Rayner Compliance Program Summary

Rayner Surgical Inc. ("Rayner") is committed to supporting an effective comprehensive compliance program ("Compliance Program") in accordance with the April 2003 publication titled "Compliance Program Guidance for Pharmaceutical Manufacturers," developed by the Office of Inspector General, U.S. Department of Health and Human Services (the "HHS-OIG Guidance").

The purpose of our Compliance Program is to ensure compliance with the laws and regulations that apply to the biopharmaceutical industry, as well as our own internal company policies, to prevent, detect, and correct violations of such laws, regulations, or policies. Rayner expects all its employees to comply with its Code of Business Conduct and Ethics and Policy on Code of Pharmaceutical Industry Business Conduct and Ethics (together the "Code") and associated policies. If Rayner becomes aware of any violations of law or company policy, we will investigate the matter and, as appropriate, take disciplinary action and implement corrective measures to prevent future violations.

The fundamental elements of our Compliance Program are laid out below. Our Compliance Program is dynamic; we make every effort to regularly review and update our Compliance Program to ensure it remains current with applicable laws and regulations.

1. Leadership and Structure.

The Compliance Officer serves as the focal point for our compliance activities and is charged with the responsibility for developing, operating, and monitoring the Compliance Program, including regular reporting to the CEO and Board of Directors. We are committed to ensuring that the Compliance Officer has the ability to effectuate change within the organization as necessary and to exercise independent judgment. The Compliance Committee, which includes members of senior management across our business functions, supports the Compliance Officer in fulfilling his or her responsibility in implementing and operating our Compliance Program.

2. Written Standards.

- The Code is our statement of ethical and compliance principles that guide our daily operations. The Code establishes that we expect management, employees, and agents of the company to act in accordance with applicable federal and state laws and regulations and related company policy. The Code articulates our fundamental principles, values, and framework for action within our organization.

- We have established state-specific guidelines where applicable. For example, we have established a specific annual dollar limit of $2,000 per medical or health professional in California on educational items and promotional activities in accordance with Cal. Health & Safety Code § 119402.

3. 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 federal and state health care program requirements. As a condition of new or continued employment, we require all employees to receive training on the Code and its associated policies. We are committed to taking all necessary steps to effectively communicate our standards and procedures to all affected personnel. To ensure that our training programs capture the intended activities and stay current with applicable laws and regulations, we will periodically review and update our training programs, as well as identify additional areas of training as needed.

4. Internal Lines of Communication.

We are committed to encouraging dialogue between management and employees. Our goal is for all employees, when seeking answers to questions or when acting in good faith to report potential instances of fraud and abuse, to know who to turn to for a meaningful response and to be able to do so without fear of retribution. We expect our employees, officers, and directors to promptly report any concerns about any suspected violation of the Code to their supervisor, manager, or directly to the Compliance Officer.

5. Auditing and Monitoring.

Our Compliance Program includes efforts to monitor, audit, and evaluate compliance with our compliance policies and procedures. These actions are intended to identify potential or existing problem areas and to take corrective measures in an effort to prevent the recurrence of non-compliance. 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.

6. Responding to Potential Violations.

The Compliance Officer reviews all reports of non-compliance and determines whether further investigation or action is necessary. If deemed necessary, the Compliance Officer, or a designee, will conduct an investigation to determine whether a violation of the Compliance Program has occurred. Our Compliance Program includes disciplinary policies that set out the consequences of violating

the law or company policy. Although each situation is considered on a case-by-case basis, we will consistently undertake appropriate disciplinary action to address inappropriate conduct and deter future violations.

7. Corrective Action Procedures.

Our Compliance Program requires the company to 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.

This Compliance Program Summary is not intended to nor does it act to create any contractual right.

Click here for a PDF copy of the Compliance Program Summary

State Specific Requirements

Click here for a PDF copy of the California Declaration of Compliance

Access to Investigational Products

Rayner is committed to helping patients by discovering, developing, and obtaining regulatory approval for novel therapeutics. As part of therapeutic development, we engage in clinical research to evaluate our product candidates' safety and efficacy. For information about our clinical trials that are currently recruiting, visit clinicaltrials.gov.

Rayner is aware that some patients may not be able to wait until a product is approved to treat their illness or condition and may not be able to participate in a clinical trial. Rayner is sometimes able to provide such patients with early access to investigational products based on considerations including, but not limited to, the following criteria:

- The patient has a serious or immediately life-threatening disease or condition.
- There is no comparable or satisfactory alternative therapy for the disease or condition available to the patient.
- The patient does not qualify for participation in, or have access to, any of Rayner' ongoing clinical trials.
- There is sufficient clinical evidence to anticipate that the patient might well experience a clinically meaningful benefit and that the investigational product will have an acceptable safety profile in the relevant indication such that the potential benefit justifies the potential risks.
- Providing expanded access to the investigational product will not interfere with the development of the product.
- Rayner has adequate supply of the investigational product.

- The request for expanded access to the product has been made by a qualified and licensed physician with expertise and facilities appropriate for the administration of the therapy and for the monitoring, managing, and reporting of side effects as well as clinical outcomes.

Rayner will consider the above criteria in determining whether to offer expanded access to its investigational products; however, Rayner cannot guarantee that the investigational product will be made available to a particular patient.

A patient's physician may request additional information on how to apply for access to one of Rayner' investigational products by contacting Rayner Medical Affairs at compassionateuse@Rayner.com. Rayner will endeavor to acknowledge expanded access requests within 5-10 business days of receipt. Physicians who receive any of Rayner' investigational products through expanded access are required to comply with all applicable laws and regulations, as well as any contractual conditions, including those relating to safety reporting.