



## COMPREHENSIVE COMPLIANCE PROGRAM POLICY

*July 1, 2024*

Dendreon Pharmaceuticals LLC (“Dendreon” or “Company”) is committed to conducting its business consistent with all applicable laws and regulations and the highest standards of business integrity. To help ensure this, Dendreon has established and will maintain an effective compliance program in accordance with the OIG Compliance Program Guidance for Pharmaceutical Manufacturers (“OIG Guidance”) issued by the Office of Inspector General, U.S. Department of Health and Human Services (“OIG”). Dendreon’s compliance program is a central component of its commitment to fostering a culture of compliance where integrity is the bottom line. Dendreon’s Board of Directors oversees and fully supports the compliance program.

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 primary purpose of Dendreon’s compliance program is to prevent and detect violations of applicable laws, regulations or Company policies. As the OIG Guidance recognizes, the implementation of such a program cannot guarantee that all improper employee conduct will be eliminated. Nonetheless, it is Dendreon’s expectation that its employees will comply with all applicable laws, regulations and Company policies established in support of the compliance program. In the event that Dendreon becomes aware of violations of applicable laws, regulations or Company policies, Dendreon is committed to investigating the matter and, where appropriate, taking disciplinary action and implementing corrective measures to prevent further violations.

Described below are the fundamental elements of Dendreon’s compliance program, which are aligned with the philosophy and specific requirements of the OIG Guidance. Consistent with the OIG Guidance, the compliance program is tailored to fit Dendreon’s unique environment. Additionally, Dendreon intends to regularly review and enhance the compliance program to meet its evolving compliance needs.

### **I. WRITTEN POLICIES AND PROCEDURES**

The Code of Business Conduct (the “Code”) is Dendreon’s statement of ethical and compliance principles that guide the Company’s operations. The Code establishes Dendreon’s expectations that management and employees of the Company will act in accordance with all applicable laws, regulations and Company policies. The Code sets forth Dendreon’s basic principles, values and framework for action within the Company. The Code is provided to all employees who are required to sign annual certifications confirming their intent to comply with the Code. The Code is also available on the web at [Dendreon's Corporate Governance Page](#).

The OIG has identified through its guidance several potential risk areas for pharmaceutical manufacturers and has urged manufacturers to develop compliance policies to address these risk

areas. These risk areas include (i) data integrity pertaining to government reimbursement practices, and (ii) kickbacks and other illegal remuneration. In addition, the OIG has suggested that compliance with the PhRMA Code of Interactions with Healthcare Professionals (hereinafter “PhRMA Code”) demonstrates “a good faith effort to comply with applicable federal health care program requirements.” (Fed. Reg. Vol. 68, No. 86, p. 23737).

Dendreon has established written policies and procedures to address the specific risk areas identified by the OIG in its guidance and areas discussed in the PhRMA Code and to ensure compliance with various laws and regulations, including the Code, and numerous other policies and procedures that outline our commitment to compliance and corporate accountability. The standards set forth in the policies and procedures apply to our officers, employees and, in certain situations, our agents and independent contractors (“Dendreon Representatives”) according to their job function and responsibilities, and adherence to the applicable company’s policies and procedures is a condition of employment. Dendreon expects all officers and managers to ensure that their employees are trained on the pertinent policies and procedures and that their employees adhere to these policies and procedures, and applicable laws, guidance and regulations. These policies and procedures are provided to all employees who are affected by their contents.

## **II. COMPLIANCE OFFICER AND COMPLIANCE COMMITTEE**

Dendreon has designated a Chief Compliance Officer to serve as the focal point for the Company’s compliance activities. The Chief Compliance Officer (“CCO”) reports directly to the President and Chief Executive Officer, is a member of the Executive Committee and has direct access to the Company’s Board of Directors, senior management and outside legal counsel. The CCO is charged with the development, implementation, and monitoring of the compliance program.

Dendreon has also established a Compliance Committee to advise the CCO and to assist in the implementation of the compliance program. The Compliance Committee is comprised of senior leaders from various departments within the Company. The Compliance Committee is chaired by the CCO and meets on a regular basis to consider compliance and policy issues encountered in the various business areas.

Compliance Committee members shall treat information presented or distributed in connection with Compliance Committee business as confidential, and shall refrain from discussing any matter related to the Compliance Committee outside of the established process or using information obtained in their capacity as Compliance Committee members other than for the purpose for which that information was originally collected.

## **III. TRAINING AND EDUCATION**

The training and education of Dendreon’s employees on their legal and ethical obligations under applicable laws, regulations and Company policies (including those under federal health care program requirements) is a critical element of the Company’s compliance program. Thus, Dendreon is committed to communicating its standards, policies and procedures to all affected personnel. Additionally, Dendreon will regularly review and update its training programs, as

well as identify additional areas of training as needed based on new developments.

All Dendreon employees receive general compliance training on this Compliance Program and the Code including the content as well as training on policies and procedures applicable to their job function and responsibilities. Specialized training occurs in specific departments where a need for additional training has been identified. Dendreon Representatives are trained on how to report compliance concerns through appropriate channels, including anonymously either online or via telephone.

#### **IV. LINES OF COMMUNICATION**

Dendreon is committed to fostering dialogue between management and employees through multiple channels. Dendreon's goal is that employees should know where to turn when they are seeking answers to questions or reporting potential instances of fraud and abuse, or other potential violations of applicable law, regulations or Company policies. Employees should feel free to make these inquiries or reports without fear of retribution.

To facilitate these goals, Dendreon expects its supervisors to maintain an open-door environment and does not tolerate retaliation by any employee against another employee for good faith reports of potential violations of laws, regulations or Company policies. Dendreon's open-door and non-retaliation policies are described in more detail in the Code.

In addition, Dendreon has established the following means of communicating to the Company:

- The Dendreon compliance email, [compliance@dendreon.com](mailto:compliance@dendreon.com) (non-anonymous);
- The Dendreon **Ethics and Compliance Hotline** hosted by Navex Global, a leading ethics and compliance software company. The **Hotline** can be accessed via the web at <https://dendreon.ethicspoint.com>, or toll-free at 844-450-1716 (anonymous).

The **Hotline** is available 24 hours a day, 7 days a week. Employees may make anonymous reports regarding potential violations of laws, regulations or Company policies. Employees may also report potential violations to their supervisors, the human resources or legal departments, or to the CCO.

#### **V. AUDITING AND MONITORING**

Dendreon's compliance program includes ongoing efforts to monitor, assess, audit and evaluate the effectiveness of the compliance program, including the Company's policies and procedures, training programs, lines of communication and other components. Auditing and monitoring activities are designed to identify matters which require further investigation and opportunities for improvement. Auditing and monitoring results may be used to make changes in Dendreon's business practices or policies and procedures. Dendreon considers a number of factors in connection with the nature, frequency, and extent of such reviews, including changes in applicable law and regulation or areas of particular concern or interest.

## **VI. DISCIPLINARY ACTION**

Dendreon believes it is important to take reasonable and consistent disciplinary action to address compliance violations and deter potential future misconduct. Disciplinary action for noncompliance may include oral or written warnings, remedial compliance training, suspension or termination of employment, or other sanctions, as appropriate.

## **VII. INVESTIGATIONS**

Violations of applicable laws, regulations or Company policies threaten the Company's status as a reliable, honest and trustworthy participant in the health care industry. Therefore, Dendreon is committed to investigating any suspected violations of applicable laws, regulations or Company policies 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 investigations will assess whether the non-compliance is due to gaps in Dendreon's policies or internal controls, and the Company will take appropriate action to address any gaps so as to prevent future violations. The CCO, in consultation with the Compliance Committee as appropriate, will direct investigations of suspected non-compliance and document the nature and results of such investigations.

## **POLICY ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS IN CALIFORNIA**

Dendreon's California Declaration may be found at: [Dendreon's Corporate Governance Page](#).

Dendreon's policies that regulate its interactions with health care professionals in the United States reflect its commitment to compliance with applicable federal and state laws and regulations. Dendreon reviews and/or revises its policies as it deems appropriate to meet the requirements of a dynamic legal, regulatory and commercial environment.

California Health and Safety Code Section 119402(d)(1) requires pharmaceutical companies to establish a specific annual upper dollar limit on gifts, promotional materials, or items or activities that the pharmaceutical Company may give or otherwise provide to an individual medical or health care professional licensed in the state of California. The statute excludes from the annual limit such items as drug samples given to medical or health care professionals intended for free distribution to patients, financial support for continuing medical education forums, financial support for health education scholarships, and payments made at fair market value for legitimate professional services provided by a medical or health care professional.

*Pursuant to California Health and Safety Code Section 119402(d)(1), Dendreon has established an annual spending limit of no more than \$1,500 per covered medical or health care professional licensed in California. This figure is a maximum limit and not a spending goal. The annual spending limit applies to activities occurring in the calendar year, initially commencing on the date the Food and Drug Administration approves Dendreon's first commercial product. Dendreon reserves the right to modify the annual spending limit at any time, based on changing internal and/or external circumstances.*

Any promotional items provided to a medical or health care professional licensed in California must comply with Dendreon's internal policies and the PhRMA Code. Such items generally are provided to physicians and certain other health care professionals in order to facilitate an educational or scientific discussion about the Company's product(s), the Company's research and development efforts, and other health care-related issues.

## **CONCLUSION**

Dendreon's compliance program, including the Code and relevant policies and procedures adopted in furtherance of the program, is part of Dendreon's commitment to honest and ethical business dealings and corporate responsibility. The compliance program was established in accordance with the OIG Guidance, PhRMA Code and other relevant industry guidelines to help ensure compliance with applicable federal and state laws and regulations.

A copy of this Comprehensive Compliance Program, the Code and/or Dendreon's written Declaration of Compliance with this Comprehensive Compliance Program can be obtained by emailing [compliance@dendreon.com](mailto:compliance@dendreon.com), by calling the Dendreon Ethics and Compliance Hotline, toll-free, 24 hours a day, seven days a week at 844-450-1716 or on the web at [Dendreon's Corporate Governance Page](#).