

COMPLIANCE POLICY AND 2023 DECLARATION FOR CALIFORNIA COMPLIANCE LAW

DECLARATION FOR CALIFORNIA COMPLIANCE LAW

As part of PROTEGA Pharmaceuticals LLC (“PROTEGA” or “Company”) ongoing efforts in the area of compliance, we have developed a Comprehensive Compliance Program that is designed to comply with applicable federal and state laws and industry standards relating to the marketing and promotion of our products. To our knowledge as of the date of this declaration, PROTEGA is in compliance with our Comprehensive Compliance Program, as described here, and with California Health & Safety Code sections 119400-119402.

Copies of our Comprehensive Compliance Program (“CCP”) and our Annual Declaration of Compliance can be obtained by calling us at (609) 423-1568 or emailing us at contact@protegapharma.com.

Last updated: May 17, 2023. PROTEGA has established a program designed to comply with applicable federal and state laws and industry standards relating to the marketing and promotion of its products.

COMPREHENSIVE COMPLIANCE PROGRAM

PROTEGA has established a program designed to comply with applicable federal and state laws and industry standards relating to the marketing and promotion of its products. Additionally, PROTEGA recognizes that adherence to these standards can be furthered through a compliance program that complies with the Compliance Program Guidance for Pharmaceutical Manufacturers, published by the Office of Inspector General of the U.S. Department of Health and Human Services (the “OIG Guidance”). The OIG Guidance advises that effective compliance programs are comprised of seven elements, which are outlined below. As described below, these elements form the basis of PROTEGA’S program for compliance with the standards regulating the marketing and promotion of its products. In addition, PROTEGA has implemented and maintains a website (protegapharma.com) and a compliance hotline to facilitate communication and requests for information related to California State requirements.

Written Policies and Procedures

PROTEGA has written policies and procedures to assure substantial compliance with the applicable laws, regulations and standards governing the marketing and promotion of our products. PROTEGA follows the *Pharmaceutical Research and Manufacturers of America Code on Interactions with Health Care Professionals* (“PhRMA Code”). PROTEGA has established written policies and procedures that govern activities involving communicating with health care professionals about the appropriate use of our products, including appropriate instruction and education required for the safe and effective use of our products. PROTEGA also has policies and procedures governing activities involving the advancement of scientific and educational activities supporting medical research and education. These policies and procedures include:

- **Policy on Educational Grants and Research Grants**
 PROTEGA may provide grants for specific educational purposes that benefit health care professionals. These may include, but are not limited to, continuing medical and paraprofessional education programs, fellowships provided to teaching institutions and similar organizations with a demonstrated commitment to scientific and technical education, and programs operated by organizations that provide high-quality, nationally recognized education. Funding of educational programs will generally be provided only to organizations and institutions and not to individual practitioners. Research grants to support physician-initiated research may be provided for programs involving research in areas of legitimate interest to PROTEGA. All requests are subject to scientific review prior to funding approval.
- **Policy on Travel Expense Reimbursement for CME, Promotional or Product Training Meetings**
 PROTEGA may reimburse attendees for their reasonable travel and lodging expenses associated with attendance at training meetings conducted by PROTEGA. Training meetings will be conducted in locations conducive to the exchange of information such as educational or conference settings. Where face-to-face health care professionals training reasonably necessary for the safe and effective use of PROTEGA products is required, PROTEGA may provide training at PROTEGA facilities, at independent teaching centers such as medical institutions, or in other appropriate clinical settings.
- **Policy on Business Meals**
 PROTEGA may occasionally offer a modest meal as part of an educational presentation or a business discussion. Entertainment or recreation at such meetings is not permitted. Attendance by spouses or guests at such meetings is not permitted unless the spouse or guest has a bona fide reason for attending, e.g., they are a health care professional interested in prescribing a PROTEGA product.
- **Policy on the Provision of Educational and Practice-Related Items**
 Subject to approval from the PROTEGA Compliance Officer, PROTEGA representatives may provide items that benefit patients or serve a genuine educational function for health care professionals.
- **Total Annual Dollar Limit for California Health Care Professionals**
 PROTEGA has established an annual limit for meals and educational items that may be provided to California health care professionals pursuant to the requirements of Cal. Health & Safety Code § 119402 (S.B. 1765).
- **Policy Prohibiting Entertainment**
 It is the policy of PROTEGA not to provide entertainment (e.g., sporting events, golf outings, concerts, etc.) to health care professionals.

- **Assigned Compliance Officer**
PROTEGA has a Compliance Officer. Our Compliance Officer is empowered with appropriate authority to exercise independent judgment and access to senior management. PROTEGA has a Compliance Committee. The committee is comprised of the Company's Compliance Officer and members of the Company's management team.
- **Training**
PROTEGA has an annual Compliance Training process. New employees receive training at the time of hire and at least annually thereafter. The training covers applicable guidelines governing our compliance program. Employees are trained on the consequences of failure to comply with the requirements of the Company's compliance program.
- **Communication**
PROTEGA encourages open and candid discussion between management and employees regarding any compliance concern. PROTEGA employees are encouraged to report their concerns to their manager or to the Compliance Officer. Employees also have the option to report potential violations anonymously using the PROTEGA Compliance Hotline.
- **Auditing and Monitoring**
PROTEGA monitors and periodically audits its compliance with its policies and procedures.
- **Enforcement and Disciplinary Guidelines**
PROTEGA may take disciplinary action, up to and including discharge/termination, in response to violation of the Company's compliance policies or procedures. PROTEGA may conduct an investigation of matters that are brought to the Company's attention in order to ensure the consistent application of the Company's standards.
- **Responses to Detected Problems and Actions to Correct Issues**
PROTEGA requires a prompt and diligent response to potential violations of the Company's compliance program, including its standards regulating the marketing and promotion of our products. Actions in response to detected problems may include improving policies, procedures, training, communication and monitoring or may require disciplinary action to prevent future violations.
- **Risk Assessment**
In addition to the seven elements outlined herein, PROTEGA also periodically performs health care compliance risk assessments.