

# California Compliance Policy and Declaration

NOTICE: this information is provided pursuant to the requirements of California Health & Safety Code § 119402 (S.B. 1765), which requires certain pharmaceutical and medical device companies doing business in California to make available their program for compliance with applicable federal and state laws and industry standards regulating the marketing and promotion of their products.

## 1. INTRODUCTION

Rare Disease Therapeutics, Inc. (RDT) has established a program designed to materially comply with applicable federal and state laws and industry standards relating to the marketing and promotion of its products. Additionally, RDT recognizes that adherence to these standards can be furthered through a compliance program that is informed by 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 Guide”). The OIG Guide advises that effective compliance programs are comprised of seven elements. As described below, these elements form the basis of RDT’s program for compliance with the standards regulating the marketing and promotion of its products.

## 2. OVERVIEW OF COMPLIANCE PROGRAM

### 1. Written Policies and Procedures

RDT has written policies to assure substantial compliance with the applicable laws and regulations and standards governing the marketing and promotion of our products. Among these standards are recognized industry codes of conduct including the PhRMA Code on Interactions with Healthcare Professionals (PhRMA Code) published by the Pharmaceutical Research and Manufacturers of America (PhRMA). RDT has established written policies that govern activities involving communicating with customers about the appropriate use of our products; advancing scientific and educational activities; and supporting medical research and education. These policies include:

#### **Policy on Educational Grants and Research Grants**

RDT may provide grants for specific educational purposes that benefit patients and customers. 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 patient education. Funding of

educational programs will generally be provided only to organizations and institutions and not to individual practitioners.

Research grants to support customer-initiated research may be provided for programs involving research in areas of legitimate interest to the company. All requests are subject to scientific review prior to funding approval.

#### **Policy on Charitable Contributions and Patient Assistance**

RDT will consider charitable contributions and requests for patient assistance in the areas of children's health, health care education, access to health care and community responsibility, consistent with RDT policies.

#### **Policy on Travel Expense Reimbursement for CME, Promotional or Product Training Meetings**

RDT will, with very limited exceptions that are in accordance with nationally recognized standards, not reimburse for travel and lodging expenses of attendees at promotional and educational programs.

#### **Policy on Business Meals**

RDT may occasionally offer a modest meal, consistent with the standards of the PhRMA Code, as part of an educational presentation or a business discussion. Venues that feature entertainment or recreation, and attendance by spouses or guests, are not permitted.

#### **Policy on the Provision of Educational and Practice-Related Items**

On occasion, RDT representatives may provide items designed primarily for the education of patients or healthcare professionals (for example an anatomical model or medical text) if the items are not of substantial value (\$100 or less) and do not have value to healthcare professionals outside of his or her professional responsibilities and are infrequent.

Promotional items such as coffee cups, pens, and notepads, and practice-related items that are not educational are not permitted under RDT policy.

#### **Total Annual Dollar Limit for Meals, and Educational or Practice-related Items**

RDT, has established an annual limit of \$2,500 for meals and educational items as the aggregate value of the items or activities that may be provided to California health care professionals.

#### **Policy Prohibiting Entertainment**

It is the policy of RDT not to provide Entertainment (e.g. sporting events, golf outings, concerts, hunting, etc.) to customers.

## **2. Assigned Compliance Officer**

RDT has appointed a Compliance Officer. Our Compliance Officer has been empowered with appropriate authority to exercise independent judgment and has free and unencumbered access to senior management.

RDT has appointed a Compliance Committee. The Compliance Committee is comprised of the company's Compliance Officer and members of RDT's management team. The Compliance Committee is the Compliance leadership team.

## **3. Training**

RDT has an annual Compliance training process that includes testing and annual certification of appropriate employees. The training covers applicable guidelines governing our compliance program. Employees are also trained on the consequences of failure to comply with the requirements of the company's compliance program.

## **4. Communication**

RDT encourages open and candid discussion between management and employees regarding any compliance concerns. RDT employees are encouraged to report their concerns to their manager, to the company's Compliance Officer or the company's hotline.

## **5. Auditing and Monitoring**

RDT self-assesses and periodically audits its compliance with its policies and procedures.

## **6. Enforcement and Disciplinary Guidelines**

RDT will take disciplinary actions in response to violation of the company's compliance policies or procedures. RDT will conduct a fair and diligent investigation of matters that are brought to the company's attention in order to ensure the consistent application of the company's standards.

## **7. Responses to Detected Problems and Actions to Correct Issues**

RDT 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.

### **3. DECLARATION FOR CALIFORNIA COMPLIANCE LAW**

As part of RDT's 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, RDT is in compliance with our Comprehensive Compliance Program, as described here, and with California Health & Safety Code sections 119400-119402. To request a copy of this declaration and a summary of RDT's Comprehensive Compliance Program, please call 1-888-429-1470.

To report potential fraud or misconduct, please contact the RDT compliance hotline:

Phone: 888-850-4754

Web: [www.lighthouse-services.com/raretx](http://www.lighthouse-services.com/raretx)

Email: [reports@lighthouse-services.com](mailto:reports@lighthouse-services.com)

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V3