



## **Corporate Compliance Program Overview**

### **Posted as Required by California Health & Safety Code s §§ 119400-119402**

Mobius Therapeutics, LLC (Mobius) is committed to conducting business in compliance with federal, state and local laws and regulations in all facets of its corporate activities. Mobius has modeled its Compliance Program after the “Compliance Program Guidance for Pharmaceutical Manufacturers” (OIG Compliance Guidance) issued by the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) on May 3, 2003. Mobius has also followed the spirit of the PhRMA Code on Interactions with Healthcare Professionals in establishing this Policy.

The OIG Guidance sets forth the federal government's views on the value and fundamental principles of compliance programs for pharmaceutical manufacturers and the specific elements that manufacturers should consider when developing and implementing an effective compliance program. The OIG Guidance is a major initiative in support of the federal government's efforts in preventing and reducing fraud and abuse in the sales and marketing of pharmaceutical products.

The purpose of Mobius' Corporate Compliance Program is to prevent and detect violations of law or company policy. As the OIG Guidance recognizes, the implementation of such a program cannot guarantee that improper employee or contractor conduct will be entirely eliminated. Nonetheless, it is Mobius' expectation that employees and subcontractors will comply with the policies and procedures established in support of our Corporate Compliance Program. In the event that Mobius becomes aware of violations of law or company policies and procedures, we will investigate the matter and, where appropriate, take disciplinary action and implement corrective measures to prevent future violations. Mobius' relationships with healthcare professionals are intended to benefit patients and to enhance the practice of medicine. All Mobius interactions with healthcare professionals should be focused on informing the healthcare professionals about products, providing scientific and educational information, and supporting medical research and education.

The following general standards and principles should at all times guide our interactions with customers:

- Mobius will encourage ethical business practices and socially responsible industry conduct, and will not use any unlawful inducement in order to sell or recommend or arrange for the sale or prescription of its products.
- At Mobius, we believe that enduring customer relationships are based on integrity and trust. We seek to gain advantage over competitors through superior products, research, manufacturing, marketing and service, never through improper business practices.
- Mobius' relationships with customers are intended to benefit patient care and enhance the practice of medicine. Interactions should be focused on informing customers and prospective customers about products, providing scientific and educational information, and supporting medical research and education and should not, at any time, entice representatives of customers to place their own personal or corporate interests above those of the organizations they represent or the patients who will use or need Mobius' products.
- Mobius will not, directly or indirectly, offer or solicit any kind of payments or contributions for the purpose of obtaining, giving, keeping or rewarding business.

The following elements are incorporated in the compliance program:

### **1. Written Policies and Procedures**

Written standard operating procedures (SOPs) will be adopted from time to time addressing specific areas of concern with and susceptibility to potential violations of the law in the interaction with healthcare professionals and other customers. The SOPs are the primary tools used by employees and subcontractors who are tasked with implementing Company policy as they do their work each day and are confronted with real life issues in which the law and regulations interact with how the Company interfaces and works with health care professionals. The SOPs provide further policy detail and the process and procedure the Company has set forth for the review and approval of decisions and programs that effectuate the sale and marketing goals of Mobius.

## **2. Compliance Officer and Compliance Committee**

A Corporate Compliance Officer has been designated whose job is to develop, operate and monitor the compliance program. The Corporate Compliance Officer has the authority to report issues directly to the CEO and Board of Directors of the company.

## **3. Education and Training**

The development of a regular, effective education and training program for all affected employees and subcontractors is a priority at Mobius. We will regularly review and update training programs to keep employees and subcontractors current in regards to education and training on their legal and ethical obligations under applicable federal health care program requirements.

## **4. Effective Lines of Communication**

Mobius has adopted open-door policies and has established a toll-free Compliance Helpline (877-393-6486 x 6934) where employees, subcontractors and others outside the company may anonymously report any concerns or suspected violation of laws, regulations or company policy. Employees and subcontractors are required to bring to the company's attention any known or suspected violations of law or policy. All reports shall be documented and reported to the Compliance Officer.

## **5. Internal Monitoring and Auditing**

Mobius' program includes an annual review of the compliance program by management to identify problem areas and to address gaps and opportunities for improvement.

## **6. Enforcement of Standards**

Employees and subcontractors who violate the law, regulations or company policy will be subject to appropriate consequences. Such consequences could range from oral warnings to suspension, termination or other sanctions, as appropriate. Although each situation is considered on a case-by-case basis, we will consistently undertake appropriate disciplinary action to address non-compliance and deter future violations.

## **7. Investigations and Corrective Action to Detected Problems**

Mobius will investigate suspected non-compliance with its policies and procedures as well as all applicable laws and regulations in a manner designed to promptly and accurately ascertain the facts and to determine the underlying cause or causes of any

substantiated, non-compliant conduct. The investigation will assess whether the non-compliance is due to gaps in policies or internal controls and take appropriate action to address any gaps so as to prevent future violations. The Corporate Compliance Department will direct investigations of suspected non-compliance and document the nature and results of such investigations.

Prompt and appropriate disciplinary action will be taken against employees and subcontractors who have violated company policies and/or procedures and applicable federal health care program requirements. Mobius will not knowingly hire, retain or do business with any person or organization that has been excluded from participation in federal health care programs. Mobius will not hire, retain, or offer any type of appointment to any person from senior manager or above who has been debarred, suspended, proposed for debarment or declared ineligible for the award of contracts by any federal agency.

## **Mobius Statement regarding compliance with California Health & Safety Code § 119402**

**NOTICE: Pursuant to California Health & Safety Code, Section §119402, pharmaceutical companies doing business in the state of California are required to make available their Compliance Program and annual written declaration of compliance with the provisions of the Compliance Program. This information is provided pursuant to that requirement.**

California Health & Safety Code, Sections §119400 – 119402, (“California Compliance Law”) requires pharmaceutical companies to adopt a Compliance Program in accordance with the April 2003 publication “Compliance Program Guidance for Pharmaceutical Manufacturers” (“OIG Compliance Guidance”) developed by the United States Department of Health and Human Services Office of Inspector General (“OIG”) and policies for compliance with the Pharmaceutical Research and Manufacturers of America (“PhRMA”) “Code on Interactions with Health Care Professionals” (“PhRMA Code”) within six months of any update or revision of the PhRMA Code. Revisions to the July 1, 2002 PhRMA Code were effective January 2009.

## Annual Declaration (January 2020)

Mobius Therapeutics, LLC hereby declares that, to the best of our knowledge, and based on our good faith understanding of the statutory requirements, we have established a Comprehensive Compliance Program (“CCP”) that meets the requirements of California Health and Safety Codes §§ 11940-119402, and we are in compliance with this CCP and the requirements of the California statute. It is Mobius’ expectation that all employees and subcontractors comply with its CCP and all policies that support this program. Mobius will assess its CCP at least annually, for the purpose of declaring compliance with California Health and Safety Codes §§ 11940-119402.

In accordance with California Health and Safety Code §§ 119400-119402, Mobius has established an annual dollar limit of \$2,000 on food, gifts, and promotional materials that we may provide to individual medical or health care professionals in California, as defined by the statute. This limit is an annual limit, not an average or targeted spending limit, and the amount spent per healthcare professional is anticipated to be substantially less than this maximum amount. For purposes of clarity, this annual spending limit does not include the value of: (1) drug samples given to physician and healthcare professional intended for free distribution to patients; (2) financial support of independent education including continuing medical education; (3) financial support for health education scholarships; and (4) payments made for legitimate professional services provided by a healthcare professional so long as the amount paid is based up the fair market value of the services provided.

*This declaration is made as of January 1, 2020. To request a copy of the Mobius Therapeutics, LLC Compliance Program overview, please call our Customer Service Department at 1-877-393-6486 x 6931 (toll free) or submit an e-mail to [corporate.compliance@Mobiustx.com](mailto:corporate.compliance@Mobiustx.com). The overview can also be obtained from our web site at [www.Mobiustherapeutics.com](http://www.Mobiustherapeutics.com)*

### **Additional resources can be found at:**

*[The Government Accountability Project](#) promotes corporate and government accountability by defending whistleblowers.*

*[The Project on Government Oversight](#) provides support and information for employees blowing the whistle on government and contractor corruption and fraud.*

*[Westlaw Journal, February 2017, Volume 22, Issue 8: Blowing the Whistle on Fraud In The Health Care Industry.](#)*