

## Summary of Eli Lilly and Company's Comprehensive Compliance Program

### I. INTRODUCTION

One of the core values of Eli Lilly and Company ("Lilly") is that we conduct our business consistent with all applicable laws, and are honest in our dealings with customers, employees, shareholders, partners, suppliers, competitors, and the community. Consistent with this value, Lilly is committed to establishing and maintaining an effective and comprehensive compliance program in accordance with the "Compliance Program Guidance for Pharmaceutical Manufacturers," published by the Office of the Inspector General, U.S. Department of Health and Human Services (hereinafter "OIG Guidance"). Lilly's compliance program is a central component of its commitment to the highest standards of corporate conduct in all of its dealings. Lilly's board of directors fully supports the compliance program.

The primary purpose of Lilly's compliance program is to prevent and to detect violations of laws, regulations, and company policy. However, as the OIG Guidance explicitly recognizes, the implementation of a compliance program cannot guarantee that all improper employee conduct will be eliminated. It is Lilly's expectation that its employees will comply with its Code of Conduct, and the policies that have been established in support of that Code. In the event that Lilly becomes aware of violations of law, regulations, or company policies, Lilly is committed to investigating the matter, and where appropriate, taking disciplinary action, and implementing corrective measures to prevent further such violations.

Lilly has described below the fundamental elements of its compliance program. As the OIG has called for in its Guidance, Lilly has tailored its compliance program to fit the unique environment that is Eli Lilly and Company. Additionally, Lilly's compliance program is a living, breathing entity, constantly evolving and changing to meet the evolving needs and demands of the compliance environment and of Lilly. Lilly continuously reviews and enhances its compliance program, and reserves the right to continue to do so at any time in the future without notice.

### II. Overview of the Compliance Program

#### 1. **Leadership and Structure**

- **Chief Compliance Officer:** Lilly has appointed a senior vice president and chief compliance officer, to serve as the focal point for compliance activities. Lilly is committed that the chief compliance officer has the ability to lead change within the organization as necessary and to exercise independent judgment. The chief compliance officer is charged with the responsibility for developing, operating, and monitoring the compliance program.

The chief compliance officer reports both directly to Lilly chief executive officer and compliance committee.

- Compliance Committee: Lilly has established a compliance committee to advise the chief compliance officer, and to assist in the implementation of the compliance program. The compliance committee is chaired by the chief compliance officer, and reports at least annually through the chief compliance officer to the public policy and compliance committee of the board of directors on the state of Lilly's compliance program.

## 2. **Written Standards**

- Lilly's Code of Conduct (the Lilly "Red Book") is Lilly's statement of ethical and compliance principles that guide the company's daily operations. "The Red Book" establishes Lilly's expectations that management, employees, and agents of the company will act in accordance with laws, regulations, and applicable company policies. "The Red Book" sets forth Lilly's basic principles, values, and the framework for action within the company. For more information, view The Red Book online at [http://www.lilly.com/pdf/lilly\\_red\\_book\\_public.pdf](http://www.lilly.com/pdf/lilly_red_book_public.pdf).
- 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: (1) data integrity pertaining to government reimbursement practices; (2) kickbacks and other illegal remuneration; and (3) compliance with laws regulating drug sampling. In addition, the OIG has suggested that compliance with the PhRMA Code on 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). Lilly has adopted policies and procedures designed to address the both the specific risk areas identified by the OIG in its Guidance, and areas discussed in the PhRMA Code.
- Lilly has established annual spending limits as per California Business and Professional Code §119402(d)(1) for certain promotional activities directed toward healthcare professionals in California in accordance with the OIG Guidance and the PhRMA Code. Spending limits are established as the maximum boundaries for spending, and do not represent a spending "goal" or "average." In most cases, the Company spends significantly less per physician than the listed spending limit.

## 3. **Education and Training**

- The continuing training and education of its employees on their legal and ethical obligations under applicable laws, regulations, and policies (including those under federal health care program requirements) is a critical element of Lilly's compliance program. Lilly is committed to taking all necessary steps to communicating effectively its standards, policies, and procedures to all affected personnel. Additionally, Lilly will regularly review and update its training programs, as well as identify additional areas of training as needed based on new developments.
- Lilly trains all its employees on "The Red Book," including its content and application to daily activities.

- Lilly also provides targeted training in key risk areas to those employees whose job functions are affected by those risk areas, such as employees in marketing, sales, business-to-business, and so forth.

#### 4. **Internal Lines of Communication**

- Lilly is committed to fostering dialogue between management and employees through multiple channels. Lilly'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 law, regulations, or company policies. Employees also should feel free to make these inquiries or reports without fear of retribution.
- To facilitate these goals, Lilly 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 law, regulations, or company policies. To find the statements on these rules in the Company Code of Conduct, visit "The Red Book" online at [http://www.lilly.com/pdf/lilly\\_red\\_book\\_public.pdf](http://www.lilly.com/pdf/lilly_red_book_public.pdf).
- In addition, Lilly has established a hotline, which is available to employees 24 hours a day, 7 days a week, through which potential violations of laws, regulations, and policies may be reported. Anonymity and translation services are available. Employees may also report potential violations through their chains of command, to HR, to a company attorney, to the compliance department, to the general auditor, or to the chief compliance officer.

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

- Lilly's compliance program includes ongoing efforts to monitor, assess, audit, and evaluate compliance with the company's compliance policies and procedures. Lilly notes that in accordance with the OIG Guidance, the nature of its reviews, as well as the extent and frequency of its compliance monitoring, assessing, and auditing varies according to a variety of factors, including new regulatory requirements, changes in business practices, and other considerations.
- Lilly's compliance program includes a risk-based monitoring program for sales and marketing activities, with an annually updated plan to monitor a statistically significant number of sales and marketing events based upon the total number of events planned to take place during the year. The plan is continuously tracked and updated throughout the year as necessary, as the number of events is changed by the sales and marketing organizations, and to reflect changes in the risk environment.
- Lilly's corporate audit service has a dedicated group that conducts both for cause and risk-based audits on the sales and marketing functions.

#### 6. **Responding to Potential Violations**

- Lilly's compliance program includes clear disciplinary policies that set out the consequences of violating the law, regulations, or company policies. Although each situation is considered on a case-by-case basis, Lilly consistently undertakes appropriate disciplinary action to address inappropriate conduct and to deter future violations.

- “The Red Book” states: “Employees who violate the law, ‘The Red Book,’ or company policies may be disciplined up to and including termination of employment. Disciplinary action also may be taken for:
  - authorizing or participating in a violation
  - failing to report a violation or suspected violation
  - refusing to cooperate with the investigation of a suspected violation
  - retaliating against an individual who reported in good faith a suspected violation
  - failing to complete required training.

Supervisors may be disciplined for failing to detect a violation in their area if the failure results from inadequate supervision of employees.”

#### 7. **Corrective Action Procedures**

- A compliance program increases the likelihood of preventing, or at least identifying unlawful and unethical behavior. However, HHS-OIG recognizes that even an effective compliance program may not prevent all violations.
- In recognition of that fact, Lilly’s compliance program requires the company to respond promptly to potential violations of law, regulations, or company policies; take appropriate disciplinary action as necessary; assess whether the violation is in part due to gaps in Lilly’s policies, practices, or internal controls; and, if necessary, take action to prevent future violations from occurring.

Lilly’s compliance program is part of its commitment to honest and ethical business dealings and corporate responsibility. The policies, procedures, and programmatic elements outlined above represent a program responsive to compliance concerns, and consistent with the values of Eli Lilly and Company.

For a copy of Comprehensive Compliance Program described above, call The Lilly Answers Center at 1-800-LillyRx (1-800-545-5979) or download and print the document [here](#).

**Spending Limit pursuant to Cal. Bus. & Prof. Code §119402(d)(1)**

For purposes of complying with the California Drug Marketing Practices Act, Eli Lilly and Company has established an annual limit for spending on promotional items and activities provided to a healthcare professional licensed in California. Such items generally are provided to physicians and certain other healthcare professionals in order to facilitate an educational or scientific discussion about the company's products, the company's research and development efforts, and other health care-related issues. Lilly's limit also includes items provided to a physician (such as a medical textbook) that are related to a physician's practice. Any promotional items provided to a physician must comply with internal company policies and the PhRMA Code on Interactions with Healthcare Professionals. Lilly has excluded from its spending limit all items of nominal value (\$5 or less).

Lilly has established an annual spending limit of no more than \$3,000 per healthcare professional. This figure is a maximum limit and not a spending goal. The limit takes into account that Lilly has a diverse line of pharmaceutical products, and certain healthcare professionals, such as primary care practitioners, may be visited by different Lilly sales representatives for different pharmaceutical products. Lilly's annual spending limit applies to activities occurring from July 1, 2009 – June 30, 2010. Lilly reserves the right to change its annual spending limit at any time, based on changing internal and/or external circumstances.