will have the option to remain anonymous where permitted by local law. Where available, the Integrity Hotline can be reached by phone or online via the web. The toll-free Integrity Hotline is available 24 hours a day, 365 days a year. The Compliance Hotline is operated by specially trained third-party representatives and is located in the USA.

**To Make a Report by Phone:** Toll-free in the United States, US Territories and Canada: +1-888-696-9864.

For our international employees, (Outside the US, US Territories and Canada) you will need to dial your applicable AT&T direct access number before dialing +1-888-696-9864.

**AT&T Direct Access Info:** [Dialing Instructions](#)

**To Make a Report Online:** <https://mallinckrodt.ethicspoint.com/>

For individuals in the European Union, please note that Mallinckrodt's Compliance Integrity Hotline phone and online services only allow the reporting of certain issues, depending on local law (generally: financial, accounting and auditing matters). Other matters may be reported by contacting the Mallinckrodt Compliance Department via email at [Compliance.Dept@mnk.com](mailto:Compliance.Dept@mnk.com)