

**CORPORATE INTEGRITY AGREEMENT**  
**BETWEEN THE**  
**OFFICE OF INSPECTOR GENERAL**  
**OF THE**  
**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**AND**  
**ELI LILLY AND COMPANY**

**I. PREAMBLE**

Eli Lilly and Company (Lilly) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements) and with the statutes, regulations, and written directives of the Food and Drug Administration (FDA requirements). Contemporaneously with this CIA, Lilly is entering into a Settlement Agreement with the United States. Lilly will also enter into settlement agreements with various States (State Settlement Agreement and Release) and Lilly's agreement to this CIA is a condition precedent to those agreements.

Prior to the Effective Date of this CIA (as defined below), Lilly established a voluntary compliance program applicable to all Lilly employees (Compliance Program). Lilly's Compliance Program includes a Chief Compliance Officer who reports directly to the Board of Directors and the CEO, and a Compliance Committee. The Compliance Program also includes a Code of Conduct (known as "The Red Book") applicable to all employees that is regularly reviewed and disseminated, written policies and procedures, educational and training initiatives, a Disclosure Program that allows for the confidential disclosure and investigation of potential compliance violations and appropriate disciplinary procedures, and regular monitoring and internal auditing procedures.

Lilly shall continue its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. Lilly may modify its Compliance Program as appropriate, but, at a minimum, Lilly shall ensure that during the term of this CIA, it shall comply with the obligations set forth herein.

## II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Lilly under this CIA shall be five years from the effective date of this CIA, unless otherwise specified. The effective date shall be the date by which Lilly is obligated to pay the Federal Settlement Amount as set forth in the Settlement Agreement between Eli Lilly and the United States (Effective Date). Each one-year period, beginning with the one-year period following the first day of the first calendar month following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Lilly's final Annual Report; or (2) any additional materials submitted by Lilly pursuant to OIG's request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. "Covered Persons" includes:

- a. all owners who are natural persons and: (i) have an ownership interest of 5% or more of the outstanding shares; or (ii) are involved in the business operations of Lilly or Lilly USA, LLC (Lilly USA);
- b. all officers and directors of Lilly and Lilly USA, and all employees of Lilly and Lilly USA based in the United States except as carved out below in this Section II.C.1; and
- c. all contractors, subcontractors, agents, and other persons who perform Promotional and Product Services Related Functions (as defined below in Section II.C.4) on behalf of Lilly or Lilly USA.

Notwithstanding the above, the term "Covered Persons" does not include: (i) officers or employees of Elanco; (ii) part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year.

2. "Relevant Covered Persons" includes all Covered Persons whose job responsibilities relate to Promotional and Product Services Related Functions. This group includes, but is not limited to, Covered Persons from the following groups or divisions who perform, supervise, or have responsibilities relating to, or in support of, the Promotional and Product Services Related Functions of Lilly or Lilly USA: Financial, Quality, Information Technology, Legal, Lilly Research Laboratories, Global Marketing and Sales Organization, Regulatory, Corporate Affairs, and Human Resources.
3. "Government Reimbursed Products" refers to all Lilly human pharmaceutical products that are reimbursed by Federal health care programs. This term includes all products promoted or sold by Lilly or Lilly USA in the United States.
4. The term "Promotional and Product Services Related Functions" includes: (a) the selling, detailing, marketing, advertising, promoting, or branding of Government Reimbursed Products; and (b) the preparation or dissemination of materials or information about, or the provision of services relating to, Government Reimbursed Products that are distributed in the United States.
5. The term "Third Party Educational Activity" shall mean any continuing medical education (CME), disease awareness, or other scientific, educational, or professional program, meeting, or event sponsored by Lilly, including but not limited to, sponsorship of symposia at medical conferences.
6. The term "Third Party Personnel" shall mean personnel of the entities with whom Lilly or Lilly USA have or may in the future enter into agreements to co-promote a Government Reimbursed Product in the United States or engage in joint promotional activities in the United States relating to such a product. Lilly has represented that: (1) the Third Party Personnel are employed by entities independent of Lilly or Lilly USA; (2) Lilly or Lilly USA does not control Third Party Personnel; and (3) it would be commercially impracticable to compel the compliance of Third Party Personnel with the requirements set forth in this CIA. Lilly agrees to promote compliance by Third Party

Personnel with Federal health care program and FDA requirements by complying with the provisions set forth below in Sections III.B.2, V.A.7, and V.B.4 related to Third Party Personnel who meet the definition of Covered Persons. Provided that Lilly complies with the requirements of Sections III.B.2, V.A.7, and V.B.4, Lilly shall not be required to fulfill the other CIA obligations that would otherwise apply to Third Party Personnel who meet the definition of Covered Persons.

### **III. CORPORATE INTEGRITY OBLIGATIONS**

Lilly shall establish and maintain a Compliance Program throughout the term of this CIA that includes the following elements:

#### **A. Compliance Responsibilities of Certain Lilly Employees and the Board of Directors.**

1. *Chief Compliance Officer.* Prior to the Effective Date, Lilly appointed a Chief Compliance Officer, and Lilly shall maintain a Chief Compliance Officer during the term of the CIA. The Chief Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements and FDA requirements. The Chief Compliance Officer shall be a member of senior management of Lilly, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors or a Committee of the Board of Directors of Lilly, and shall be authorized to report on such matters to the Board of Directors or such Committee at any time. The Chief Compliance Officer shall not be, or be subordinate to, the General Counsel or Chief Financial Officer. The Chief Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Lilly as well as for any reporting obligations created under this CIA.

Lilly shall report to OIG, in writing, any changes in the identity or position description of the Chief Compliance Officer, or any actions or changes that would affect the Chief Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

2. *Compliance Committee.* Prior to the Effective Date, Lilly established a Compliance Committee, and Lilly shall maintain a Compliance Committee during the term of this CIA. The Compliance Committee shall, at a minimum, include the Chief

Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as Legal, Human Resources, Lilly Research Laboratories, Corporate Affairs, Global Marketing and Sales, Regulatory, Account Based Markets-Lilly USA, Marketing and Operations – Lilly USA, and Health Care Professional Markets – Lilly USA). The Chief Compliance Officer shall chair the Compliance Committee and the Compliance Committee shall support the Chief Compliance Officer in fulfilling his/her responsibilities under the CIA (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

Lilly shall report to OIG, in writing, any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

3. *Board of Directors Compliance Obligations.* A Committee of the Board of Directors (Committee) shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA. The Committee shall, at a minimum, be responsible for the following:

a. The Committee shall meet at least quarterly to review and oversee Lilly's Compliance Program, including but not limited to evaluating its effectiveness and receiving updates about the activities of the Chief Compliance Officer and other compliance personnel.

b. The Committee shall consist of at least three members, all of whom shall be independent directors. The Chief Compliance Officer is required to make at least four reports a year to the Committee or more often, if requested by the Committee or the Chief Compliance Officer.

c. The Committee shall arrange for the performance of a review of the effectiveness of Lilly's Compliance Program (Compliance Program Review) for each Reporting Period of the CIA and shall review the results of the Compliance Program Review as part of the review and assessment of Lilly's Compliance Program. A copy of the Compliance Program Review Report shall be provided to OIG in each Annual Report submitted by Lilly.

d. For each Reporting Period of the CIA, the Committee shall adopt a resolution, signed by each individual member of the Committee, summarizing its review and oversight of Lilly's compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA.

At minimum, the resolution shall include the following language:

"The [insert name of Committee] Committee of the Board of Directors has made a reasonable inquiry into the operations of Lilly's Compliance Program, including but not limited to evaluating its effectiveness and receiving updates about the activities of its Chief Compliance Officer and other compliance personnel. The Board also has arranged for the performance of, and reviewed the result of, the Compliance Program Review. Based on its inquiry, the Committee has concluded that, to the best of its knowledge, Lilly has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the obligations of the CIA."

If the Committee is unable to provide such a conclusion in the resolution, the Committee shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to assure implementation by Lilly of an effective Compliance Program at Lilly.

Lilly shall report to OIG, in writing, any changes in the composition of the Committee, or any actions or changes that would affect the Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

The Board of Directors may by resolution reserve to itself the powers and responsibilities assigned to the Committee under this CIA. In that event, all references in this CIA to the Committee shall be deemed to be references to the Board of Directors.

4. *Management Accountability and Certifications:* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Lilly employees ("Certifying Employees") are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify, in writing or electronically, that the applicable Lilly component is compliant with Federal health care program requirements, FDA requirements, and the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following individuals from Lilly: President and Chief Executive Officer; and Executive Vice President, Global Marketing and Sales.

They also shall include, at minimum, the following individuals from Lilly USA: President, U.S. Operations; Senior Vice President, Account-Based Markets; Senior Vice President, Health Care Professional Markets; Vice President, Chief Marketing and Operations Officer; and all national and executive sales directors, brand leaders, and business unit leaders in the HCP Markets, executive directors and directors in Account-Based Markets, and executive directors and directors in Marketing and Operations.

For each Reporting Period, each Certifying Employee shall sign a certification that states:

“I have been trained on and understand the compliance requirements and responsibilities as they relate to [department or functional area], an area under my supervision. My job responsibilities include ensuring compliance with regard to the \_\_\_\_\_ [insert name of the department or functional area.] To the best of my knowledge, except as otherwise described herein, the \_\_\_\_\_ [insert name of department or functional area] of Lilly is in compliance with all applicable Federal health care program requirements, FDA requirements, and the obligations of the CIA.”

B. Written Standards.

1. *Code of Conduct.* Prior to the Effective Date, Lilly developed, implemented, and distributed a written Code of Conduct (known as “The Red Book”) to all Covered Persons. Lilly currently requires all newly employed Covered Persons to certify in writing or electronically, that they have received, read, understood, and shall abide by Lilly’s Code of Conduct. Lilly shall continue to make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all Covered Persons.

The Code of Conduct sets forth and shall continue to set forth, at a minimum, the following:

- a. Lilly’s commitment to full compliance with all Federal health care program and FDA requirements, including its commitment to market, sell, promote, research, develop, provide information about, and advertise its products in accordance with Federal health program requirements and FDA requirements;

b. Lilly's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program and FDA requirements and with Lilly's own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this CIA);

c. the requirement that all of Lilly's Covered Persons shall be expected to report to the Chief Compliance Officer, or other appropriate individual designated by Lilly, suspected violations of any Federal health care program and FDA requirements or of Lilly's own Policies and Procedures;

d. the possible consequences to both Lilly and Covered Persons of failure to comply with Federal health care program and FDA requirements and with Lilly's own Policies and Procedures and the failure to report such noncompliance; and

e. the right of all individuals to use the Disclosure Program described in Section III.E, and Lilly's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

To the extent not already accomplished, within 120 days after the Effective Date, the Code of Conduct shall be distributed to each Covered Person and each Covered Person shall certify, in writing or electronically, that he or she has received, read, understood, and shall abide by Lilly's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later.

Lilly shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code of Conduct shall be distributed within 30 days after any revisions are finalized by the Compliance Office. Each Covered Person shall certify, in writing or electronically, that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.



2. *Third Party Personnel.* Within 90 days after the Effective Date, and annually thereafter by the anniversary of the Effective Date, Lilly shall send a letter to each entity employing Third Party Personnel. The letter shall outline Lilly's obligations under the CIA and its commitment to full compliance with all Federal health care program and FDA requirements. The letter shall include a description of Lilly's Compliance Program. Lilly shall attach a copy of its Code of Conduct to the letter and shall request the entity employing Third Party Personnel to either: (a) make a copy of Lilly's Code of Conduct and a description of Lilly's Compliance Program available to its Third Party Personnel; or (b) represent to Lilly that it has and enforces a substantially comparable code of conduct and compliance program for its Third Party Personnel.

3. *Policies and Procedures.* Prior to the Effective Date, Lilly implemented written Policies and Procedures regarding the operation of the Compliance Program and Lilly's compliance with Federal health care program and FDA requirements (Policies and Procedures). To the extent not already accomplished, within 90 days after the Effective Date, Lilly shall ensure that the Policies and Procedures address or shall continue to address:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. appropriate ways to conduct Promotional and Product Services Related Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b), and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733);
- c. appropriate ways to conduct Promotional and Product Services Related Functions in compliance with all applicable FDA requirements;
- d. the materials and information that may be distributed by Lilly sales representatives and account executives about Lilly's Government Reimbursed Products and the manner in which Lilly sales representatives and account executives respond to requests for information about non-FDA approved (or "off-label") uses of Lilly's Government Reimbursed Products;

- e. the materials and information that may be distributed by the Lilly Answers Center (TLAC) and the mechanisms through, and manner in which, TLAC receives and responds to requests for information submitted by sales representatives and account executives about non-FDA approved (“off-label”) uses of Lilly’s Government Reimbursed Products; the form and content of information disseminated by Lilly in response to such requests; and the internal review process for the information disseminated.

The Policies and Procedures shall include a requirement that TLAC develop database(s) to track requests for information about Lilly’s products that are submitted by Lilly’s sales representatives and account executives, or by members of the public, to TLAC. This database shall be referred to as the “TLAC Database.” The TLAC Database shall include the following items of information for each unique inquiry (Inquiry) received for information about Lilly’s products: 1) date of Inquiry; 2) form of Inquiry (*e.g.*, fax, phone, etc.); 3) name of the requesting health care professional (HCP) or health care institution (HCI) in accordance with applicable privacy laws; 4) nature and topic of request (including exact language of the Inquiry if made in writing); 5) nature/form of the response from Lilly (including a record of the materials provided to the HCP or HCI in response to the request); and 6) the name of the Lilly representative who called on or interacted with the HCP or HCI, if known;

- f. systems, processes, policies, and procedures relating to the manner and circumstances under which Medical Liaisons and Outcomes Liaisons participate in meetings or events with HCPs or HCIs (either alone or with sales representatives or account executives) and the role of the Medical Liaisons and Outcomes Liaisons at such meetings or events, as well as how they handle responses to unsolicited requests about off-label indications of Lilly’s Government Reimbursed Products;
- g. systems, processes, policies, and procedures relating to the development, implementation, and review of call plans using

Lilly's Territory to Physician (TTP) business rules for field sales representatives who promote Government Reimbursed Products. For each Government Reimbursed Product, the Policies and Procedures shall require that Lilly review the call plans for the product and the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice are included in, or excluded from, the call plans. The Policies and Procedures shall also require that Lilly modify the call plans as necessary to ensure that Lilly is promoting its Government Reimbursed Products in a manner that complies with all applicable Federal health care program and FDA requirements. The call plan reviews shall occur at least annually and shall also occur each time when the FDA approves a new or additional indication for a Government Reimbursed Product;

- h. systems, processes, policies, and procedures relating to the development, implementation, and review of plans for the distribution of samples of Lilly's Government Reimbursed Products (Sample Distribution Plans). This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples from Lilly (including, separately, from Lilly sales representatives or account executives and/or directly from Lilly's medical services department). The Policies and Procedures shall also require that Lilly modify the Sample Distribution Plans as necessary to ensure that Lilly is promoting its products in a manner that complies with all applicable Federal health care program and FDA requirements;
- i. consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including, but not limited to speaker programs, speaker training programs, presentations, consultant task force meetings, advisory boards, and ad hoc advisory activities, and any other financial engagement or arrangement with an HCP or HCI,) and all events and expenses relating to such engagements or arrangements. These Policies and Procedures shall be designed to ensure that the arrangements and related events are

used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements. The Policies shall include requirements about the content and circumstances of such arrangements and events;

- j. programs to educate field representatives, including but not limited to presentations by HCPs at sales meetings and experience-based learning activities. These Policies and Procedures shall be designed to ensure that the programs are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements. The Policies shall include requirements about the content and circumstances of such arrangements and events;
- k. sponsorship or funding of grants (including educational grants) or charitable contributions. These Policies and Procedures shall be designed to ensure that Lilly's funding and/or sponsorship complies with all applicable Federal health care program and FDA requirements;
- l. funding of, or participation in, any Third Party Educational Activity as defined in Section II.C.5 above. These Policies and Procedures shall be designed to ensure that Lilly's funding and/or sponsorship of such programs satisfies all applicable Federal health care program and FDA requirements.

The Policies and Procedures shall require that: 1) Lilly disclose its financial support of the Third Party Educational Activity and, to the extent feasible consistent with subsection 5 below, any financial relationships with faculty, speakers, or organizers at such Activity; 2) as a condition of funding, the third party shall agree to disclose Lilly's financial support of the Third Party Educational Activity and any financial relationships that Lilly might have with faculty, speakers, or organizers at such Activity; 3) any faculty, speakers, or organizers at the Third Party Educational Activity disclose any financial relationship with Lilly; 4) the Third Party Educational Activity have an educational focus; 5) the content, organization, and operation of the Third

Party Educational Activity be independent of Lilly control; 6) Lilly support only Third Party Educational Activity that is non-promotional in tone/nature; and 7) Lilly support of a Third Party Educational Activity shall be contingent on the provider's commitment to provide information at the Educational Activity that is fair, balanced, accurate and not misleading;

- m. review of all promotional and written materials and information intended to be disseminated outside Lilly by appropriate qualified personnel (such as regulatory, medical, and/or legal personnel) in a manner designed to ensure that legal, regulatory, and medical concerns are properly addressed during Lilly's review and approval process and are elevated when appropriate. The Policies and Procedures shall be designed to ensure that such materials and information, when finally approved, comply with all applicable Federal health care program and FDA requirements;
- n. sponsorship or funding of research or related activities. These Policies and Procedures shall be designed to ensure that Lilly's funding and/or sponsorship complies with all applicable Federal health care program and FDA requirements;
- o. compensation (including salaries and bonuses) for Relevant Covered Persons. These Policies and Procedures shall be designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in improper promotion, sales, and marketing of Lilly's products; and
- p. disciplinary policies and procedures for violations of Lilly's Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

To the extent not already accomplished, within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be made available to all Covered Persons whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), Lilly shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be made available to all Covered Persons whose job functions relate to those Policies and Procedures.

C. Training and Education.

Lilly represents that it provides training to its employees on a regular basis concerning a variety of topics. The training covered by this CIA need not be separate and distinct from the regular training provided by Lilly, but instead may be integrated fully into such regular training so long as the training covers the areas specified below.

1. *General Training.* Within 120 days after the Effective Date, Lilly shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain Lilly's:

- a. CIA requirements; and
- b. Lilly's Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

To the extent that Lilly provided General Training to Covered Persons during the 180 days immediately prior to the Effective Date that satisfied the requirements set forth in Section III.C.1.b above, the OIG shall credit that training for purposes of satisfying Lilly's General Training obligations of this Section III.C.1 for the first Reporting Period. Lilly may satisfy its remaining General Training obligations for the Covered Persons who received the training described in the preceding sentence by notifying them within 90 days after the Effective Date in writing or in electronic format of the fact that Lilly entered a CIA and providing an explanation of Lilly's requirements and obligations under the CIA.

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. *Specific Training.* Within 120 days after the Effective Date, each Relevant Covered Person shall receive at least three hours of Specific Training applicable to their specific job functions in addition to the General Training required above.

This Specific Training shall include a discussion of:

- a. all applicable Federal health care program requirements relating to Promotional and Product Services Related Functions;
- b. all applicable FDA requirements relating to Promotional and Product Services Related Functions;
- c. all Lilly Policies and Procedures and other requirements applicable to Promotional and Product Services Related Functions;
- d. the personal obligation of each individual involved in Promotional and Product Services Related Functions to comply with all applicable Federal health care program and FDA requirements and all other applicable legal requirements;
- e. the legal sanctions for violations of the applicable Federal health care program and FDA requirements; and
- f. examples of proper and improper practices related to Promotional and Product Services Related Functions.

To the extent that Lilly provided Specific Training to Relevant Covered Persons during the 180 days immediately prior to the Effective Date that satisfied the requirements set forth in this Section III.C.2 above, the OIG shall credit that training for purposes of satisfying Lilly's Specific Training obligations of this Section III.C.2 for the first Reporting Period.

New Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 120 days after the Effective Date, whichever is later. A Lilly employee who has completed the Specific Training shall review or supervise (as applicable) a new Relevant Covered

Person's work, to the extent that the work relates to Promotional and Product Services Related Functions, until such time as the new Relevant Covered Person completes his or her Specific Training.

After receiving the initial Specific Training described in this Section, each Relevant Covered Person shall receive at least three hours of Specific Training in each subsequent Reporting Period.

3. *Certification.* Each individual who is required to complete training shall certify, in writing or electronically, if applicable, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Chief Compliance Officer (or designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

4. *Qualifications of Trainer.* Persons providing the training shall be knowledgeable about the subject area of the training, including applicable Federal health care program and FDA requirements. The training and education required under this Section III.C may be provided by supervisory employees, knowledgeable staff, Lilly trainers, and/or outside consultant trainers selected by Lilly, or may be satisfied by relevant continuing education programs provided they cover the topics outlined above in Section III.C.2.

5. *Update of Training.* Lilly shall review the training annually, and, where appropriate, update the training to reflect changes in Federal health care program requirements, FDA requirements, any issues discovered during any internal audits or any IRO Review, and any other relevant information.

6. *Computer-based Training.* Lilly may provide the training required under this CIA through appropriate computer-based training approaches. If Lilly chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the Covered Persons receiving such training. In addition, if Lilly chooses to provide computer-based General or Specific Training, all applicable requirements to provide a number of "hours" of training in this Section III.C may be met with respect to computer-based training by providing the required number of "normative" hours as that term is used in the computer-based training industry.

#### D. Review Procedures.

Corporate Integrity Agreement  
Eli Lilly Company



1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, Lilly shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist Lilly in assessing and evaluating its Promotional and Product Services Related Functions. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

Each IRO engaged by Lilly shall have expertise in applicable Federal health care program and FDA requirements as may be appropriate to the Review for which the IRO is retained. Each IRO shall assess, along with Lilly, whether it can perform the engagement in a professionally independent and objective fashion, as appropriate to the nature of the review, taking into account any other business relationships or other engagements that may exist.

The IRO(s) shall conduct reviews that assess Lilly's systems, processes, policies, procedures, and practices relating to Promotional and Product Services Related Functions (Promotional and Product Services Reviews).

b. *Frequency and Brief Description of Reviews.* As set forth more fully in Appendix B, the Promotional and Product Services Review shall consist of two components - a Systems Review and a Transactions Review. The Systems Review shall assess Lilly's systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions. If there are no material changes in Lilly's systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions, the Promotional and Product Services Systems Review shall be performed for the periods covering the first and fourth Reporting Periods. If Lilly materially changes its systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions, the IRO shall perform a Systems Review for the

Reporting Period in which such changes were made in addition to conducting the Systems Review for the first and fourth Reporting Periods.

The Promotional and Product Services Transactions Review shall be performed annually and shall cover each of the five Reporting Periods. The IRO(s) shall perform all components of each annual Transaction Review. As set forth more fully in Appendix B, the Transactions Review shall include several components, including a review relating to inquiries included in Lilly's TLAC Database, a review of Lilly's Call Plan Assessments, a review of Sampling Events, and a review of records relating to a sample of the Payments that are reported by Lilly pursuant to Section III.M below. In addition, each Transactions Review shall also include a review of up to three additional areas or practices of Lilly identified by the OIG in its discretion (hereafter "Additional Items".)

For purposes of identifying the Additional Items to be included in the Transactions Review for a particular Reporting Period, the OIG will consult with Lilly and may consider internal audit work conducted by Lilly and/or the Lilly Compliance Monitoring Program, Lilly's Government Reimbursed Product portfolio, the nature and scope of Lilly's promotional practices and arrangements with HCPs and HCIs, and other information known to it.

As set forth more fully in Section III.E of Appendix B, Lilly may propose to the OIG that its internal audit(s) be partially substituted for one or more of the Additional Items that would otherwise be reviewed by the IRO as part of the Transactions Review. The OIG retains sole discretion over whether, and in what manner, to allow Lilly's internal audit work to be substituted for a portion of the Additional Items review conducted by the IRO.

The OIG shall notify Lilly of the nature and scope of the IRO review for each of the Additional Items not later than 120 days prior to the end of each Reporting Period. Prior to undertaking the review of the Additional Items, the IRO and/or Lilly shall submit an audit work

plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG.

*c. Retention of Records.* The IRO and Lilly shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Lilly) related to the reviews.

2. *IRO Review Reports.* The IRO(s) shall prepare a report (or reports) based upon each Review performed. The information and content to be included in the report is described in Appendix B, which is incorporated by reference.

3. *Validation Review.* In the event OIG has reason to believe that: (a) any IRO Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the applicable IRO Review complied with the requirements of the CIA and/or the findings or Review results are inaccurate (Validation Review). Lilly shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of Lilly's final Annual Report shall be initiated no later than one year after Lilly's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Lilly of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, Lilly may request a meeting with OIG to: (a) discuss the results of any Review submissions or findings; (b) present any additional information to clarify the results of the applicable Review or to correct the inaccuracy of the Review; and/or (c) propose alternatives to the proposed Validation Review. Lilly agrees to provide any additional information as may be requested by OIG under this Section III.D.3 in an expedited manner. OIG will attempt in good faith to resolve any Review issues with Lilly prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Lilly a certification or sworn affidavit that it has evaluated its professional independence and objectivity, as appropriate to the nature of the engagement, with regard

to the applicable Review and that it has concluded that it is, in fact, independent and objective.

E. Disclosure Program.

Lilly represents that it has a disclosure program designed to facilitate communications relating to compliance with Federal health care program and FDA requirements and Lilly's policies (the "Disclosure Program"). During the term of the CIA, Lilly shall maintain a Disclosure Program that includes a mechanism (a toll-free compliance telephone line and/ or on-line electronic reporting) to enable individuals to disclose, to the Chief Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Lilly's policies, conduct, practices, or procedures with respect to a Federal health care program or FDA requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. Lilly shall continue to appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Disclosures made by individuals residing outside the United States shall be in accordance with applicable laws, including the European Union Data Protection Directive. Upon receipt of a disclosure, the Chief Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Chief Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Lilly shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Chief Compliance Officer (or designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be made available to OIG upon request.

F. Ineligible Persons.

1. *Definitions.* For purposes of this CIA:

- a. an “Ineligible Person” shall include an individual or entity who:
  - i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or
  - ii. has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.
- b. “Exclusion Lists” include:
  - i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.oig.hhs.gov>); and
  - ii. the General Services Administration’s List of Parties Excluded from Federal Programs (available through the Internet at <http://www.epls.gov>).
- c. “Screened Persons” shall include all Covered Persons.

2. *Screening Requirements.* Lilly shall ensure that all Screened Persons are not Ineligible Persons, by implementing the following screening requirements.

- a. Lilly shall screen all Screened Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Screened Persons to disclose whether they are Ineligible Persons.

b. Lilly shall screen all Screened Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.

c. Lilly shall implement a policy requiring all Screened Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in this Section affects the responsibility of (or liability for) Lilly to (if applicable) refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person. Lilly understands that items or services furnished by excluded persons are not payable by Federal health care programs and that Lilly may be liable for overpayments (if applicable) and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Lilly meets the requirements of Section III.F.

3. *Removal Requirement.* If Lilly has actual notice that a Screened Person has become an Ineligible Person, Lilly shall remove such Screened Person from responsibility for, or involvement with, Lilly's business operations related to the Federal health care programs and shall remove such Screened Person from any position for which the Screened Person's compensation or the items or services furnished, ordered, or prescribed by the Screened Person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the Screened Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If Lilly has actual notice that a Screened Person is charged with a criminal offense that falls within the ambit of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Screened Person's employment or contract term, Lilly shall take all appropriate actions to ensure that the responsibilities of that Screened Person have not and shall not adversely affect the accuracy of any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery by senior management at U.S. corporate headquarters of Lilly or Lilly USA, Lilly shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Lilly conducted or brought by a governmental entity or its agents involving an allegation that Lilly has committed a crime or has engaged in

fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Lilly shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

#### H. Reporting.

##### 1. *Reportable Events.*

a. *Definition of Reportable Event.* For purposes of this CIA, a "Reportable Event" means anything that involves:

- i. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program and/or applicable to any FDA requirements relating to the promotion of Lilly Government Reimbursed Products for which penalties or exclusion may be authorized; or
- ii. the filing of a bankruptcy petition by Lilly.

A Reportable Event may be the result of an isolated event or a series of occurrences.

b. *Reporting of Reportable Events.* If Lilly or Lilly USA determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Lilly shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:

- i. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program and/or FDA authorities implicated;
- ii. a description of Lilly's actions taken to correct the Reportable Event; and

iii. any further steps Lilly plans to take to address the Reportable Event and prevent it from recurring.

iv. If the Reportable Event involves the filing of a bankruptcy petition, the report to the OIG shall include documentation of the filing and a description of any Federal health care program authorities and/or FDA authorities implicated.

v. Lilly shall not be required to report as a Reportable Event any matter previously disclosed under Section III.G.

I. Notification of Communications with FDA.

Within 30 days after the date of any written report, correspondence, or communication between Lilly and the FDA that materially discusses Lilly's or a Covered Person's actual or potential unlawful or improper promotion of Lilly's products (including any improper dissemination of information about off-label indications), Lilly shall provide a copy of the report, correspondence, or communication to the OIG. Lilly shall also provide written notice to the OIG within 30 days after the resolution of any such disclosed off-label matter, and shall provide the OIG with a description of the findings and/or results of the matter, if any.

J. Review of Records Reflecting the Content of Detailing Sessions.

For each Reporting Period, Lilly shall obtain non-Lilly records (*e.g.*, Verbatims, message recall studies, or similar records) generated by an independent entity (Survey Entity) reflecting the purported content and subject matter of detailing interactions between Lilly sales representatives and HCPs for up to three Covered Products (as defined below). In order to satisfy its obligations under this Section III.J, Lilly may propose that it obtain an alternative type of survey record. The OIG will consider Lilly's proposal, and after considering Lilly's proposal shall, in its discretion, identify the type of survey records to be obtained.

For each Covered Product, Lilly shall contract with the Survey Entity to conduct inquiries into the content and subject matter of the detailing interactions. The OIG shall select and notify the Survey Entity of a one week period within every other quarter of the Reporting Period for which the surveys shall be conducted beginning in the second full



quarter after the Effective Date. For each Covered Product, Lilly shall obtain records reflecting the purported content and subject matter of detailing sessions during the identified week in all regions across the United States.

Prior to the start of the second Reporting Period and every Reporting Period thereafter, based on the information provided and other information known to it, and after consultation with Lilly, the OIG shall select up to three Government Reimbursed Products to be the basis for the review outlined in this Section III.J and shall notify Lilly of its selection. These identified products shall be known as the "Covered Products." The parties have already identified the Covered Products for the first Reporting Period.

Lilly shall review the records obtained from the Survey Entity and shall identify any instances in which the records appear to indicate that Covered Persons may have discussed and/or disseminated information about off-label uses of the Covered Products. Lilly shall make findings based on its review (Off-Label Findings) and shall take any responsive action it deems necessary. If necessary for purposes of its review, Lilly shall endeavor to gather additional factual information about the circumstances relating to any Off-Label Findings. As part of each Annual Report, Lilly shall provide the OIG with copies of the underlying records of the detailing interactions, a copy of Lilly's Off-Label Findings, and a description of the action(s), if any, Lilly took in response to the Off-Label Findings.

#### K. Field Force Monitoring and Review Efforts

To the extent not already accomplished, within 120 days after the Effective Date, Lilly shall establish a Field Force Monitoring Program (FFMP) to evaluate and monitor field sales force representatives' interactions with HCPs. The FFMP shall be a formalized process designed to directly observe the appropriateness of field sales force representative's interactions with HCPs and to identify potential off-label promotional activities.

Under this program, Lilly compliance personnel or appropriately trained Lilly employees who are not currently working in the marketing or the field sales organization shall conduct direct field observations (Observations) of field sales force representatives to assess whether the messages delivered and materials distributed to HCPs are consistent with Lilly's Policies and Procedures. These Observations shall be full day ride-alongs with field sales representatives, and each Observation shall consist of directly observing all meetings between a sales representative and HCPs during the workday. The

Observations shall be scheduled throughout the year, randomly selected by Lilly compliance personnel, include each therapeutic area and actively promoted product, and be conducted across the United States. At the completion of each Observation, Lilly compliance personnel or the designee shall prepare a report which includes:

- 1) the identity of the sales representative;
- 2) the identity of the Lilly compliance professional or other Lilly employee;
- 3) the date and duration of the Observation;
- 4) the product(s) promoted during the Observation;
- 5) an overall assessment of compliance with Lilly policy; and
- 6) the identification of any potential off-label promotional activity by the field sales representative.

Lilly compliance personnel shall conduct at least 50 full-day Observations during each Reporting Period. The number of inspections conducted for each therapeutic area and product shall be proportional in number to the size of each therapeutic area and product, and shall be conducted across the United States.

In the event that a compliance issue, including but not limited to a potential off-label promotion or noncompliance with Lilly's compliance program or policies and procedures, is identified during any Observation, Lilly shall investigate the incident consistent with established Policies and Procedures for the handling of investigations. As part of the formal investigation procedures, findings shall be made and all necessary and appropriate responsive action (including disciplinary action) and corrective action shall be taken. The Compliance Officer shall disclose Reportable Events pursuant to Section III.H above, if applicable. Any compliance issues identified during an Observation and any corrective action shall be recorded in the files of the compliance department.

Lilly shall include a summary of the FFMP and the results of the FFMP as part of each Annual Report. As part of each Annual Report, Lilly also shall provide the OIG with copies of the Observation report for any instances in which it was determined that improper promotion occurred and a description of the action(s) that Lilly took as a result of such determinations. Lilly shall make the Observation reports for all other Observations available to the OIG upon request.

L. Notice to Health Care Providers and Entities

Within 90 days after the Effective Date, Lilly shall send, by first class mail, postage prepaid and return receipt requested, a notice containing the language set forth below to all HCPs and HCIs that Lilly currently details. This notice shall be dated and shall be signed by Lilly's Chief Executive Officer. The body of the letter shall state the following:

As you may be aware, Eli Lilly and Company (Lilly) recently entered into a global civil, criminal, and administrative settlement with the United States and individual states in connection of its promotion of its drug Zyprexa.

This letter provides you with additional information about the settlement, explains Lilly's commitments going forward, and provides you with access to information about those commitments. In general terms, the Government alleged that Lilly unlawfully promoted the drug Zyprexa for certain uses not approved by the Food & Drug Administration (FDA). To resolve these matters, Lilly pled guilty to a misdemeanor criminal violation of the Federal Food Drug and Cosmetic Act and agreed to pay more than \$1 billion to the Federal Government and state Medicaid programs. More information about this settlement may be found at the following: **[Lilly shall include a link to the USAO, OCL, and Eli Lilly websites in the letter.]**

As part of the federal settlement, Lilly also entered into a five-year corporate integrity agreement with the Office of Inspector General of the U.S. Department of Health and Human Services. The corporate integrity agreement is available at <http://oig.hhs.gov/fraud/cia/index.html>. Under this agreement, Lilly agreed to undertake certain obligations designed to promote compliance with Federal health care program and FDA requirements. We also agreed to notify healthcare providers about the settlement and inform them that they can report any questionable practices by Lilly's representatives to Lilly's Compliance Department or the FDA.

Please call or email Lilly at **1-800-TBD** or **[Lilly shall insert website address in the letter.]** if you have questions about the settlement referenced above or to report any instances in which you believe that a Lilly representative inappropriately promoted a product or engaged in other questionable conduct. Alternatively, you may report any such instances to the FDA's Division of Drug Marketing, Advertising, and Communications at 301-796-1200. You should direct medical questions or concerns about the products to The Lilly Answer Center at 1-

800-Lilly-Rx.

We appreciate your time and attention. We are dedicated to ensuring that we bring you the scientific and medical information you need to make well-informed decisions about whether Lilly products are right for your patients.

The Chief Compliance Officer (or a designee) shall maintain a log of all calls and messages received in response to the notice. The log shall include a record and summary of each call and message received (whether anonymous or not), the status of the call or message, and any corrective action taken in response to the call or message. The disclosure log shall be made available to OIG upon request. As part of the Implementation Report and each Annual Report, Lilly shall provide to the OIG a summary of the calls and messages received.

M. Reporting of Physician Payments

1. Phase I Reporting

On or before August 1, 2009, Lilly shall post in a prominent position on its website an easily accessible and readily searchable listing of all U.S.-based physicians and Related Entities (as defined below in Section III.M.4) who or which received Phase I Payments (as defined below in Section III.M.4) directly or indirectly from Lilly or Lilly USA during the first three months of 2009 and the aggregate value of such Payments.

After the initial posting, 30 days after the end of each subsequent calendar quarter, Lilly shall also post on its website a listing of updated information about all Phase I Payments provided during the applicable calendar year during the preceding quarter(s). On or before May 1, 2010, Lilly shall also post on its website a report of the cumulative value of Phase I Payments provided to each physician and/or Related Entity during the preceding calendar year. The quarterly and annual reports shall be easily accessible and readily searchable.

Each listing made pursuant to this Section III.M.1 or Sections III.M.2 or 3 below, shall include a complete list of all individual physicians and Related Entities to whom or to which Lilly or Lilly USA directly or indirectly made the Phase I, II, or III Payments (as applicable) in the preceding calendar quarter or year (as applicable). Each listing shall be arranged alphabetically according to the physicians' last name or the name of the Related

Entity. The Payment amounts in the lists shall be reported in \$10,000 increments (e.g., \$0 - \$10,000; \$10,001- \$20,000; etc.) For each physician, the applicable listing shall include the following information: i) physician's full name; ii) name of Related Entity (if applicable); iii) city and state that the physician or the Related Entity has provided to Lilly for contact purposes; and (iv) the aggregate value of the payment(s) in the preceding quarter(s) or year (as applicable). If payments for multiple physicians have been made to one Related Entity, the aggregate value of all payments to the Related Entity will be the reported amount.

## 2. Phase II Reporting

On or before August 1, 2010, Lilly shall post in a prominent position on its website an easily accessible and readily searchable listing of all U.S.-based physicians and Related Entities (as defined below in Section III.M.4) who provided or which received Phase II Payments (as defined below in Section III.M.4) directly or indirectly from Lilly or Lilly USA during the first three months of 2010 and the aggregate value of such Payments.

After the initial posting, 30 days after the end of each subsequent calendar quarter, Lilly shall also post on its website a listing of updated information about all Phase II Payments provided during the applicable calendar year during the preceding quarter(s). On or before May 1, 2011, Lilly shall also post on its website a report of the cumulative value of Phase II Payments provided to each physician and/or Related Entity during the preceding calendar year. The quarterly and annual reports shall be easily accessible and readily searchable.

## 3. Phase III Reporting

On or before August 1, 2011, Lilly shall post in a prominent position on its website an easily accessible and readily searchable listing of all U.S.-based physicians and Related Entities (as defined below in Section III.M.4) who or which received Phase III Payments (as defined below in Section III.M.4) directly or indirectly from Lilly or Lilly USA during the first three months of 2011 and the aggregate value of such Payments.

After the initial posting, 30 days after the end of each subsequent calendar quarter, Lilly shall also post on its website a listing of updated information about all Phase III Payments provided during the applicable calendar year during the preceding quarter(s). On or before May 1, 2012, Lilly shall also post on its website a report of the cumulative

value of Phase III Payments provided to each physician and/or Related Entity during the preceding calendar year. Thereafter, on or before May 1 of each subsequent year, Lilly shall post a report of the cumulative value of Payments provided to each physician and/or Related Entity during the preceding calendar year. The quarterly and annual reports shall be easily accessible and readily searchable.

#### 4. Definitions and Miscellaneous Provisions

Lilly shall continue to make each annual listing and the most recent quarterly listing of Phase I, Phase II, and Phase III Reporting available on its website at least throughout the term of this CIA. Lilly shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and records related to all applicable Payments and to the annual and quarterly listings of Payments. Nothing in this Section III.M affects the responsibility of Lilly to comply with (or liability for noncompliance with) all applicable Federal health care program requirements and state laws as they relate to all applicable Payments made to physicians or Related Entities.

If the proposed Physician Payments Sunshine Act of 2008 or similar legislation is enacted, the OIG shall determine whether the purposes of this Section III.M are reasonably satisfied by Lilly's compliance with such legislation. In such case, and in its sole discretion, the OIG may agree to modify or terminate provisions of Section III.M as appropriate.

For purposes of this Section III.M, the term "Phase I Payments" is defined as all honoraria payments made in connection with physicians serving as speakers, participating in speaker training, or serving as consultants (including participating in advisory boards, providing training to Lilly employees, or providing ad hoc advising.)

For purposes of this Section III.M, the term "Phase II Payments" is defined as all payments (including, for example, honoraria payments, other payments, and reimbursement for lodging, travel and other expenses) made in connection with physicians serving as speakers, participating in speaker training, or serving as consultants (including participating in advisory boards, providing training to Lilly employees, or providing ad hoc advising).

For purposes of this Section III.M, the term "Phase III Payments" is defined to include all payments or transfers of value (whether in cash or in kind) made to physicians. The term also includes all payments or transfers of value made to Related Entities on

behalf of, at the request of, for the benefit or use of, or under the name of a physician for whom Lilly would otherwise report a Payment if made directly to the physician. Phase III Payments includes all Phase I and Phase II Payments. Phase III Payments include, for example, payments or compensation for services rendered; grants; fees; and payments relating to research or education. The term Phase III Payments also includes payment or reimbursement for food, entertainment, gifts, trips or travel, product(s)/item(s) provided for less than fair market value, or other economic benefit paid or transferred. Phase III Payments do not include: i) samples of drug products that meet the definition set forth in 21 C.F.R. § 203.3(i), or ii) discounts, rebates, or other pricing terms.

For purposes of this Section III.M, the term “Related Entity” is defined to be any entity by or in which any physician receiving Phase I, II, or III Payments is employed, has tenure, or has an ownership interest.

#### **IV. CHANGES TO BUSINESS UNITS OR LOCATIONS**

A. Change or Closure of Unit or Location. In the event that, after the Effective Date, Lilly or Lilly USA changes locations or closes a business unit or location related to Promotional and Product Services Related Functions, Lilly shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change or closure of the location.

B. Purchase or Establishment of New Unit or Location. In the event that, after the Effective Date, Lilly or Lilly USA purchases or establishes a new business unit or location related to Promotional and Product Services Related Functions, Lilly shall notify OIG no later than the date that the purchase or establishment is publicly disclosed by Lilly. This notification shall include the address of the new business unit or location, phone number, fax number, Federal health care program provider or supplier number (if applicable), and the name and address of the contractor that issued each number (if applicable). Each new business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements of this CIA.

C. Sale of Unit or Location. In the event that, after the Effective Date, Lilly or Lilly USA proposes to sell any or all of its business units or locations related to the Promotional and Product Services-Related Functions that are subject to this CIA, Lilly shall notify OIG of the proposed sale no later than the date the sale is publicly disclosed by Lilly. This notification shall include a description of the business unit or location to be sold, a brief description of the terms of the sale, and the name and contact information of

the prospective purchaser. This CIA shall be binding on the purchaser of such business unit or location, unless otherwise determined and agreed to in writing by the OIG.

**V. IMPLEMENTATION AND ANNUAL REPORTS**

A. Implementation Report. Within 150 days after the Effective Date, Lilly shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A.1, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
2. the names and positions of the members of the Compliance Committee required by Section III.A.2;
3. the names of the members of the Committee of the Board referenced in Section III.A.3;
4. the names and positions of the Certifying Employees required by Section III.A.4;
5. a copy of Lilly's Code of Conduct required by Section III.B.1;
6. the number of Covered Persons required to complete the Code of Conduct certification required by Section III.B.1, the percentage of Covered Persons who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
7. (a) a copy of the letter (including all attachments) required by Sections II.C.6 and III.B.2 sent to each party employing Third Party Personnel; (b) a list of all such existing agreements; and (c) a description of the entities' response to Lilly's letter;
8. to the extent not already provided to the OIG, a copy of all Policies and Procedures required by Section III.B.3;



9. the following information regarding each type of training required by Section III.C:

- a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and
- b. the number of Covered Persons required to be trained, percentage of Covered Persons actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request;

10. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; and (c) a summary and description of any and all current and prior engagements and agreements between Lilly and the IRO;

11. a certification from the IRO regarding its professional independence and objectivity with respect to Lilly;

12. a description of the Disclosure Program required by Section III.E;

13. a description of the process by which Lilly fulfills the requirements of Section III.F regarding Ineligible Persons;

14. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken in response to the screening and removal obligations set forth in Section III.F;

15. a certification by the Chief Compliance Officer that the notice required by Section III.L was mailed to each HCP and HCI, the number of HCPs and HCIs that received a copy of the notice, a sample copy of the notice required by Section III.L, and a summary of the calls or messages received in response to the notice;

16. a certification from the Chief Compliance Officer that, if required under Section III.M and to the best of his/her knowledge, information regarding Payments has been posted on Lilly's website as required by Section III.M;

17. a list of all of Lilly's U.S. locations (including locations and mailing addresses) at which it performs Promotional and Product Services Related Functions; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal health care program provider or supplier number(s) (if applicable), and the name and address of each Federal health care program contractor to which Lilly currently submits claims (if applicable);

18. a description of Lilly's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

19. the certifications required by Section V.C.

B. Annual Reports. Lilly shall submit to OIG annually a report with respect to the status of, and findings regarding, Lilly's compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. an explanation of any change in the identity, position description, or other noncompliance job responsibilities of the Chief Compliance Officer and any change in the membership of the Compliance Committee, the compliance Committee of the Board of Directors, or the group of Certifying Employees described in Sections III.A.2-4, and a copy of the Compliance Program Review Report described in Section III.A.3;

2. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in applicable requirements);

3. the number of Covered Persons required to complete the Code of Conduct certification required by Section III.B.1, the percentage of Covered Persons who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

4. (a) a copy of the letter (including all attachments) required by Sections II.C.6 and III.B.2 sent to each entity employing Third Party Personnel; (b) a list of all such existing agreements; and (c) a description of the entities' response to Lilly's letter;

5. the following information regarding each type of training required by Section III.C:

a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and

b. the number of Covered Persons required to be trained, percentage of Covered Persons actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

6. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter (if applicable);

7. Lilly's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.D;

8. a summary and description of any and all current and prior engagements and agreements between Lilly and the IRO, if different from what was submitted as part of the Implementation Report;

9. a certification from the IRO regarding its professional independence and objectivity with respect to Lilly;

10. a summary of the disclosures in the disclosure log required by Section III.E that relate to Federal health care programs;

11. any changes to the process by which Lilly fulfills the requirements of Section III.F regarding Ineligible Persons;

12. the name, title, and responsibilities of any person who is determined to

be an Ineligible Person under Section III.F; the actions taken by Lilly in response to the screening and removal obligations set forth in Section III.F;

13. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

14. a summary of Reportable Events (as defined in Section III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;

15. a summary describing any written communication with the FDA required to have been reported pursuant to Section III.I. This summary shall include a description of the matter and the status of the matter;

16. all information required by Section III.J;

17. all information required by Section III.K;

18. a summary of the calls and messages received in response to the notice required by Section III.L and the disposition of those calls and messages

19. a description of all changes to the most recently provided list of Lilly's locations (including addresses) as required by Section V.A.17; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal health care program provider or supplier number(s) (if applicable), and the name and address of each Federal health care program contractor to which Lilly currently submits claims (if applicable); and

20. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications. The following certifications shall be included in the Implementation Report and Annual Reports:

1. Certifying Employees: In each Annual Report, Lilly shall include the certifications of Certifying Employees as required by Section III.A.4;

2. Chief Compliance Officer: In the Implementation Report and Annual Reports, Lilly shall include the following individual certification by the Chief Compliance Officer:

a. he or she has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information in the Report is accurate and truthful;

b. to the best of his or her knowledge, except as otherwise described in the applicable report, Lilly is in compliance with the Federal health care program and FDA requirements and the obligations of the CIA;

c. to the best of his or her knowledge, Lilly has complied with its obligations under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs;

d. Lilly's: 1) Policies and Procedures as referenced in Section III.B.3 above; 2) templates for standardized contracts and other similar documents; and 3) the training materials used for purposes of Section III.C all have been reviewed by competent legal counsel and/or legal personnel working at their direction and have been found to be in compliance with all applicable Federal health care program and FDA requirements. In addition, Lilly's promotional materials containing claims or information about Government Reimbursed Products and other materials and information intended to be disseminated outside Lilly have been reviewed by competent regulatory, medical, and/or legal personnel in accordance with applicable Policies and Procedures to ensure that legal, medical, and regulatory concerns are properly addressed and are elevated when appropriate, and that the materials and information when finally approved are in compliance with all applicable Federal health care program and FDA requirements. If the

applicable legal requirements have not changed, after the initial review of the documents listed above, only material changes to the documents must be reviewed by competent regulatory, medical, and/or legal personnel. The certification shall include a description of the document(s) reviewed and approximately when the review was completed. The documentation supporting this certification shall be available to OIG, upon request; and

e. Lilly's call plans for Government Reimbursed Products were reviewed at least once during the Reporting Period (consistent with Section III.B.3.g) and, for each product the call plans were found to be consistent with Lilly's policy objectives as referenced above in Section III.B.3.g.

D. Designation of Information. Lilly shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Lilly shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

## **VI. NOTIFICATIONS AND SUBMISSION OF REPORTS**

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG: Administrative and Civil Remedies Branch  
Office of Counsel to the Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services  
Cohen Building, Room 5527  
330 Independence Avenue, S.W.  
Washington, DC 20201  
Telephone: 202.619.2078  
Facsimile: 202.205.0604

Lilly: Chief Compliance Officer  
Eli Lilly and Company  
Lilly Corporate Center, DC 1114  
Indianapolis, IN 46285  
Telephone: 317.276.9937

Facsimile: 317.655.1921

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt. Upon request by OIG, Lilly may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), either instead of or in addition to, a paper copy.

#### **VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS**

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Lilly's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Lilly's locations for the purpose of verifying and evaluating: (a) Lilly's compliance with the terms of this CIA; and (b) Lilly's compliance with the requirements of the Federal health care programs in which it participates and with all applicable FDA requirements. The documentation described above shall be made available by Lilly to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Lilly's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Lilly shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Lilly's employees may elect to be interviewed with or without a representative of Lilly present.

#### **VIII. DOCUMENT AND RECORD RETENTION**

Lilly shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA, for six years (or longer if otherwise required by law) from the Effective Date.

#### **IX. DISCLOSURES**

Corporate Integrity Agreement  
Eli Lilly Company

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Lilly prior to any release by OIG of information submitted by Lilly pursuant to its obligations under this CIA and identified upon submission by Lilly as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Lilly shall have the rights set forth at 45 C.F.R. § 5.65(d).

**X. BREACH AND DEFAULT PROVISIONS**

Lilly is expected to fully and timely comply with all of its CIA obligations. The breach and default remedies available to the OIG under this Section X do not preempt or limit any actions that individual States may take against Lilly under applicable legal authorities or under any applicable settlement agreement or consent decree between the State and Lilly.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Lilly and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Lilly fails to establish, implement, or accomplish any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. the resolution from the Committee of the Board;
- d. a written Code of Conduct;
- e. written Policies and Procedures;
- f. the training of Covered Persons and Relevant Covered Persons;
- g. a Disclosure Program;



- h. Ineligible Persons screening and removal requirements;
- i. notification of Government investigations or legal proceedings;
- j. notification of written communications with FDA as required by Section III.I;
- k. a review of records reflecting the content of detailing sessions;
- l. a program for FFMP;
- l. notification to HCPs and HCIs as required by Section III.L;
- m. posting of any Payments as required by Section III.M.

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Lilly fails to engage an IRO, as required in Section III.D and Appendices A-B.

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Lilly fails to submit the Implementation Report or the Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Lilly fails to submit the annual IRO Review Report(s) in accordance with the requirements of Section III.D and Appendices A-B.

5. A Stipulated Penalty of \$1,500 for each day Lilly fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Lilly fails to grant access.)

6. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Lilly as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of \$1,000 for each day Lilly fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Lilly, stating the specific grounds for its determination that Lilly has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Lilly shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Lilly receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-6 of this Section.

B. Timely Written Requests for Extensions. Lilly may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Lilly fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Lilly receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that Lilly has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Lilly of: (a) Lilly's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Lilly shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Lilly elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Lilly cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one

of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Lilly has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

1. *Definition of Material Breach.* A material breach of this CIA means:

- a. a failure by Lilly to report a Reportable Event and take corrective action, as required in Section III.H;
- b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C;
- d. a failure to engage and use an IRO in accordance with Section III.D; or
- e. a failure of the Committee of the Board to issue a resolution in accordance with Section III.A.3.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Lilly constitutes an independent basis for Lilly's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Lilly has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Lilly of: (a) Lilly's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred

to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* Lilly shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

- a. Lilly is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Lilly has begun to take action to cure the material breach; (ii) Lilly is pursuing such action with due diligence; and (iii) Lilly has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Lilly fails to satisfy the requirements of Section X.D.3, OIG may exclude Lilly from participation in the Federal health care programs. OIG shall notify Lilly in writing of its determination to exclude Lilly (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Lilly's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Lilly may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

#### E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to Lilly of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Lilly shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS

Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Lilly was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Lilly shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Lilly to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Lilly requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

- a. whether Lilly was in material breach of this CIA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Lilly had begun to take action to cure the material breach within that period; (ii) Lilly has pursued and is pursuing such action with due diligence; and (iii) Lilly provided to OIG within that period a reasonable timetable for curing the material breach and Lilly has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Lilly, only after a DAB

decision in favor of OIG. Lilly's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Lilly upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Lilly may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Lilly shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Lilly, Lilly shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

#### **XI. EFFECTIVE AND BINDING AGREEMENT**

Lilly and OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns, and transferees of Lilly;
- B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;
- C. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA;
- D. The undersigned Lilly signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA; and
- E. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

ON BEHALF OF ELI LILLY AND COMPANY

/Robert A. Armitage/

Robert A. Armitage  
Senior Vice President and General Counsel

14 January 2009

Date

/Anne Nobles/

Anne Nobles  
Lilly Chief Compliance Officer

1/14/09

Date

/Paul Kalb/

Paul Kalb  
Kristin Koehler  
Counsel for Eli Lilly and Company

1/14/09

Date

**ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL  
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**

/Gregory E. Demske/

—  
Gregory E. Demske  
Assistant Inspector General for Legal Affairs  
Office of Inspector General  
U. S. Department of Health and Human Services

1/14/09  
DATE



## APPENDIX A

### INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.D of the CIA.

#### A. IRO Engagement

Lilly shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Lilly if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Lilly may continue to engage the IRO.

If Lilly engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Lilly shall submit the information identified in Section V.A.8 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Lilly if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Lilly may continue to engage the IRO.

#### B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the Promotional and Product Services Review who have expertise in all applicable Federal health care program and FDA requirements relating to Promotional and Product Services Related Functions. The assigned individuals shall also be knowledgeable about the general requirements of the Federal health care program(s) under which Lilly products are reimbursed;

2. assign individuals to design and select the samples for the Transaction Reviews who are knowledgeable about the appropriate statistical sampling techniques; and

3. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

#### C. IRO Responsibilities.

The IRO shall:

1. perform each Promotional and Product Services Review in accordance with the specific requirements of the CIA;
2. follow all applicable Federal health care program and FDA requirements in making assessments in each Promotional and Product Services Review;
3. if in doubt of the application of a particular Federal health care program or FDA requirement, policy, or regulation, request clarification from the appropriate authority (e.g., CMS or FDA);
4. respond to all OIG inquiries in a prompt, objective, and factual manner; and
5. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. IRO Independence and Objectivity.

The IRO must perform the Promotional and Product Services Review in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and Lilly .

E. IRO Removal/Termination.

1. *Lilly Termination of IRO.* If Lilly terminates its IRO during the course of the engagement, Lilly must submit a notice explaining its reasons to OIG no later than 30 days after termination. Lilly must engage a new IRO in accordance with Paragraph A of this Appendix.

2. *OIG Removal of IRO.* In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and/or objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Lilly to engage a new IRO in accordance with Paragraph A of this Appendix.

Prior to requiring Lilly to engage a new IRO, OIG shall notify Lilly of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Lilly may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence or performance of its responsibilities and to present additional information regarding these matters. Lilly shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with Lilly prior to requiring Lilly to terminate the IRO. However, the final determination

as to whether or not to require Lilly to engage a new IRO shall be made at the sole discretion of OIG.

**Appendix B to CIA  
Promotional and Product Services Review**

I. Promotional and Product Services Review, General Description

As specified more fully below, Lilly shall retain an Independent Review Organization (IRO) to perform reviews to assist Lilly in assessing and evaluating its systems, processes, policies, procedures, and practices related to Lilly's Promotional and Product Services Related Functions (Promotional and Product Services Review). The Promotional and Product Services Review shall consist of two components - a systems review (the "Promotional and Product Services Systems Review" or "Systems Review"), and a transactions review (the "Promotional and Product Services Transactions Review" or "Transactions Review") as described more fully below. Lilly may engage, at its discretion, a single IRO to perform both components of the Promotional and Product Services Review provided that the entity has the necessary expertise and capabilities to perform both.

If there are no material changes in Lilly's systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions, the IRO shall perform the Promotional and Product Services Systems Review for the first and fourth Reporting Periods. If Lilly materially changes its systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions, the IRO shall perform a Promotional and Product Services Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Review for the first and fourth Reporting Periods. The additional Systems Review(s) shall consist of: 1) an identification of the material changes; 2) an assessment of whether other systems, processes, policies, and procedures previously reported did not materially change; and 3) a review of the systems, processes, policies, and procedures that materially changed. The IRO shall conduct the Promotional and Product Services Transactions Review for each Reporting Period of the CIA.

II. Promotional and Product Services Systems Review

A. Description of Reviewed Policies and Procedures

The Promotional and Product Services Systems Review shall be a review of Lilly's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to certain Promotional and Product Services Related Functions. Where practical, Lilly personnel may compile documentation, schedule and organize interviews, and undertake other efforts to assist the IRO in performing the Systems Review. The IRO is not

required to undertake a de novo review of the information gathered or activities undertaken by Lilly pursuant to the preceding sentence.

Specifically, the IRO shall review Lilly's systems, processes, policies, and procedures associated with the following (hereafter "Reviewed Policies and Procedures"):

1) Lilly's systems, policies, processes, and procedures applicable to the manner in which Lilly sales representatives and account executives handle and submit requests or inquiries to The Lilly Answers Center ("TLAC") relating to information about the uses of Lilly's Government Reimbursed Products (including non-FDA-approved (*i.e.*, off-label) uses) and the dissemination of materials relating to off-label uses of Lilly's Government Reimbursed Products. This review includes:

- a) the manner in which Lilly sales representatives and account executives handle and submit requests for information about off-label uses of Lilly's Government Reimbursed Products to TLAC;
- b) the manner in which TLAC personnel, handle and respond to requests submitted by sales representatives and account executives for information about off-label uses of Lilly's Government Reimbursed Products (including tracking the requests and using pre-approved materials for purposes of responding to the request);
- c) the form and content of information and materials related to Lilly's Government Reimbursed Products disseminated to physicians, pharmacists, or other health care professionals (collectively "HCPs") or health care institutions (HCIs) by Lilly;
- d) Lilly's systems, processes, and procedures (including the TLAC Database) used to track requests for information submitted by sales representatives and account executives to TLAC about off-label uses of Lilly's Government Reimbursed Products and responses to those requests;
- e) the manner in which Lilly collects and supports information reported in any systems used to track and respond to requests for product information, including the TLAC Database;

- f) the processes and procedures by which TLAC and Lilly's Compliance Office or their designee monitor and identify situations in which it appears that improper off-label promotion may have occurred; and
  - g) Lilly's processes and procedures for investigating, documenting, resolving, and taking appropriate disciplinary action for potential situations involving off-label promotion;
- 2) Lilly's policies and procedures applicable to the manner and circumstances under which its Medical Liaisons and Outcomes Liaisons participate in meetings or events with HCPs or HCIs (either alone or with sales representatives or account executives) and the role of the Medical Liaisons and Outcomes Liaisons at such meetings or events, including use of the Eli Lilly Contact Information Management (ELCIM) system to document requests and/or the use of LillyMedical.com to respond to requests for medical information;
- 3) Lilly's systems, policies, processes, and procedures relating to Lilly's internal review and approval of information and materials related to Lilly's Government Reimbursed Products disseminated to HCPs or HCIs by Lilly;
- 4) Lilly's systems, policies, processes and procedures relating to incentive compensation for Covered Persons who are sales representatives, with regard to whether the systems, policies, processes, and procedures are designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in the improper promotion, sales, and marketing of Lilly's Government Reimbursed Products. This shall include a review of the bases upon which compensation is determined and the extent to which compensation is based on product performance;
- 5) Lilly's systems, processes, policies, and procedures relating to the development and review of call plans for Lilly's Government Reimbursed Products. This shall include a review of the bases upon which HCPs and HCIs belonging to specified medical specialties are included in, or excluded from, the call plans based on expected utilization of Lilly Government Reimbursed Products for FDA-approved uses or non-FDA-approved uses; and
- 6) Lilly's systems, processes, policies, and procedures relating to the development, implementation, and review of Sample Distribution

Plans. This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples from Lilly (including, separately, from Lilly sales representatives and Lilly's medical services department).

#### B. Promotional and Product Services Systems Review Report

The IRO shall prepare a report based upon each Systems Review. For each of the Reviewed Policies and Procedures identified in Section II.A above, the report shall include the following items:

- 1) a description of the documentation (including policies) reviewed and any personnel interviewed;
- 2) a detailed description of Lilly's systems, policies, processes, and procedures relating to the items identified in Sections II.A.1-6 above, including a general description of Lilly's control and accountability systems (e.g., documentation and approval requirements, and tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;
- 3) a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Sections II.A.1-6 above are made known or disseminated within Lilly;
- 4) a detailed description of any system(s) used to track and respond to requests for information submitted by sales representatives and account executives about Lilly's Government Reimbursed Products (including the TLAC Database);
- 5) a detailed description of Lilly's incentive compensation system for Covered Persons who are sales representatives, including a description of the bases upon which compensation is determined and the extent to which compensation is based on product performance. To the extent that Lilly may establish compensation differently for individual products, the IRO shall report separately on each such type of compensation arrangement;
- 6) findings and supporting rationale regarding any weaknesses in Lilly's systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and

- 7) recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

### III. Promotional and Product Services Transaction Review

As described more fully below in Sections III.A-E, the Promotional and Product Services Transactions Review shall include: (1) a review of a sample of Inquiries reflected in the TLAC Database; (2) a review of Lilly's call plans and Lilly's call plan review process; (3) a review of Sampling Events as defined below in Section III.C; (4) a review of records relating to a sample of the Payments that are reported by Lilly pursuant to Section III.M of the CIA; and (5) a review of up to three additional items identified by the OIG in accordance with Section III.D.1.b of the CIA (hereafter "Additional Items".) The IRO shall report on all aspects of its reviews in the Promotional and Product Services Transactions Review Reports.

#### A. Review of Inquiries and TLAC Database

##### 1) Description of TLAC Database

As set forth in Section III.B.3.e of the CIA, Lilly shall establish a database (hereafter, "TLAC database") to track information relating to requests for information submitted by Lilly sales representatives and account executives to TLAC about its products (hereafter "Inquiries"). Specifically, Lilly shall document and record all Inquiries submitted based on requests from HCPs or HCIs regarding Lilly's Government Reimbursed Products in the TLAC database. Lilly shall record in the TLAC Database the following information for each Inquiry received: 1) date of Inquiry; 2) form of Inquiry (e.g., fax, phone, medical information request form); 3) name of requesting HCP or HCI, in accordance with applicable privacy laws; 4) nature and topic of request (including exact language of the Inquiry if made in writing); 5) nature/form of the response from Lilly (including a record of any materials provided in response to the request); and 6) the name of the Lilly representative who called upon or interacted with the HCP or HCI, if known.

##### 2) Internal Review of TLAC Database

On a semi-annual basis, the Lilly's Compliance Office or designee shall review the TLAC Database and related information, as



appropriate, and shall generate a report summarizing the items of information outlined in Section III.A.1 above for each Inquiry received during the preceding two quarters ("TLAC Database Report"). Lilly's Compliance Office or designee shall review the TLAC Database Reports to assess whether the information contained in the report suggests that improper off-label promotion may have occurred in connection with any Inquiry(ies). If the Lilly's Compliance Office or designee, in consultation with other appropriate Lilly personnel, suspects that improper off-label promotion may have occurred in connection with any Inquiry, the Lilly's Compliance Office or designee shall undertake a follow-up review of the Inquiry (hereafter "Off-Label Review"), make specific findings based on the Off-Label Review, and take all appropriate corrective action (including disciplinary action of the Covered Person and reporting of the conduct, including disclosing Reportable Events pursuant to Section III.H of the CIA, if applicable).

3) IRO Review of Inquiries Reflected in the TLAC Database

The IRO shall select and review a random sample of 60 Inquiries from among the Inquiries reflected in the TLAC Database for each Reporting Period. Forty-five of the Inquiries reviewed by the IRO shall be Inquiries for which Lilly conducted an Off-Label Review, and the other 15 shall be Inquiries for which Lilly did not conduct an Off-Label Review. If Lilly conducted an Off-Label Review on fewer than 45 Inquiries, additional Inquiries may be selected for which an Off-Label Review was not conducted to reach a total of 60 Inquiries. For each Inquiry reviewed, the IRO shall determine:

- a) Whether each item of information listed above in Section III.A.1 is reflected in the TLAC Database for each reviewed Inquiry; and
- b) For each Inquiry for which Lilly's Compliance Office or designee conducted an Off-Label Review, the basis for suspecting that improper off-label promotion may have occurred; the steps undertaken as part of the Off-Label Review; the findings of the Lilly's Compliance Office or designee as a result of the Off-Label Review; and any follow-up actions taken by Lilly based on the Off-Label Review findings.

B. IRO Review of Lilly's Call Plans and Call Plan Review Process

The IRO shall conduct a review and assessment of Lilly's review of its call plans for Government Reimbursed Products as set forth in Section III.B.3.g of the CIA. Lilly shall provide the IRO with: i) a list of products promoted by Lilly during the Reporting Period; ii) information about the FDA-approved uses for each Lilly product; and iii) the call plans for each product. Lilly shall also provide the IRO with information about the reviews of call plans that Lilly conducted during the Reporting Period and any modifications to the call plans made as a result of Lilly's reviews.

For each call plan, the IRO shall select a sample of 50 of the HCPs and HCIs included on the call plan. For each call plan, the IRO shall compare the sampled HCPs and HCIs against the criteria (e.g., medical specialty or practice area) used by Lilly in conducting its review and/or modification of the call plan in order to determine whether Lilly followed its criteria and Policies and Procedures in reviewing and modifying the call plan.

The IRO shall note any instances in which it appears that the sampled HCPs and HCIs on a particular call plan are inconsistent with Lilly's criteria relating to the call plan and/or Lilly's Policies and Procedures. The IRO shall also note any instances in which it appears that Lilly failed to follow its criteria or Policies and Procedures.

#### C. IRO Review of the Distribution of Samples of Lilly's Government Reimbursed Products

The IRO shall conduct a review and assessment of the distribution of samples of Lilly's Government Reimbursed Products to HCPs and HCIs. Lilly shall provide the IRO with: i) a list of products for which Lilly distributed samples during the Reporting Period; ii) information about the FDA-approved uses for each Lilly product; and iii) information about Lilly's policies and procedures relating to the distribution of samples of each type of product, including Lilly's Sample Distribution Plan showing which type samples may be distributed by sales representatives to HCPs and HCIs of particular medical specialties or types of clinical practices. Lilly shall also provide the IRO with information about: (1) the reviews of Sample Distribution Plans that Lilly conducted during the Reporting Period; and (2) any modifications to the distribution plans made or corrective actions that may be taken as a result of Lilly's reviews, including investigating, documenting, resolving, and taking disciplinary action.

For each product for which Lilly distributed samples during the Reporting Period, the IRO shall randomly select a sample of 50 separate instances in which Lilly provided samples of the product to HCPs or HCIs either through sales

representation distribution or direct shipment. Each such instance shall be known as a "Sampling Event."

For each Sampling Event, the IRO shall review all documents and information relating to the distribution of the sample to the HCP or HCI, including the sample card, direct shipment request form and/or the electronic call record. The reviewed materials shall include information about the following: 1) the quantity, dosage, and form of the Lilly product provided to the HCP or HCI; 2) the identity and type of medical specialty or clinical practice of the HCP or HCI; 3) which individual Lilly sales representative accepted the sample request form or provided the sample to the HCP or HCI; 4) the manner and mechanism through which the sample was requested (e.g., sample card or direct shipment request form); and 5) the manner and mechanism through which the request was fulfilled (e.g., sales representative distribution or direct shipment.)

For each Sampling Event, the IRO shall evaluate whether the sample was provided to an HCP or HCI whose medical specialty or clinical practice is consistent with the uses of the product approved by the FDA and whether the sample was distributed by a Lilly representative in a manner consistent with Lilly's sample distribution policy for the product(s) provided during the Sampling Event. To the extent that a sample was provided to an HCP or HCI by a Lilly representative other than a sales representative, the IRO shall contact the HCP or HCI by letter. The letter shall request that the HCP or HCI: 1) verify that he/she/it received the quantity and type of samples identified by the IRO as the Sampling Event; 2) verify that he/she/it requested the samples provided during the Sampling Event; 3) explain or confirm its type of medical specialty or clinical practice; and 4) identify the basis for requesting the sample (e.g., conversations with a Lilly sales representative, conversation with a representative of Lilly's medical services department, independent research or knowledge of the HCP or HCI, *etc.*)

For each Sampling Event, the IRO shall compare the medical specialty and type of clinical practice of the HCPs and HCIs that received the sample with uses of the product approved by the FDA. The IRO shall note any instances in which it appears that the medical specialty or clinical practice of the HCPs or HCIs that received a sample during a Sampling Event were not consistent with the uses of the product approved by the FDA. For each such situation, the IRO shall note the process followed by Lilly in determining that it was appropriate to provide a sample to such HCP or HCI and the basis for such determination. For each Sampling Event, the IRO shall also note any instances in which it appears that Lilly failed to follow its Sample Distribution Plan and sample policies and procedures for the product(s) provided during the Sampling Event and, if so, whether Lilly already had taken corrective action, including investigating, documenting, resolving, and taking disciplinary action, if appropriate.

## D. IRO Review of Physician Payment Listings

### 1) Information Contained in Physician Payment Listings

As set forth in Section III.M of the CIA, Lilly shall post quarterly and annual listings of physicians and Related Entities who received Phase I, II, or III Payments, as defined in the CIA, directly or indirectly from Lilly. For purposes of the IRO review as set forth in this Section III.C, each annual listing shall be referred to as the "Physician Payment Listing" or "Listing." For each physician and Related Entity, each Physician Payment Listing shall include the following information: i) physician's full name; ii) name of Related Entity (if applicable); iii) city and state that the physician or the Related Entity has provided to Lilly for contact purposes; and (iv) the aggregate value of the payment(s) in the preceding quarter(s) or year (as applicable). If payments for multiple physicians have been made to one Related Entity, the aggregate value of all payments to the Related Entity will be the reported amount.

For purposes of this IRO review, the term "Control Documents" shall include all documents or electronic records associated with each Payment reflected in the Physician Payments Listing for the sampled physician and/or Related Entity. For example, the term "Control Documents" includes, but is not limited to, documents relating to the nature, purpose, and amount of all Payments reflected in the Listing; contracts relating to the Payment(s) reflected in the Listing; documents relating to the occurrence of Payment(s) reflected in the Listing; documents reflecting any work product generated in connection with the Payment(s); documents submitted by sales representatives or headquarters personnel to request approval for the Payment(s); and business rationale or justification forms relating to the Payment(s).

### 2) Selection of Sample for Review

For each Reporting Period, the OIG shall have the discretion to identify up to 50 physicians or Related Entities from the applicable Physician Payment Listing that will be subject to the IRO review described below. If the OIG elects to exercise this discretion, it shall notify the IRO of the physicians and/or Related Entities subject to the IRO review. If the OIG elects not to exercise its discretion as described above, the IRO shall randomly select 50 physicians and/or Related Entities to be included in the review. For each selected physician and/or Related Entity, the IRO shall review the entry in the Physician Payment Listing and the Control Documents relating to Payments reflected in Listing identified by the IRO as necessary and sufficient to validate the Payment information in the Listing.

3) IRO Review of Control Documents for Selected Physicians and/or Related Entities

For each physician and/or Related Entity selected as part of the sample, the IRO shall review the Control Documents identified by the IRO as necessary and sufficient to validate each Payment reflected in the Listing to evaluate the following:

- a) Whether Control Documents are available relating to each Payment reflected in the Listing for the sampled physician and/or Related Entity;
  - b) Whether the Control Documents were completed and archived in accordance with the requirements set forth in Lilly's policies;
  - c) Whether the aggregate value of the Payment(s) as reflected in the Listing for the sampled physician or Related Entity is consistent with the value of the Payments(s) reflected in the Control Documents; and
  - d) Whether the Control Documents reflect that Lilly's policies were followed in connection with Payment(s) reflected in the Listing (e.g., all required written approvals for the activity were obtained in accordance with Lilly's policies.)
- 4) Identification of Material Errors and Additional Review

A Material Error is defined as any of the following:

- a) A situation in which all required Control Documents relating to Payments reflected in the Listing for the sampled physician and/or Related Entity do not exist and:
  - i. no corrective action was initiated prior to the selection of the sampled physicians and/or Related Entities; or
  - ii. the IRO cannot confirm that Lilly otherwise followed its policies and procedures relating to the entry in the Listing for the sampled physician or Related Entity, including its policies and procedures relating to any Payment(s) reflected in the Listing; or

- b) Information or data is omitted from key fields in the Control Documents that prevents the IRO from assessing compliance with Lilly's policies and procedures, and the IRO cannot obtain this information or data from reviewing other Control Documents.

If a Control Document does not exist, but Lilly has initiated corrective action prior to the selection of the sampled physicians and/or Related Entities, or if a Control Document does not exist but the IRO can determine that Lilly otherwise followed its policies and procedures with regard to each entry in the Listing for a sampled physician or Related Entity, the IRO shall consider such a situation to be an exception (rather than a Material Error) and the IRO shall report the situation as such. The IRO shall note as exceptions any Control Documents for which non-material information or data is omitted.

If the IRO identifies any Material Errors, the IRO shall conduct such Additional Review of the underlying Payment associated with the erroneous Control Documents as may be necessary to determine the root cause of the Material Errors. For example, the IRO may need to review additional documentation and/or conduct interviews with appropriate personnel to identify the root cause of the Material Error(s) discovered.

#### E. IRO Review of Additional Items

As set forth in Section III.D.1.b of the CIA, for each Reporting Period, the OIG at its discretion may identify up to three additional items for the IRO to review (hereafter "Additional Items".) No later than 120 days prior to the end of the applicable Reporting Period, the OIG shall notify Lilly of the nature and scope of the IRO review to be conducted for each of the Additional Items. Prior to undertaking the review of the Additional Items, the IRO and/or Lilly shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG. The IRO shall include information about its review of each Additional Item in the Transactions Review Report (including a description of the review conducted for each Additional Item; the IRO's findings based on its review for each Additional Item; and the IRO's recommendations for any changes in Lilly's systems, processes, policies, and procedures based on its review of each Additional Item.)

Lilly may propose to the OIG that its internal audit(s) and/or reviews conducted as part of the Lilly Compliance Monitoring Program be partially substituted for one or more of the Additional Items that would otherwise be reviewed by the IRO for the applicable Reporting Period. The Lilly Compliance

Monitoring Plan is a monitoring plan developed by Lilly's Compliance Office that includes the following types of events: Advisory Board Meetings, Consultant Task Force Activities, Speaker Trainings, Speaker Programs, Exhibits, Internal Meetings, Field Sales Meetings, Sales Representative Ride-Alongs, Medical or Outcome Liaison Ride-Alongs, Good Business Practice Reviews, Grant Committee Meetings, and Activities Funded by Lilly Grant Office. The OIG retains sole discretion over whether, and in what manner, to allow Lilly's internal audit work to be substituted for a portion of the Additional Items review conducted by the IRO.

In making its decision, the OIG agrees to consider, among other factors, the nature and scope of Lilly's planned internal audit work and/or reviews conducted under the Compliance Monitoring Program, the results of the Transactions Review(s) during prior Reporting Period(s), and Lilly's demonstrated audit capabilities to perform the proposed audit work internally. If the OIG denies Lilly's request to permit its internal audit work to be substituted for a portion of the IRO's review of Additional Items in a given Reporting Period, Lilly shall engage the IRO to perform the Review as outlined in this Section III.

If the OIG agrees to permit certain of Lilly's internal audit work for a given Reporting Period to be substituted for a portion of Additional Items review, such internal work would be subject to verification by the IRO (Verification Review). In such an instance, the OIG would provide additional details about the scope of the Verification Review to be conducted by the IRO. However, for purposes of any Verification Review, the IRO shall review of at least 20% of the sampling units reviewed by Lilly in its internal audits.

#### F. Promotional and Product Services Transactions Review Report

For each Reporting Period, the IRO shall prepare a report based on its Promotional and Product Services Transactions Review. The report shall include the following:

- 1) General Elements to Be Included in Report
  - a) Review Objectives: A clear statement of the objectives intended to be achieved by each part of the review;
  - b) Review Protocol: A detailed narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for each sample reviewed; and

- c) Sources of Data: A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Promotional and Product Services Transactions Review.

2) Results to be Included in Report

The following results shall be included in each Promotional and Product Services Review Report:

(Relating to the Review of Inquiries)

- a) in connection with the review of Inquiries, a description of each type of sample unit reviewed, including the number of each type of sample units reviewed (e.g., the number of Inquiries) and an identification of the types of documents and information reviewed for the Inquiries;
- b) for each Inquiry sample unit, the IRO shall summarize the information about the Inquiry contained in the TLAC Database;
- c) for each Inquiry sample unit, findings and supporting rationale as to whether: (i) each item of information listed in Section III.A.1 is reflected in the TLAC Database; and (ii) for each Inquiry for which an Off-Label Review was conducted, the basis for suspecting that improper off-label promotion may have occurred; the steps undertaken as part of the Off-Label Review; the findings of Lilly's Compliance Office as a result of the Off-Label Review; and any follow-up actions taken by Lilly as a result of Lilly's Compliance Office findings;
- d) the findings and supporting rationale regarding any weaknesses in Lilly's systems, processes, policies, procedures, and practices relating to the Inquiries, and the TLAC Database, if any;
- e) recommendations for improvement in Lilly's systems, processes, policies, procedures, and practices relating to the Inquiries and the TLAC Database, if any;

(Relating to the Call Plan Reviews)



- f) a list of the Government Reimbursed Products promoted by Lilly during the Reporting Period and a summary of the FDA-approved uses for such products;
- g) for each Lilly Government Reimbursed Product: i) a description of the criteria used by Lilly in developing or reviewing the call plans and for including or excluding specified types of HCPs or HCIs from the call plans; ii) a description of the review conducted by Lilly of the call plans and an indication of whether Lilly reviewed the call plans as required by Section III.B.3.g of the CIA; iii) a description of all instances for each call plan in which it appears that the HCPs and HCIs included on the call plan are inconsistent with Lilly's criteria relating to the call plan and/or Lilly's Policies and Procedures; and iv) a description of all instances in which it appears that Lilly failed to follow its criteria or Policies and Procedures relating to call plans or the review of the call plans;
- h) the findings and supporting rationale regarding any weaknesses in Lilly's systems, processes, policies, procedures, and practices relating to Lilly's call plans or the review of the call plans, if any;
- i) recommendations, if any, for changes in Lilly's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to call plans or the review of the call plans;

(Relating to the Sampling Event Reviews)

- j) for each Lilly product distributed during the Reporting Period: i) a description of Sample Distribution Plan (including whether sales representatives may provide samples of the product and, if so, to HCPs or HCIs of which medical specialty or type of clinical practice a sales representative may provide samples); ii) a detailed description of any instances from the reviews by the IRO in which it appears that the medical specialty or clinical practice of the HCPs or HCIs that received a sample during a Sampling Event were not consistent with the uses of the product approved by the

FDA. This description shall include a description of the process followed by Lilly in determining that it was appropriate to provide a sample to such HCP or HCI and the basis for such determination; and iii) a detailed description of any instances in which it appears that Lilly failed to follow its Sample Distribution Plan for the product(s) provided during the Sampling Event;

- k) the findings and supporting rationale regarding any weaknesses in Lilly's systems, processes, policies, procedures, and practices relating to Lilly's distribution of samples of Lilly's Government Reimbursed Products, if any;
- l) recommendations, if any, for changes in Lilly's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to the distribution of samples;

(Relating to the Physician Payment Listing Reviews)

- m) a description of the entries in the Physician Payment Listing for each physician or Related Entity sampled and a description of Control Documents reviewed in connection with each selected physician or Related Entity;
- n) for each sampled physician or Related Entity, findings and supporting rationale as to whether: (i) all required Control Documents exist; (ii) each Control Document was completed in accordance with all of the requirements set forth in the applicable Lilly policy; (iii) the aggregate value of the Payment(s) as reflected in the Listing for the sampled physician or entity is consistent with the value of the Payment(s) reflected in the Control Documents; (iv) each Control Document reflects that Lilly's policies were followed in connection with the underlying activity reflected in the document (e.g., all required approvals were obtained); and (v) any corrective action or disciplinary action was undertaken in those instances in which Lilly policies were not followed;
- o) for each sampled physician or Related Entity unit reviewed, an identification and description of all exceptions discovered. The report shall also describe those instances in which

corrective action was initiated prior to the selection of the sampled physicians or Related Entities, including a description of the circumstances requiring corrective action and the nature of the corrective action;

- p) if any Material Errors are discovered in any sample unit reviewed, a description of the error, the Additional Review procedures performed and a statement of findings as to the root cause(s) of the Material Error;

(Relating to the Review of Additional Items)

- q) for each Additional Item reviewed, a description of the review conducted;
- r) for each Additional Item reviewed, the IRO's findings based on its review;
- s) for each Additional Item reviewed, the findings and supporting rationale regarding any weaknesses in Lilly's systems, processes, policies, procedures, and practices relating to the Additional Item, if any; and
- t) for each Additional Item reviewed, recommendations, if any, for changes in Lilly's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the review.