

**CORPORATE INTEGRITY AGREEMENT**  
**BETWEEN THE**  
**OFFICE OF INSPECTOR GENERAL**  
**OF THE**  
**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**AND**  
**GLAXOSMITHKLINE LLC**

**I. PREAMBLE**

GlaxoSmithKline LLC (GSK) 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, GSK is entering into Settlement Agreements with the United States. GSK will also enter into settlement agreements with various States (State Settlement Agreements) and GSK's agreement to this CIA is a condition precedent to those agreements. Effective October 26, 2010, GSK entered into a Settlement Agreement with the United States to resolve allegations regarding certain drugs manufactured at SB Pharmco's Cidra, Puerto Rico facility.

Prior to the Effective Date of this CIA (as defined below), GSK and GSK Affiliates (as defined below in Section II.C.10) established a worldwide voluntary compliance program designed to address the companies' operations globally. In the United States, the compliance program is designed to address, among other things, compliance with Federal health care program and FDA requirements (Compliance Program).

GSK shall continue its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. GSK may modify its Compliance Program as appropriate, but, at a minimum, GSK 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. Unless otherwise specified, the period of the compliance obligations assumed by GSK and its Affiliates under this CIA shall be five reporting periods, as defined below. The “Effective Date” shall be the date on which the final signatory of this CIA executes this CIA. The first Reporting Period shall be from the Effective Date through December 31, 2013. The second and subsequent Reporting Periods shall be from January 1 through December 31 of each of the subsequent four calendar years.

B. Sections VII, X, and XI shall expire no later than 120 days after OIG’s receipt of: (1) GSK’s final Annual Report; or (2) any additional materials submitted by GSK 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 of GlaxoSmithKline PLC who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5% and (2) acquired the ownership interest through public trading or in connection with the operation of employee long term incentive plans) and all directors of GlaxoSmithKline PLC;

b. all employees of GSK or any GSK Affiliate who are engaged in or supervise personnel who are engaged in any of the Covered Functions (as defined below in Section II.C.7); and

c. contractors, subcontractors, agents and other persons (including, but not limited to, third party vendors who provide services relating to the Covered Functions) who perform any of the Covered Functions on behalf of GSK or any GSK Affiliate and who in that capacity either: (i) interact directly with health care professionals (HCPs), healthcare institutions (HCIs), or consumers; or (ii) perform activities, provide services, or create materials relating to the Covered Functions and those activities, services, or materials are not reviewed or supervised by a Covered Person prior to execution or dissemination.

Notwithstanding the above, the term Covered Persons does not include 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 who engage in Covered Functions or who supervise Covered Persons who engage in Covered Functions.
3. “Government Reimbursed Products” refers to all GSK prescription<sup>1</sup> pharmaceutical products that are marketed or sold by GSK (including by its Pharma, Stiefel, Vaccines, and Oncology division) in the United States (or pursuant to contracts with the United States) that are reimbursed by Federal health care programs.
4. The term “Promotional Functions” includes: (a) the selling, detailing, marketing, advertising, promoting, or branding of Government Reimbursed Products; and (b) the preparation or external dissemination of promotional materials or information about, or the provision of promotional services relating to, Government Reimbursed Products, including those functions relating to any applicable review committees, including GSK’s Copy Approval Team (CAT).
5. The term “Product Related Functions” includes: (a) the preparation or external dissemination of non-promotional materials that are governed by Federal healthcare program and/or FDA requirements and distributed to HCPs and HCIs about Government Reimbursed Products, including those functions relating to GSK’s CAT or other applicable review committee(s) and activities by GSK’s North America Medical Affairs department (Medical Affairs); (b) contracting with HCPs and HCIs in the United States to conduct post-marketing clinical trials, investigator sponsored studies (ISSs), and other post-marketing studies relating to Government Reimbursed Products; (c) authorship, publication, and

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<sup>1</sup> GSK represents that its Consumer Healthcare business unit shall not market, detail, or otherwise promote prescription pharmaceutical products for the duration of the CIA. Should the Consumer Healthcare business unit begin to do so, it shall become subject to the terms of the CIA.

disclosure of articles or study results relating to post-marketing clinical trials and other post-marketing studies for Government Reimbursed Products (including studies of investigational and other uses and indications outside the currently approved uses and conditions of use); and (d) activities related to the submission of information about Government Reimbursed Products to compendia (such as DrugDex or other compendia of information about Government Reimbursed Products as defined below in Section III.B.3.t.)

6. The term “Payer Related Functions” refers to activities of GSK’s Policy, Payers and Vaccines (PPV) Unit and includes Promotional Functions and Product Related Functions as they relate to interactions between GSK and entities that provide a drug health benefit program for Government Reimbursed Products, including but not limited to government payers (e.g., Medicaid and Medicare) or individuals or entities under contract with or acting on behalf of government payers and commercial health plans (collectively referred to as “Payers”). Payer Related Functions also includes interactions with Payers related to formulary placement, supplemental rebate agreements, and other types of rebate agreements.
7. The term “Covered Functions” refers to “Promotional Functions,” “Product Related Functions,” and “Payer Related Functions” collectively.
8. The term “Third Party Educational Activity” shall mean any scientific, educational, or professional program, meeting, or event for HCPs conducted by a third party and supported by GSK, including but not limited to, continuing medical education (CME), disease awareness, or sponsorship of symposia at medical conferences.
9. The term “Third Party Personnel” shall mean employees of entities with whom GSK currently has, or in the future does, enter into agreements to promote or co-promote a Government Reimbursed Product or to engage in joint promotional activities relating to such a product. GSK represents that: (1) the Third Party Personnel are employed by independent entities other than GSK; (2) GSK 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. GSK agrees to promote compliance by Third Party Personnel with Federal health care program requirements and FDA requirements by complying with the provisions set forth below in Sections III.B.2, V.A.8, and V.B.4 related to Third Party Personnel. Provided that GSK complies with the requirements of Sections III.B.2, V.A.8, and V.B.4, GSK shall not be required to fulfill the remaining CIA obligations that would otherwise apply to Third Party Personnel who meet the definition of Covered Persons.

10. The term “GSK Affiliate” shall mean GlaxoSmithKline PLC and any other entity (other than GlaxoSmithKline LLC) that is majority owned or controlled, directly or indirectly, by GlaxoSmithKline PLC and whose employees or contractors perform Covered Functions.

D. Appendix D to the CIA sets forth the obligations to which GSK and its Affiliates agree relating to manufacturing operations in connection with the settlement regarding the Cidra facility reference above in the Preamble. To the extent that certain general provisions and obligations are not specifically addressed in Appendix D, the terms of this CIA shall apply to CGMP Activities, Manufacturing Covered Persons, and to GSK and its Affiliates as specified herein.

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

GSK shall establish and maintain a Compliance Program that includes the following elements:

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

1. *Compliance Officer.* Prior to the Effective Date, GSK appointed an individual to serve as Vice President and Compliance Officer for its North America Pharma division (Compliance Officer). GSK shall maintain a Compliance Officer for the term of the CIA. During the term of this CIA, the Compliance Officer shall be authorized to oversee compliance with Federal health care program and FDA requirements and with the requirements of this CIA. The Compliance Officer is, and shall continue to 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 and FDA requirements. The Compliance Officer shall be a member of senior management of GSK, and shall report directly to the Senior Vice President for Governance, Ethics, and Assurance of GlaxoSmithKline PLC who, in turn, reports to the Chief Executive Officer of GlaxoSmithKline PLC. The Compliance Officer shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of GlaxoSmithKline PLC or any authorized committee thereof (hereinafter, “the Board”), and shall be authorized to report on such matters to the Board at any time. The Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by GSK as well as for any reporting obligations created under this CIA. Any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer’s ability to perform the duties outlined in this CIA.

GSK shall report to OIG, in writing, any change in the identity of the Compliance Officer, or any actions or changes that would affect the Compliance Officer’s ability to perform the duties necessary to meet the obligations in this CIA, within five days after such a change.

2. *Compliance Committee.* Prior to the Effective Date, GSK formed compliance committee known as the NA Pharma Risk Management & Compliance Board (hereafter “Compliance Committee”) which, in conjunction with the Compliance Officer, assists in the implementation and enhancement of the Compliance Program. GSK shall continue the Compliance Committee during the term of this CIA. The Compliance Committee shall, at a minimum, include the 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 such as legal, Medical Affairs, regulatory affairs, sales, marketing, human resources, research and development, global manufacturing quality control, and operations.) In addition, GSK’s Audit function provides regular reports to the Compliance Committee. The Compliance Officer and the President of GSK shall co-chair the Compliance Committee. The Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the GSK’s risk areas and shall oversee monitoring of internal and external compliance-related audits and investigations). The Compliance Committee shall meet at least quarterly.

GSK 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.* The Board 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 Board shall, at a minimum, be responsible for the following:

a. The Board shall meet at least quarterly to review and oversee GSK's Compliance Program, including but not limited to the performance of the Compliance Officer and other compliance personnel. The Board shall evaluate the effectiveness of the Compliance Program, including, at a minimum, by receiving updates about the activities of the Compliance Officer and other compliance personnel and updates about adoption and implementation of policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with applicable Federal health care program and FDA requirements.

b. For each Reporting Period of the CIA, the Board shall adopt a resolution, signed by each individual member of the Board, summarizing its review and oversight of GSK'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 Board of Directors has made a reasonable inquiry into the operations of GSK's Compliance Program as applicable to the CIA (including its Appendices) for the time period **[insert time period]**, including the performance of the Compliance Officer and the compliance personnel who are Covered Persons under this CIA. The Board has concluded that, to the best of its knowledge, GSK has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the obligations of the CIA."

If the Board is unable to provide such a conclusion in the resolution, the Board 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 implement an effective Compliance Program at GSK.

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

4. *Deputy Compliance Officers.* Prior to the Effective Date, GSK appointed Deputy Compliance Officers (DCOs) for each U.S. Pharma commercial business unit and for NA Pharma Medical Affairs, and GSK shall maintain the DCOs for the term of the CIA. Each DCO shall be a member of senior management of his/her respective business unit(s) and shall report directly to the Compliance Officer. The DCOs shall be responsible for working together with the Compliance Officer to oversee the development and implementation of policies, procedures, and practices designed to ensure business unit compliance with the requirements set forth in this CIA and with Federal health care program and FDA requirements. Any noncompliance job responsibilities of the DCOs shall be limited and shall not interfere with each DCO's ability to perform the duties outline in this CIA.

5. *Integrity Champions.* Prior to the Effective Date, GSK implemented a program through which indentified individuals serve as Integrity Champions within each U.S. Pharma commercial business unit. Each individual selected to be an Integrity Champion shall be at least a manager within his/her respective business unit, and the responsibilities undertaken as an Integrity Champion shall be in addition to the individuals' existing management responsibilities. Integrity Champions shall be responsible for facilitating local implementation of, and adherence to, GSK policies and procedures, Federal health care program and FDA requirements, and the requirements of this CIA. Integrity Champions shall meet with their respective DCO on a regular basis. The performance of Integrity Champions, as such, will be a factor in their annual performance reviews.

6. *Management Accountability and Certifications:* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain GSK officers or employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable business unit is compliant with applicable Federal health care program and FDA requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: President, GSK; the heads of the U.S. Pharma commercial business units; Chairman, Research and Development; Vice President, Strategic, Planning and Operations; Senior Vice President, NA Medical Affairs; President, Pharmaceuticals Research and Development; President, Vaccines; and Vice

President, Stiefel North America Dermatology, and, to the extent that a business unit performs Covered Functions and is not covered by the certification of one of the above-listed individuals, such other executives, vice-presidents, and directors of business units as would be necessary to ensure that there is a Certifying Employee from each such business unit.

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] with all applicable Federal health care program requirements, FDA requirements, obligations of the Corporate Integrity Agreement, and GSK policies, and I have taken steps to promote such compliance. To the best of my knowledge, except as otherwise described herein, the \_\_\_\_\_ [insert name of department or functional area] of GSK is in compliance with all applicable Federal health care program requirements, FDA requirements, and the obligations of the CIA. I understand that this certification is being provided to and relied upon by the United States.”

If any Certifying Employee is unable to provide such a conclusion in the certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above and the steps being taken to address the issue(s) identified in the certification.

#### B. Written Standards.

1. *Code of Conduct.* Prior to the Effective Date, GSK developed and implemented a written Code of Conduct. Within 120 days after the Effective Date, GSK shall distribute the written Code of Conduct to all Covered Persons. GSK shall make adherence to the Code of Conduct an element in evaluating the performance of all employees who are Covered Persons. The Code of Conduct includes, or within 120 days after the Effective Date shall be revised to address the following:

- a. GSK’s commitment to full compliance with all Federal health care program requirements and FDA requirements, including its

commitment to comply with all requirements relating to the Covered Functions;

b. GSK's requirement that all of its Covered Persons shall be expected to comply with all applicable Federal health care program requirements, FDA Requirements, and with GSK's own Policies and Procedures;

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

d. the personal obligations of each Covered Person to comply with Federal health care program requirements, FDA requirements, and GSK's Policies and Procedures; and

e. the right of all individuals to use the Disclosure Program described in Section III.F, and GSK'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, each Covered Person shall certify, in writing or electronically, that he or she has received, read, understood, and shall abide by the 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.

GSK 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. 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 120 days after the Effective Date and annually thereafter by the anniversary of the Effective Date, GSK shall send a letter to each entity employing Third Party Personnel. The letter shall describe GSK's obligations under the CIA and its commitment to full compliance with all Federal health care program requirements and FDA requirements. The letter shall include a description of GSK's Compliance Program. GSK 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 GSK's Code of Conduct and a description of GSK's Compliance Program available to its employees who meet the definition of Third Party Personnel as set forth in Section II.C.9; or (b) represent to GSK that it has and enforces a substantially comparable set of code of conduct and Compliance Program for its employees who meet the definition of Third Party Personnel as set forth in Section II.C.9.

3. *Policies and Procedures.* To the extent not already accomplished, GSK shall implement written policies and procedures regarding the operation of the Compliance Program and GSK's compliance with Federal health care program and FDA requirements (Policies and Procedures). At a minimum, the Policies and Procedures must address the following:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. appropriate ways to conduct Promotional 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(b)), and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733) and in compliance with all applicable FDA requirements;
- c. appropriate ways to conduct Product 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(b)), and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733) and in compliance with all applicable FDA requirements;
- d. appropriate ways to conduct Payer Related Functions in compliance with all applicable Federal health care program

requirements, including but not limited to the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b(b)); the False Claims Act (codified at 31 U.S.C. §§ 3729-3733); applicable FDA requirements; and applicable state laws. During the term of the CIA, the Policies and Procedures shall be consistent with GSK's US Commercial Practices Policy regarding "Administration of Contracts with Payers."

- e. the materials and information that may be distributed by GSK sales personnel about Government Reimbursed Products and the manner in which GSK sales personnel respond to requests for information about non-FDA approved (or "off-label") uses of Government Reimbursed Products. These Policies and Procedures shall require that sales personnel may not engage in off-label promotion (directly or indirectly) and must refer all requests for information about off-label uses of Government Reimbursed Products to Medical Affairs;
- f. the materials and information that may be distributed by GSK personnel from the PPV Unit and the manner in which PPV personnel respond to requests for information about off-label uses of Government Reimbursed Products. These Policies and Procedures shall require that all requests for information about off-label uses of Government Reimbursed Products be referred to Medical Affairs (i.e., Medical Information Scientists (MISs), Medical Science Liaisons (MSLs), and/or Health Outcome Liaisons (HOLs));
- g. the materials and information (including product information and product dossiers about Government Reimbursed Products) that may be distributed by Medical Affairs and the mechanisms through, and manner in which, Medical Affairs receives and responds to requests for information from an HCP or another individual or entity about off-label uses of GSK's Government Reimbursed Products; the form and content of information disseminated by GSK in response to such requests; and the internal review and approval process for the information disseminated. These Policies and Procedures shall require that

GSK sales personnel obtain a signature from the medical professional who verbally requested the written information confirming what information was requested and the request was unsolicited.

The Policies and Procedures shall include a requirement that Medical Affairs develop a database (“Inquiries Database”) to track all requests for information about Government Reimbursed Products to Medical Affairs. The Inquiries Database shall include the following items of information for each unique inquiry (Inquiry) received for information about GSK’s products: (1) date of Inquiry; (2) form of Inquiry (e.g., fax, phone, etc.); (3) name of the requesting HCP, HCI, or other individual or entity; (4) nature and topic of request (including exact language of the Inquiry if made in writing); (5) an evaluation of whether the Inquiry relates to information about an off-label use for the product; (6) nature/form of the response from GSK (including a record of the materials provided to the HCP or HCI in response to the request); and (7) the name of the GSK representative who called on or interacted with the HCP, customer, or HCI, if known;

- h. the materials and information that may be distributed or made available by GSK through social media and/or through direct-to-consumer advertising. These policies and procedures shall be designed to ensure that GSK’s activities in this area and the information distributed or made available complies with all applicable Federal health care program and FDA requirements, and have been reviewed and approved by GSK before they are disseminated;
- i. the manner and circumstances under which medical personnel from Medical Affairs interact with or participate in meetings or events with HCPs or HCIs (either alone or with sales representatives or account executives) and the role of the medical personnel at such meetings or events, as well as how they handle responses to unsolicited requests about off-label indications of Government Reimbursed Products;

- j. the development, implementation, and review of target plans for sales personnel and other GSK personnel who promote and sell Government Reimbursed Products (Target Plans). For each Government Reimbursed Product, the Policies and Procedures shall require that GSK review Target 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 Target Plans. The Policies and Procedures shall also require that GSK modify the Target Plans as necessary to ensure that GSK is promoting Government Reimbursed Products in a manner that complies with all applicable Federal health care program and FDA requirements. The Target 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;
- k. the development, implementation, and review of policies and procedures (including excluded specialties lists) for the distribution of samples of, or coupons or vouchers for, Government Reimbursed Products (collectively “Sample Distribution Policies and Procedures”). 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, coupons, or vouchers from GSK. GSK shall modify the Sample Distribution Policies and Procedures as necessary to ensure that GSK is promoting Government Reimbursed Products in a manner that complies with all applicable Federal health care program and FDA requirements;
- l. consultant or other fee-for-service arrangements entered into with HCPs or HCIs relating to Covered Functions (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 and shall include requirements about the content and circumstances of such arrangements and events. The Policies and Procedures shall require that compensation be based on fair market value, include caps on the total amount of payment that may be provided annually, and that HCPs who sit on formulary boards or develop clinical guidelines are required to disclose their relationship with GSK;

- m. programs to educate sales personnel, including but not limited to presentations by HCPs at sales meetings and experience-based learning activities, if any. 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;
- n. sponsorship or funding of grants to healthcare-related organizations and donations to community partners in the United States (including support of any educational programs they conduct for non-HCP audiences). These Policies and Procedures shall be designed to ensure that GSK's funding and/or sponsorship complies with all applicable Federal health care program and FDA requirements. In addition, the Policies and Procedures continue to limit the situations in which GSK shall make grants and donations and shall state that GSK does not provide funding in order to influence the use of GSK products or services;
- o. funding of, or participation in, any Third Party Educational Activity as defined in Section II.C.8 above. These Policies and Procedures shall be designed to ensure that any GSK funding and/or sponsorship of such programs satisfies all applicable Federal health care program and FDA requirements. Prior to the

Effective Date of the CIA, GSK implemented policies restricting funding for Third Party Educational Activity to a limited number of specific types of entities (i.e., academic medical centers and their affiliated teaching and patient care institutions and professional medical associations that represent HCPs responsible for the delivery of patient care). These Policies and Procedures prohibit funding for independent medical education by commercial providers. During the term of the CIA, the Policies and Procedures shall continue to require that GSK provide funding for Third Party Educational Activity in accordance with its Policies and Procedures and practices outlined in this Section III.B.3.o and below in Section III.M.4.

The Policies and Procedures shall also require that: (1) GSK disclose its financial support of the Third Party Educational Activity and, to the extent feasible consistent with subsection III.B.3.o.4 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 GSK's financial support of the Third Party Educational Activity and to require faculty, speakers, or organizers at such Activity to disclose any financial relationship with GSK; (3) the Third Party Educational Activity have an educational focus; (4) the content, organization, and operation of the Third Party Educational Activity (including the faculty, educational methods, materials, and venue) be independent of GSK's control; (5) GSK support only Third Party Educational Activity that is non-promotional in tone/nature; and (6) GSK's support of a Third Party Educational Activity shall be contingent on the provider's commitment to provide information at the Third Party Educational Activity that is fair, balanced, accurate and not misleading;

- p. review of promotional materials and information intended to be disseminated outside GSK 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 GSK's review and approval process and are elevated when appropriate. The Policies and

Procedures shall be designed to ensure that such materials and information comply with all applicable Federal health care program and FDA requirements. The Policies and Procedures shall require that: (1) applicable review committees (including the overall Copy Approval Team (CAT) and the CAT for each product) review all promotional materials prior to the distribution or use of such materials; (2) GSK's copy review and approval process ensure that FDA communications relevant to the product are considered and appropriately reflected in promotional materials and in a copy approval repository maintained by each CAT; and that (3) deviations from the standard review committee practices and protocols (including timetables for the submission of materials for review) shall be documented and referred for appropriate follow-up;

- q. sponsorship, funding of, and disclosures relating to Product Related Functions. These Policies and Procedures shall be designed to ensure that GSK's funding, sponsorship, and disclosure complies with all applicable Federal health care program and FDA requirements;
- r. compensation (including through salaries, bonuses, or other means) for Covered Persons. These Policies and Procedures shall: (1) be designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in improper promotion, sales, and marketing of GSK's Government Reimbursed Products; and (2) include mechanisms, where appropriate, to exclude from incentive compensation sales that may indicate off-label promotion of Government Reimbursed Products.

GSK represents that, prior to the Effective Date, it implemented a program in the United States to eliminate incentive compensative based on territory/individual level sales goals for prescriber-facing sales personnel (e.g., sales representatives) and their direct managers (Patient First Program). The Patient First Program is described in more detail below in Section III.H. GSK shall

continue its Patient First Program, or a substantially equivalent program, during the term of the CIA.

- s. GSK's right to recoup or cause the forfeiture of annual performance pay of GSK employees and Covered Executives if certain triggering events relating to misconduct by the employees or executives occur;
- t. the submission of information about any Government Reimbursed Product to any compendia such as Drugdex or other published source of information used in connection with the determination of coverage by a Federal health care program for the product (hereafter "Compendia"). This includes any initial submission of information to any Compendia and the submission of any additional, updated, supplemental, or changed information (e.g., any changes based on GSK's discovery of erroneous or scientifically unsound information or data associated with the information in the Compendia.) The Policies and Procedures shall include a requirement that GSK conduct an annual review of all arrangements, processing fees, or other payments or financial support (if any) provided by GSK to any Compendia. GSK U.S. compliance personnel or other appropriately trained GSK personnel who are independent from the functional unit being reviewed shall be involved in this review;
- u. sponsorship by GSK of human subject research of Government Reimbursed Products (i.e., post-marketing clinical trials and post-marketing studies (collectively, "GSK-Sponsored Research")), and support by GSK of investigator-sponsored studies of Government Reimbursed Products (ISSs) (collectively, GSK-Sponsored Research and ISSs shall be referred to as "Research"), including the decision to provide financial or other support for Research; the manner in which Research support is provided; the publication of information about the Research, including the publication of information about the Research results and trial outcomes, and uses made of publications relating to Research;

Policies/Procedures regarding Sponsorship or Support of Studies Involving Government Reimbursed Products: GSK represents that it requires Research to be approved by its medical and/or research organizations. Under GSK's current policies and procedures, sales, marketing, or other commercial personnel may not participate in the design, conduct, or publication of GSK-Sponsored Research, with limited exceptions relating to non-interventional health outcomes studies (for which a relevant GSK medical group has oversight). GSK also represents that its human subject research and any resulting publications are intended to foster increased understanding of scientific, clinical or medical issues. To the extent not already accomplished, GSK shall require as a condition of its funding that all researchers disclose in any publication of Research, GSK's support and any financial interest the researcher may have in GSK.

Posting of Study Results and Protocols/Registry of Studies: GSK represents that, prior to the Effective Date, it developed a Clinical Study Register on which it posts, within a specified number of months from study completion and with rare exception, summary results from all GSK-Sponsored interventional Research studies of Government Reimbursed Products; and from GSK-Sponsored observational studies designed to inform the safety, efficacy or effectiveness, including cost-effectiveness, of Government Reimbursed Products; and from GSK-Sponsored meta-analyses and pooled analyses designed to inform appropriate, effective or safe use of Government Reimbursed Products. In addition, GSK posts summaries of its protocols for the studies and analyses described in the preceding sentence (including amendments that change the content of the summary) in its Register. GSK shall continue these practices throughout the term of the CIA.

In addition, GSK represents that it has established policies, systems, and practices to publish results from and information about discontinued studies on its Clinical Register, including the fact that the study terminated early. GSK shall continue these practices throughout the term of the CIA.

GSK represents that it registers summary results from all applicable GSK-sponsored clinical trials of GSK products and reports results of such clinical trials on the National Institutes of Health (NIH) sponsored website ([www.clinicaltrials.gov](http://www.clinicaltrials.gov)) in compliance with all Federal requirements. GSK shall continue to comply with Federal requirements or other applicable requirements relating to the registration and results reporting of clinical studies throughout the term of this CIA. In addition, if there is a change in Federal requirements or other applicable requirements relating to registration and results reporting of clinical study information, GSK shall fully comply with such requirements.

Publication of Study Results: GSK represents that it generally seeks publication of the results of all GSK-Sponsored interventional Research in peer-reviewed, searchable journals and imposes specified timeframes for the drafting and submission of manuscripts following completion of a study. For purposes of these publication requirements, GSK's publication policy includes certain GSK-Sponsored observational Research studies and certain GSK-Sponsored meta-analyses and pooled analyses.

In addition, GSK represents that it has established policies and "operating practices" governing scientific engagement, which included detailed directions regarding publications. Among other things, the operating practices require the implementation of data dissemination plans that establish prospective publication strategies for GSK-Sponsored Research and address requirements for appropriateness, accuracy, and balance in publications of GSK-Sponsored Research. In all publications about GSK-Sponsored Research, GSK shall acknowledge its role as the funding source.

In addition, GSK represents that it has established policies, systems, and practices designed to ensure that adverse event data is properly reported to the FDA. In addition, GSK requires investigators to report study-related information and data,

including data about adverse events before receiving final payment from GSK.

The standards, policies, and practices described above shall hereafter be referred to collectively as the “Research and Publication Practices.” GSK shall maintain its Research and Publication Practices (or standards and practices substantially equivalent to those set forth above) for studies initiated or completed after the Effective Date for the term of the CIA. To the extent that GSK intends to materially change these Research and Publication Practices, it shall notify the OIG about the change 30 days in advance of the effective date of the change;

- v. authorship of journal articles or other publications about GSK-Sponsored Research or about therapeutic areas or disease states that may be treated with Government Reimbursed Products, including, but not limited to, the disclosure of any and all financial relationships between the author and GSK, the identification of all authors or contributors (including professional writers) associated with a given publication, and that research results be made available to each author or contributor.

Authorship Requirements: GSK represents that it requires all authors of journal articles about GSK-Sponsored Research to adhere to International Committee of Medical Journal Editors (ICMJE) requirements regarding authorship except when a particular journal requires an alternative procedure. In addition, GSK requires all authors of articles on GSK-Sponsored Research to disclose any GSK financial support for the study and any financial relationship with GSK (including any financial interest the author may have in GSK or a GSK product). In addition, GSK represents that individuals may be considered an “author” on a GSK publication of GSK-Sponsored Research only if the individual has made substantial contributions to the study and has given final approval to the version of the publication ultimately published.

GSK shall require that its employees and medical writing contractors complete certain certification as to any GSK publication of GSK-Sponsored Research on which the individual is listed as an author or contributor. The standards, policies and practices described above shall be referred to collectively as “Authorship-Related Practices”; and

- w. disciplinary policies and procedures for violations of GSK’s Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

To the extent not already accomplished, within 150 days after the Effective Date, the Policies and Procedures shall be made available to all Covered Persons. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

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

### C. Training and Education.

1. *General Training.* To the extent not already accomplished, within 120 days after the Effective Date, GSK shall provide at least one hour of General Training to each Covered Person. This training, at a minimum, shall explain GSK’s:

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

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.* GSK shall provide annual training to each Relevant Covered Person relating to his or her specific job responsibilities. This training shall be known as Specific Training.

By December 31, 2012, each Relevant Covered Person engaged in Promotional Functions, Product Related Functions, or Payer Related Functions shall receive at least three hours of Specific Training in addition to the General Training required above.

For Relevant Covered Persons engaged in Promotional Functions or Product Related Functions, this Specific Training shall include a discussion of:

- a. all applicable Federal health care program requirements relating to Promotional Functions and to Product Related Functions;
- b. all applicable FDA requirements relating to Promotional Functions and to Product Related Functions;
- c. all GSK Policies and Procedures and other requirements applicable to Promotional Functions and Product Related Functions;
- d. the personal obligation of each individual involved in Promotional Functions and Product 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 Functions and Product Related Functions.

For Relevant Covered Persons engaged in Payer Related Functions, this Specific Training shall include a discussion of topics a-f above, as well as:

- g. all applicable Federal health care program requirements and FDA requirements relating to Payer Related Functions;

- h. GSK's systems and processes applicable to Payer Related Functions;
- i. all GSK Policies and Procedures and other requirements applicable to Promotional Functions and Product Related Functions;
- j. the personal obligation of each individual involved in Payer Related Functions to ensure that all information provided or reported to Payers is complete, accurate and not misleading;
- k. the legal sanctions for violations of the applicable Federal health care program and FDA requirements; and
- l. examples of proper and improper practices relating to Payer Related Functions.

New Relevant Covered Persons shall receive their Specific Training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or by December 31, 2012, whichever is later. A GSK employee who has completed the Specific Training shall oversee a new Relevant Covered Person's work, to the extent that the work relates to any of the Covered 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. *Compliance Training for Management.* By December 31, 2012, GSK shall provide to managers of employees performing Covered Functions and supervisors of sales personnel (collectively "Management") at least three hours of specialized compliance-related training applicable to the functional area of the manager (Management Compliance Training). This training shall address the responsibility of Management to promote compliance and to identify and mitigate compliance-related risks in their functional areas.

New members of Management shall receive the Management Compliance Training within 30 days after becoming a member of Management or by December 31, 2012, whichever is later.

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

4. *Board Member Training.* Within 150 days after the Effective Date, GSK shall provide at least two hours of training to each member of the Board of Directors, in addition to the General Training. This training shall address the responsibilities of board members and corporate governance.

New members of the Board of Directors shall receive the Board Member Training described above within 30 days after becoming a board member or within 120 days after the Effective Date, whichever is later.

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

6. *Qualifications of Trainer.* Persons responsible for providing the training described above shall be knowledgeable about the subject area of the training, including about applicable Federal health care program and FDA requirements.

7. *Update of Training.* GSK shall review its training annually, and, where appropriate, shall update the training to reflect changes in Federal health care program requirements, FDA requirements, any issues discovered during internal audits or the IRO Reviews, the TRACER program (defined below in Section III.D), and any other relevant information.

8. *Computer-based Training.* GSK may provide the training required under this CIA through appropriate computer-based training approaches. If GSK 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 individuals receiving such training. All applicable requirements to provide a number

of “hours” of training as set forth 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. Risk Assessment and Mitigation Process.

GSK represents that prior to the Effective Date, GSK began to implement a standardized process to allow GSK compliance, legal, and business unit leaders to assess and identify risks associated with Government Reimbursed Products that have field force support in the United States (GSK Products). This program is referred to as the Targeted Risk-based Analysis Compliance Evaluations and Review (TRACER) program and is described in more detail in Appendix C. TRACER involves an annual evaluation and mitigation of risks associated with the marketing of the GSK Products. GSK shall maintain a TRACER process for the duration of the CIA.

E. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 120 days after the Effective Date, GSK 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 GSK in assessing and evaluating its Covered Functions. More specifically, the IRO(s) shall conduct reviews that assess GSK’s systems, processes, policies, procedures, and practices relating to the Covered Functions (including Research and Publication Practices and Authorship-Related Practices) and the TRACER program (collectively “IRO Reviews”).

The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference. Each IRO engaged by GSK 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 including expertise in the pharmaceutical industry with regard to risk identification and mitigation in relation to pharmaceutical product marketing and promotion. Each IRO shall assess, along with GSK,

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.

b. *Frequency and Brief Description of Reviews.* As set forth more fully in Appendices B and C, the IRO Reviews shall consist of three components: (1) Systems Reviews and Transactions Reviews relating to the Covered Functions; (2) Additional Items reviews; and (3) Systems Reviews and Transaction Reviews relating to the TRACER program. The Systems Reviews shall assess GSK's systems, processes, policies, and procedures relating to the Covered Functions and the TRACER program.

The IRO Reviews shall cover each of the six calendar years of the CIA. The first IRO Reporting Period shall cover the time from the Effective Date through December 31, 2012. The second through sixth IRO Reporting Periods shall cover, respectively, 2013 and each subsequent calendar year through 2017 (hereafter the "IRO Reporting Periods.") If there are no material changes in GSK's relevant systems, processes, policies, and procedures, the Systems Review shall be performed for the periods covering the second and fifth IRO Reporting Periods. If GSK materially changes its relevant systems, processes, policies, and procedures, the IRO shall perform Systems Reviews for the IRO Reporting Periods in which such changes were made in addition to conducting the Systems Reviews for the second and fifth IRO Reporting Periods, as set forth more fully in Appendices B and C.

The IRO shall perform a limited Transactions Review for the first IRO Reporting Period as set forth more fully in Appendix B. For each of the remaining IRO Reporting Periods, the IRO shall perform full Transaction Reviews as set forth in Appendices B and C. The IRO(s) shall perform all components of each annual Transaction Review.

In addition, the Transactions Reviews for the second through sixth IRO Reporting Periods shall also include a review of up to three

additional areas or practices of GSK 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 IRO Reporting Period, the OIG will consult with GSK and may consider internal audit work conducted by GSK, the Government Reimbursed Product portfolio, the nature and scope of GSK’s promotional practices and arrangements with HCPs and HCIs, and other information known to it.

As set forth more fully in Appendix B, GSK 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 GSK’s internal audit work to be substituted for a portion of the Additional Items review conducted by the IRO.

The OIG shall notify GSK of the nature and scope of the IRO review for each of the Additional Items not later than 150 days prior to the end of each applicable IRO Reporting Period. Prior to undertaking the review of the Additional Items, the IRO and/or GSK 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 GSK shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and GSK) related to the IRO Reviews.

2. *IRO Review Reports.* The IRO shall prepare a report based upon each IRO Review performed (IRO Review Report). Information to be included in each IRO Review Report is described in Appendices B and C.

3. *Validation Review.* In the event OIG has reason to believe that: (a) any of GSK’s IRO Reviews 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). GSK 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 GSK's final Annual Report shall be initiated no later than one year after GSK's final submission (as described in Section II.B) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify GSK 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, GSK may request a meeting with OIG to: (a) discuss the results of any IRO Review submissions or findings; (b) present any additional information to clarify the results of the IRO Review or to correct the inaccuracy of the IRO Review; and/or (c) propose alternatives to the proposed Validation Review. GSK agrees to provide any additional information as may be requested by OIG under this Section III.E.3 in an expedited manner. OIG will attempt in good faith to resolve any IRO Review issues with GSK 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 GSK a certification that the IRO has: (a) evaluated its professional independence and objectivity with respect to the reviews conducted under this Section III.E; and (b) concluded that it is, in fact, independent and objective in accordance with the requirements specified in Appendix A.

#### F. Disclosure Program.

Prior to the GSK Effective Date, GSK and its Affiliates established a Disclosure Program that includes a mechanism (the toll free "Integrity Helpline") to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with GSK's or a GSK Affiliate's policies, conduct, practices, or procedures with respect to a Federal health care program or an FDA requirement (including as they relate to CGMP Activities) believed by the individual to be a potential violation of criminal, civil, or administrative law. The Integrity Helpline may be used by employees of third party suppliers that contract with GSK. GSK and its Affiliates publicize, and shall continue to appropriately publicize, the existence of the Disclosure Program and the Integrity Helpline (e.g., via periodic e-mails to employees, by posting the information in prominent common areas, or through references in the Code of Conduct and during training.)

The Disclosure Program shall emphasize a nonretribution, non-retaliation policy and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that it obtains all necessary information 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, GSK and/or any applicable Affiliate shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

GSK shall maintain, a disclosure log, which includes 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. This disclosure log shall be made available to OIG upon request.

#### G. 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 scope 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>).

2. *Screening Requirements.* GSK shall ensure that all prospective and current Covered Persons and Manufacturing Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

a. as part of the hiring or contracting process, GSK shall require all prospective and current Covered Persons and Manufacturing Covered Persons to disclose whether they are Ineligible Persons and shall screen potential Covered Persons and Manufacturing Covered Persons against the Exclusion Lists prior to engaging their services.

b. GSK shall screen all Covered Persons and Manufacturing Covered Persons against the Exclusion Lists within 120 days after the Effective Date and on an annual basis thereafter.

c. GSK shall maintain a policy requiring all Covered Persons and Manufacturing Covered Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

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

3. *Removal Requirement.* If GSK has actual notice that a Covered Person or Manufacturing Covered Person has become an Ineligible Person, GSK shall remove such Covered Person or Manufacturing Covered Person from responsibility for, or involvement with, GSK's business operations related to the Federal health care programs and shall remove such Covered Person or Manufacturing Covered Person from any position for which the Covered Person's or Manufacturing Covered Person's

compensation or the items or services furnished, ordered, or prescribed by the Covered Person or Manufacturing Covered 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 Covered Person or Manufacturing Covered Person is reinstated into participation in the Federal health care programs.

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

#### H. Employee and Executive Incentive Compensation and Recoupment Policies and Practices.

Pursuant to its existing Patient First program, GSK agrees that it will not provide financial reward (through compensation, including incentive compensation or otherwise) or discipline (through tangible employment action) its prescribing-customer-facing field sales professionals (pharmaceutical sales representatives) or their direct managers based upon the volume of sales of GSK products within a given employee's own territory or the manager's district. The Patient First program includes evaluations for sales representatives based on business acumen, customer engagement, and scientific knowledge about GSK's products. GSK shall continue its Patient First Program, or a substantially equivalent program, during the term of this CIA. GSK commits to maintaining for at least the duration of the CIA, absent agreement otherwise with the OIG, the restrictions on such tangible employment decisions set forth in its Use of Territory/Individual Sales Data policy.

In addition, GSK shall establish and maintain throughout the term of this CIA a financial recoupment program that puts at risk of forfeiture and recoupment an amount equivalent to up to 3 years of annual performance pay (*i.e.*, annual bonus, plus long term incentives) for an executive who is discovered to have been involved in any significant misconduct (Executive Financial Recoupment Program). This financial recoupment program shall apply to both covered executives who are either current GSK employees or who are former GSK employees at the time of a Recoupment Determination. The

specific terms and conditions of the Executive Financial Recoupment Program are set forth in Appendix E. GSK commits to maintaining an Executive Financial Recoupment Program consistent with the terms of Appendix E for at least the duration of the CIA absent agreement otherwise by the OIG.

I. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, GSK shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to GSK conducted or brought by a U.S.-based governmental entity or its agents involving an allegation that GSK or a GSK Affiliate 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. GSK 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.

J. Reportable Events.

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

- a. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;
- b. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any FDA requirements relating to the promotion of Government Reimbursed Products (including an FDA Warning Letter issued to GSK);
- c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or
- d. the filing of a bankruptcy petition by GSK.

A Reportable Event may be the result of an isolated event or a series of occurrences. A Reportable Event that meets the one of the definitions set forth above may arise from within the operations of GSK or any GSK Affiliate.

2. *Reporting of Reportable Events.* If GSK determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, GSK shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Sections III.J.1.a-c.* For Reportable Events under Sections III.J.1.a-c, the report to OIG shall include:

- a. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program or FDA authorities implicated;
- b. a description of GSK's actions taken to correct the Reportable Event; and
- c. any further that steps GSK plans to take to address the Reportable Event and prevent it from recurring.

GSK shall not be required to report any Reportable Event which is the subject of an ongoing investigation or legal proceeding by a governmental entity or its agents previously disclosed under Section III.I above.

4. *Reportable Events under Section III.J.1.d.* For Reportable Events under Section III.J.1.d, the report to the OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program and/or FDA authorities implicated.

K. Notification of Communications with FDA. Within 30 days after the date of any written report, correspondence, or communication between GSK and the FDA that materially discusses GSK's or a Covered Person's actual or potential unlawful or improper promotion of GSK's products (including any improper dissemination of information about off-label indications), GSK shall provide a copy of the report, correspondence, or communication to the OIG. GSK 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.

L. Field Force Monitoring and Review Efforts.

To the extent not already accomplished, within 120 days after the Effective Date, GSK shall establish a comprehensive Field Force Monitoring Program (FFMP) to evaluate and monitor its sales personnel's interactions with HCPs and HCIs. The FFMP shall be a formalized process designed to directly and indirectly observe the appropriateness of sales personnel's interactions with HCPs and HCIs and to identify potential off-label promotional activities or other improper conduct. As described in more detail below, the FFMP shall include: (1) a Speaker Monitoring Program; (2) direct field observations (Observations) of sales personnel; and (3) the monitoring and review of other records relating to sales personnel's interactions with HCPs and HCIs (Records Reviews).

1. *Speaker Program Activities.* With regard to speaker programs, GSK shall maintain processes to require all speakers to complete training and enter written agreements that describe the scope of work to be performed, the speaker fees to be paid, and compliance obligations for the speakers (including requirements that the speaker may only use GSK approved materials and may not directly or indirectly promote the product for off-label uses.) GSK shall maintain a centralized electronic system through which all speaker programs are administered. This system shall establish controls regarding eligibility and qualifications of speakers and venues for the programs and require that speakers are paid according to a centrally managed, pre-set rate structure determined based on a fair-market value analysis conducted by GSK. GSK shall maintain a comprehensive list of speaker program attendees through its centralized system. In addition, GSK shall track and review the aggregate amount (including speaker fees, travel, and other expenses) paid to each speaker in connection with speaker programs conducted during each Reporting Period. GSK shall require certified evaluations by sales personnel regarding whether a speaker program complied with GSK requirements, and in the event of non-compliance, GSK shall require the identification of the policy violation and ensure appropriate follow up activity to address the violation.

To the extent not already accomplished, GSK shall institute a Speaker Monitoring Program under which GSK compliance or other appropriately trained GSK personnel who are independent from the functional area being monitored (hereinafter "GSK Monitoring Personnel") shall attend speaker programs during each Reporting Period and

conduct live audits of the programs (Speaker Program Audits). For the first Reporting Period, GSK shall conduct live audits of 150 speaker programs and for the subsequent Reporting Periods, GSK shall conduct live audits of 75 speaker programs. The programs subject to Speaker Program Audits shall be selected both on a risk-based targeting approach and on a sampling approach. For each program reviewed, personnel conducting the Speaker Program Audits shall review slide materials and other materials used as part of the speaker program, speaker statements made during the program, and GSK representative activities during the program to assess whether the programs were conducted in a manner consistent with GSK's Policies and Procedures. GSK shall maintain the controls around speaker programs as described above, and shall conduct its Speaker Program Audits as described above throughout the term of the CIA.

2. *Observations.* As a component of the FFMP, GSK Monitoring Personnel shall conduct observations of field personnel (e.g., sales personnel, MSLs, HOLs, and account managers and directors from the PPV group) to assess whether the messages delivered and materials distributed to HCPs, HCIs, and others are consistent with applicable legal requirements and with GSK's Policies and Procedures. These observations shall be full day ride-alongs with the field personnel (Observations), and each Observation shall consist of directly observing all meetings between field personnel and HCPs during the workday. The Observations shall be scheduled throughout the year, selected by GSK Monitoring Personnel both on a risk-based targeting approach and on a sampling approach, include each therapeutic area and actively promoted product, and be conducted across the United States. At the completion of each Observation, GSK Monitoring Personnel shall prepare a report which includes:

- 1) the identity of the field personnel;
- 2) the identity of the GSK Monitoring Personnel;
- 3) the date and duration of the Observation;
- 4) the product(s) promoted during the Observation;
- 5) an overall assessment of compliance with GSK policy; and
- 6) the identification of any potential off-label promotional activity or other improper conduct by the field personnel.

GSK Monitoring Personnel shall conduct at least 50 Observations during the first Reporting Period, and shall conduct at least 25 Observations during the subsequent Reporting Periods.

3. *Records Reviews.* As a component of the FFMP, GSK shall also review various types of records to assess sales personnel interactions with HCPs and HCIs in order to identify potential or actual compliance violations. For each Reporting Period, GSK shall develop and implement a plan for conducting Records Reviews associated with at least three Government Reimbursed Products and a sampling of the personnel supporting those products in regions across the country (as agreed with the OIG for each Reporting Period.) The OIG shall have the discretion to identify the three Government Reimbursed Products to be reviewed for each Reporting Period. The OIG will select the products based on information about GSK's products provided by GSK, upon request by the OIG no later than 60 days prior to the beginning of the Reporting Period, and other information known to the OIG. If the OIG does not identify the Government Reimbursed Products to be reviewed within the first 30 days of the Reporting Period, GSK shall select the three products to be reviewed.

These Records Reviews shall include the monitoring and review of: (1) records and systems relating to sales personnel interactions with HCPs and HCIs (including records from the electronic call reporting system used by sales personnel (which includes call notes), sales communications from managers, sample distribution records, and expense reports); (2) requests for medical information about, or inquiries relating to, Government Reimbursed Products; (3) message recall studies or other similar records (such as Verbatims) purporting to reflect the details of sales personnel interactions with HCPs and HCIs; (4) sales personnel e-mails and other electronic records; and (5) recorded results of the Observations of sales representatives and applicable notes or information from the sales personnel managers.

4. *Reporting and Follow-up.* Personnel conducting the Speaker Program Audits, Observations, and Records Reviews shall have access to all relevant records and information necessary to assess potential or actual compliance violations. Results from the FFMP audits, including the identification of potential violations of policies and/or legal requirements, shall be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow-up as appropriate. In the event that a potential violation of GSK's Policies and Procedures or of legal or compliance requirements, including but not limited to potential off-label promotion, is identified during any aspect of the FFMP, GSK shall investigate the incident consistent with established policies and procedures for the handling of investigations and shall take all necessary and appropriate responsive action (including disciplinary action) and corrective action, including the disclosure of Reportable Events pursuant to Section III.J above, if applicable. Any compliance issues identified during a Speaker Program Audit,

Observation and/or Records Review and any corrective action shall be recorded in the files of the Compliance Officer (or compliance personnel designee).

GSK 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, GSK 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 GSK took as a result of such determinations. GSK shall make the Observation reports for all other Observations available to the OIG upon request.

M. Monitoring of Non-Promotional Activities.

To the extent not already accomplished, within 120 days after the Effective Date GSK shall develop and implement a monitoring program for the following types of activities: (1) consultant arrangement activities; (2) research-related activities; (3) publication activities; and (4) medical education grants. This program shall be referred to as the Non-Promotional Monitoring Program.

1. *Consultant Arrangement Activities.* To the extent that GSK engages U.S.-based HCPs or HCIs for services that relate to Promotional Functions or to Product Related Functions other than for speaker programs, research-related activities, or publication activities (e.g., as a member of an advisory board or to attend consultant meetings), such HCPs or HCIs shall be referred to herein as Consultants. GSK shall require all Consultants to enter written agreements describing the scope of work to be performed, the fees to be paid, and compliance obligations for the Consultants. Consultants shall be paid according to a centrally managed, pre-set rate structure that is determined based on a fair-market value analysis conducted by GSK.

To the extent not already accomplished, within 120 days after the Effective Date, GSK shall establish a process to develop annual budgeting plans that identify the business needs for, and the estimated numbers of, various Consultant engagements and activities to occur during the following year. The annual Consultant budgeting plans shall also identify the budgeted amounts to be spent on Consultant-related activities. GSK's Monitoring Personnel shall be involved in the review and approval of such budgeting plans, including any subsequent modification of an approved plan. The purpose of this review shall be to ensure that Consultant arrangements and related events are used for legitimate purposes in accordance with applicable GSK Policies and Procedures.

To the extent not already accomplished, within 120 days after the Effective Date, GSK shall establish a process to ensure that a needs assessment has been completed to justify the retention of a Consultant prior to the retention of the Consultant. The needs assessment shall identify the business need for the retention of the Consultant and provide specific details about the consulting arrangement (e.g., information about the numbers and qualifications of the HCPs or HCIs to be engaged, the agenda for the proposed meeting, and a description of the proposed work to be done and type of work product to be generated.) Any deviations from the Consultant budgeting plans shall be documented in the needs assessment form and shall be subject to review and approval by GSK Monitoring Personnel.

To the extent not already accomplished, within 120 days after the Effective Date, GSK shall amend its policies and procedures in a manner designed to ensure that each Consultant performed the work for which the Consultant was engaged and that, as applicable, GSK received the work product generated by the Consultant.

Within 120 days after the Effective Date, GSK shall establish a Consultant Monitoring Program through which it shall conduct audits for each Reporting Period (Consultant Program Audits) of at least 50 Consultant arrangements with HCPs for the first Reporting Period and 25 Consultant arrangements for subsequent Reporting Periods. The Consultant Monitoring Program shall review Consultant arrangements both on a risk-based targeting approach and on a sampling approach. GSK Monitoring Personnel conducting the Consultant Program Audits shall review needs assessment documents, consultant contracts, and materials relating to the program or work of the Consultant (including work product resulting from any program or event), in order to assess whether the programs and arrangements were conducted in a manner consistent with GSK's Policies and Procedures. Results from the Consultant Program Audits, including the identification of potential violations of policies, shall be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow-up as appropriate.

2. *Research-Related Activities.* To the extent that GSK engages or supports U.S.-based HCPs or HCIs to conduct Research (as defined above in Section III.B.3.u), such HCPs and HCIs shall be referred to collectively as "Researchers". GSK shall require all Researchers to enter written agreements describing the scope of the clinical research or other work to be performed, the fees to be paid or support to be given, and compliance obligations for the Researchers. Researchers retained to conduct Research shall be paid

according to a centrally managed, pre-set rate structure that is determined based on a fair-market value analysis conducted by GSK.

To the extent not already accomplished, within 120 days after the Effective Date, GSK shall establish an annual budgeting plan for Researchers that identifies the business or scientific need or scientific opportunity for, and the estimated numbers of, the various Researcher engagements and activities to occur during the year. The annual Researcher budgeting plan shall also identify the budgeted amounts to be spent on Researcher-related activities during the year. GSK Monitoring Personnel shall be involved in the review and approval of such budgeting plans, including any subsequent modification of an approved plan. The purpose of this review shall be to ensure that Research arrangements and related events are used for legitimate purposes in accordance with GSK Policies and Procedures.

To the extent not already accomplished, within 120 days after the Effective Date, GSK shall establish a process to ensure that a needs assessment has been completed to justify the retention of the Researcher prior to the retention of the Researcher. The needs assessment shall identify the business or scientific need for the information to be provided by the Researcher and provide specific details about the research arrangement (including, for example, information about the numbers and qualifications of the HCPs or HCIs to be engaged, a description of the proposed research to be done (including the research protocol) and type of work product to be generated). Any deviations from the Researcher budgeting plans shall be documented in the needs assessment form (or elsewhere, as appropriate) and shall be subject to review and approval by GSK Monitoring Personnel.

To the extent not already accomplished, within 120 days after the Effective Date, GSK shall amend its policies and procedures in a manner designed to ensure that each Researcher performed the work for which the Researcher was engaged.

Within 120 days after the Effective Date, GSK shall establish a Researcher Monitoring Program through which it shall conduct audits for each Reporting Period (Researcher Program Audits). GSK shall review 20 Researcher arrangements with HCPs or HCIs for the first Reporting Period and 10 Researcher Arrangements for subsequent Reporting Periods. The Researcher Monitoring Program shall review Researcher arrangements both on a risk-based targeting approach and on a sampling approach. GSK Monitoring Personnel conducting the Researcher Program Audits shall review needs assessment documents, proposal and/or protocol documents, approval documents, contracts, and payments in order to assess whether the programs and arrangements were

supported by GSK and performed by the Researchers in a manner consistent with GSK's Policies and Procedures. Results from the Researcher Program Audits, including identification of potential violations of policies, shall be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow-up as appropriate.

3. *Publication Activities.* GSK represents that it generally does not engage HCPs or HCIs exclusively to produce articles or other publications relating to GSK-Sponsored Research, and that generally HCPs or HCIs who perform this work do so as part of an engagement for Research Related Activities. To the extent that, in connection with Research Related Activities, U.S.-based HCPs or HCIs produce articles or other publications relating to GSK-Sponsored Research (collectively "Publication Activities") such HCPs or HCIs shall be referred to as Authors. GSK shall require all Authors to enter written agreements describing the terms of the arrangement between GSK and the Author and compliance obligations of the Authors. Authors shall be paid according to the centrally managed, pre-set rate structure that is established for Research Related Activities but will not be paid separately for authorship or other publication-specific activity (provided that GSK may reimburse travel expenses incurred to make public presentations of data from GSK-Sponsored Research Studies). If, in a departure from usual practice, GSK engages an HCP or HCI for a stand-alone project involving the production of an article or other publication relating to GSK-Sponsored Research (*e.g.*, a review article summarizing research in a field that includes GSK-Sponsored Research), GSK will require a written agreement with the same compliance obligations as it requires of Author generally and will pay for the work according to the centrally managed, pre-set rate structure as applied to Consultants generally.

To the extent not already accomplished, within 120 days after the Effective Date, GSK shall establish a process to develop annual plans that identify the business needs for and the estimated numbers of various Publication Activities (Publications Plans). The annual Publications Plan shall also identify the budgeted amounts to be spent on Publication Activities. GSK's U.S. compliance personnel shall be involved in the review and approval of such annual Publications Plans, including any modification of an approved plan. The purpose of this review shall be to ensure that Publication Activities and related events are used for legitimate purposes in accordance with GSK Policies and Procedures.

To the extent not already accomplished, within 120 days after the Effective Date, GSK shall establish a needs assessment process for Publication Activities. This process

shall ensure that a needs assessment has been completed prior to the retention of an Author for a Publication Activity. The needs assessment shall provide specific details about Publication Activities to be performed (including a description of the proposed work to be done, type of work product to be generated, and the purpose for the work.) Any deviations from the Publications Plan shall be documented in the needs assessment form (or elsewhere, as appropriate) and shall be subject to review and approval by GSK Monitoring Personnel.

Within 120 days after the Effective Date, GSK shall establish a Publication Monitoring Program through which it shall conduct audits for each Reporting Period of at least 50 Publication Activities for the first Reporting Period and 25 Publication Activities for subsequent Reporting Periods. The Publication Monitoring Program shall select publications for review both on a risk-based targeting approach and on a sampling approach. GSK Monitoring Personnel conducting the Publication Monitoring Program shall review needs assessment documents, proposal documents, approval documents, contracts, payments and materials relating to the Publication Activities (including work product resulting from the Activities), in order to assess whether the activities were conducted in a manner consistent with GSK's Policies and Procedures. Results from the Publication Monitoring Programs, including the identification of potential violations of policies, shall be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow-up as appropriate.

4. *Medical Education Grant Activities.* GSK represents that it provides grants for medical education of HCPs on a limited basis and that it provides such grants only to educational providers (including academic medical centers, hospital or delivery systems, or professional medical associations that represent HCPs who deliver patient care) that satisfy pre-set criteria established by GSK. Potentially eligible educational providers are selected annually and invited to submit grant proposals for a future fiscal year. GSK represents that it does not provide funding to any commercial providers of medical education.

GSK's Medical Affairs organization reviews the grant proposals from the potential providers and makes recommendations for approval based on objective criteria, compliance policies and procedures, and budget availability. GSK represents that its commercial organization (including the sales and marketing departments) has no involvement in, or influence over, the review and approval of medical education grants. GSK shall continue the medical education grant process described above (or an equivalent process) throughout the term of the CIA, and shall notify the OIG in writing at

least 60 days prior to the implementation of any new system subsequent to the Effective Date.

To the extent not already accomplished, within 120 days after the Effective Date, GSK shall establish a Grants Monitoring Program through which it shall conduct audits for each Reporting Period of at least 10 medical education grants for the first Reporting Period and 5 medical education grants for subsequent Reporting Periods. The Grants Monitoring Program shall select grants for review both on a risk-based targeting approach and on a sampling approach. GSK Monitoring Personnel conducting the Grants Monitoring Program shall review proposal documents (including grant requests), approval documents, contracts, payments and materials relating to the grant office's review of the requests, and documents and materials relating to the grants and any events or activities funded through the grants in order to assess whether the activities were conducted in a manner consistent with GSK's Policies and Procedures. Results from the Grant Monitoring Programs, including the identification of potential violations of policies, shall be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow-up as appropriate.

5. *Follow Up Reviews and Reporting.* In the event that a potential violation of GSK's Policies and Procedures or of legal or compliance requirements, including but not limited to potential improper promotion, are identified during any aspect of the Non-Promotional Monitoring Program, GSK shall investigate the incident consistent with established Policies and Procedures for the handling of investigations and shall take all necessary and appropriate responsive action (including disciplinary action) and corrective action, including the disclosure of Reportable Events pursuant to Section III.J above, if applicable. Any compliance issues identified during any Non-Promotional Monitoring Program referenced above, and any corrective action, shall be recorded in the files of the U.S. Compliance Department.

GSK shall include a summary of the Non-Promotional Monitoring Program and the results of the Non-Promotional Monitoring Program as part of each Annual Report. As part of each Annual Report, GSK also shall provide the OIG with descriptions of any instances identified through the Non-Promotional Monitoring Program in which it was determined that improper promotion of Government Reimbursed Products occurred or the activities violated GSK's requirements or Policies and Procedures, and a description of the action(s) that GSK took as a result of such determinations. GSK shall make the documents relating to the Non-Promotional Monitoring Program available to the OIG upon request.

N. Notices to Health Care Providers, Entities, Payers. Within 90 days after the Effective Date, GSK shall send, by first class mail, postage prepaid with delivery confirmation, a notice containing the language set forth below to all HCPs and HCIs that GSK currently details. This notice shall be dated and shall be signed by GSK's President. The body of the letter shall state the following:

As you may be aware, GSK recently entered into a global civil, criminal, and administrative settlement with the United States and individual states in connection with the promotion and use of some of its products. This letter provides you with additional information about the settlement, explains GSK's commitments going forward, and provides you with access to information about those commitments.

In general terms, the Government alleged that GSK unlawfully promoted Wellbutrin, Paxil, Advair, Lamictal, and Zofran for uses not approved by the Food & Drug Administration (FDA) and that GSK engaged in other improper conduct relating to several of its other drugs including Avandia. To resolve these matters, GSK pled guilty to three misdemeanor criminal violations of the Federal Food, Drug & Cosmetic Act and agreed to pay a criminal fine of \$1 billion. In addition, the Government alleged that GSK violated the False Claims Act and GSK entered into three civil settlements to resolve these allegations pursuant to which GSK agreed to pay \$ 2 billion to the Federal Government and State Medicaid programs. More information about this settlement may be found at the following: **[GSK shall include a link to the USAO, OCL, and GSK websites in the letter.]**

As part of the federal settlement, GSK also entered into a five-year corporate integrity agreement (CIA) with the Office of Inspector General of the U.S. Department of Health and Human Services. The CIA is available at <http://oig.hhs.gov/fraud/cia/index.html>. Under this agreement, GSK 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 GSK's representatives to GSK's Compliance Department or the FDA.

GSK is fully committed to meeting the terms of the CIA and to sales and

marketing practices that promote compliance. We have fundamentally changed our procedures for compliance, marketing and selling in the United States. For example, we now compensate our medical sales representatives based on the quality of service they deliver to customers, not on sales targets.

Please call GSK at **XXXX** or **visit us at [insert name of web link]** if you have questions about the settlement referenced above or to report any instances in which you believe that a GSK representative inappropriately promoted a product or engaged in other questionable conduct. Alternatively, you may report any improper conduct associated with prescription drug marketing committed by a GSK representative to the FDA's Office of Prescription Drug Promotion at 301-796-1200. You should direct medical questions or concerns about the products to **XXXXX**.

Within 90 days after the Effective Date, GSK shall send to all Payers with whom GSK currently has contracts or enters into contracts for formulary access or rebates (including all state Medicaid programs), by first class mail, postage prepaid with delivery confirmation, a notice containing the language set forth. This notice shall be dated and shall be signed by GSK's President. The body of the letter shall state the following:

As you may be aware, GSK recently entered into a global civil, criminal, and administrative settlement with the United States and individual states in connection with the promotion and of some of its products. This letter provides you with additional information about the settlement, explains GSK's commitments going forward, and provides you with access to information about those commitments.

In general terms, the Government alleged that GSK unlawfully promoted Wellbutrin, Paxil, Advair, Lamictal, and Zofran for uses not approved by the Food & Drug Administration (FDA) and that GSK engaged in other improper conduct relating to several of its other drugs including Avandia. To resolve these matters, GSK pled guilty to three misdemeanor criminal violations of the Federal Food, Drug & Cosmetic Act (FDCA) and agreed to pay a criminal fine of \$ 1 billion. In addition, the Government alleged that GSK violated the False Claims Act and GSK entered into three civil settlements to resolve these allegations pursuant to which GSK agreed to pay \$ 2 billion to the Federal Government and State Medicaid programs.

More information about this settlement may be found at the following:  
**[GSK shall include a link to the USAO, OCL, and GSK websites in the letter.]**

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GSK is fully committed to meeting the terms of the CIA and to sales and marketing practices that promote compliance. We have fundamentally changed our procedures for compliance, marketing and selling in the United States. For example, we now compensate our medical sales representatives based on the quality of service they deliver to customers, not on sales targets.

In addition, GSK is committed to promoting its products in a manner consistent with the FDA approved label for the product. GSK will pay rebates under applicable agreements (Rebates) involving a prior authorization or formulary requirement (a "Restriction") in relation to the drugs at issue in this settlement, and will not reduce or alter its Rebates due to such a Restriction, provided that the Restriction: (1) does not limit any patient from receiving such drugs, including at the point of sale, for uses that are consistent with the FDA-approved label for each product; (2) is applied consistently across the therapeutic class; (3) is consistent with GSK's policies, procedures and financial guidelines; and, (4) does not require the use of another manufacturer's drug for a use that is not consistent with the FDA approved label for the other product. This paragraph shall not be interpreted to require GSK to contract or not to contract with any Payer. GSK shall administer its agreements with Payers in a manner consistent with the requirements of this paragraph, including agreeing to amend or modify applicable agreements to be consistent with this provision.

Please call GSK at **XXXX** or **visit us at [insert name of web link]** if you have questions about the settlement referenced above or to report any instances in which you believe that a GSK representative inappropriately promoted a product or engaged in other questionable conduct. Alternatively, you may report any improper conduct associated with prescription drug marketing committed by a GSK representative to the FDA's Office of Prescription Drug Promotion at 301-796-1200. You should direct medical questions or concerns about the products to **XXXXX**.

The Compliance Officer (or a designee) shall maintain a log of all calls and messages received in response to the notices. 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 log of all calls and messages received in response to the notices shall be made available to OIG upon request. As part of the Implementation Report and each Annual Report, GSK shall provide to the OIG a summary of the calls and messages received.

O. Reporting of Physician Payments.

Prior to the Effective Date, GSK began a voluntary Physician Payment Transparency Program through which GSK posted on its corporate website quarterly reports of payments to physicians for speaking and consulting fees. GSK shall continue to post such reports until the Annual Reporting requirements of Section III.O.1 take effect.

1. *Reporting of Payment Information.*

Quarterly Reporting: On or before March 1, 2013, GSK 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 who or which received Payments (as defined in Section III.O.2) directly or indirectly from GSK during the fourth quarter of 2012 and the aggregate value of such Payments. Thereafter, 60 days after the end of each calendar quarter, GSK shall post on its website a report of the cumulative value of the Payments provided to each physician and Related Entity during the preceding calendar quarter.

Annual Reporting: On or before March 1, 2013, and 60 days after the end of each subsequent calendar year, GSK shall post on its website a report of the cumulative value

of the Payments provided to all U.S.-based physicians and Related Entities directly or indirectly from GSK during the prior applicable calendar year. Each quarterly and annual report shall be easily accessible and readily searchable.

Each listing made pursuant to this Section III.O shall include a complete list of all individual physicians or Related Entities to whom or which GSK made Payments in the preceding quarter or year (as applicable). Each listing shall be arranged alphabetically according to the physicians' last name or name of Related Entity. The Payment amounts in the lists shall be reported in the actual amount paid for all physicians or Related Entity on the listing. For each physician, the applicable listing shall include the following information: i) physician's full name; ii) name of any Related Entities (if applicable); iii) city and state that the physician has provided to GSK for contact purposes; and (iv) the aggregate value of the payment(s) in the preceding quarter 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. *Definitions and Miscellaneous Provisions.*

(i) GSK shall continue to make each annual listing and the most recent quarterly listing of Payments available on its website during the term of the CIA. GSK shall retain and make available to OIG, upon request, all supporting documentation, correspondence, and records related to all applicable Payments and to the annual and/or quarterly listings of Payments. Nothing in this Section III.O affects the responsibility of GSK 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 Entity.

(ii) For purposes of Section III.O.1, "Payments" is defined to include all "payments or other transfers of value" as that term is defined in §1128G(e)(10) under Section 6002 of the Affordable Care Act and any regulations promulgated thereunder. The term Payments includes, by way of example, the types of payments or transfers of value enumerated in §1128G(a)(1)(A)(vi) of the Affordable Care Act. The term 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 GSK would otherwise report a Payment if made directly to the physician. The term Payments also includes any payments or transfers of value made, directly by GSK or by a vendor retained by GSK to a physician or Related Entity in connection with, or under the auspices of, a co-promotion arrangement.

(iii) For purposes of its annual and quarterly website postings as described above, and only with regard to payments made pursuant to product research or development agreements and clinical investigations as set forth in § 1128G(c)(E) of the Affordable Care Act, GSK may delay the inclusion of such payments on its website listings consistent with § 1128G(c)(E) of the Act and any subsequent regulations promulgated thereunder.

(iv) The term “Payments” does not include transfers of value or other items that are not included in or are excluded from the definition of “payment” as set forth in § 1128G(e)(10) under Section 6002 of the Affordable Care Act and any regulations promulgated thereunder.

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

P. Other Transparency/Disclosure Initiatives.

GSK represents that it posts on its company website the following information with respect to both grants and charitable contributions in the United States: GSK shall continue to post (and provide updates to) the above-described information about grants and charitable contributions throughout the term of this CIA. GSK shall notify the OIG in writing at least 60 days prior to any change in the substance of its policies regarding the funding of grants and charitable contributions or posting of the above-referenced information relating to such funding.

GSK shall require all Consultants to comply fully with all applicable disclosure obligations relating to their relationship with GSK that may be externally imposed on the Consultants based on their affiliation with formulary or P&T committees or committees associated with the development of treatment protocols or standards. GSK shall maintain this requirement throughout the term of this CIA. GSK represents that within 120 days after the Effective Date, GSK shall, if necessary, amend its policies relating to Consultants to explicitly state that GSK requires all Consultants to fully comply with all applicable disclosure obligations relating to their relationship with GSK that may be externally imposed on the Consultants based on their affiliation with formulary, P&T committees, or committees associated with the development of treatment protocols or standards or that are required by any HCI, medical committee, or other medical or scientific organization with which the Consultants are affiliated. In addition, for any

amendment to its contracts with Consultants and in any new contracts with Consultants entered into after 150 days following the Effective Date, GSK shall include an explicit requirement that the Consultants fully comply with all applicable disclosure requirements, as referenced above in this paragraph. GSK shall continue these disclosure requirements throughout the term of this CIA.

To the extent not already accomplished, within 120 days after the Effective Date, GSK shall post or make available information on its company website about FDA postmarketing commitments (PMCs). The GSK website or links included therein shall provide access to general information about the PMC process, descriptions of ongoing GSK studies, and information about the nature and status of the post-marketing commitments. GSK shall continue to post or make available the above-described information about PMCs on its website or links included therein throughout the term of this CIA.

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

A. Change or Closure of Unit or Location. In the event that, after the Effective Date, GSK changes locations or closes a business unit or location related to or engaged in any of the Covered Functions or in CGMP Activities, GSK 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, GSK purchases or establishes a new business unit or location related to or engaged in any of the Covered Functions or in cGMP Activities, GSK shall notify OIG no later than five days after the date that the purchase or establishment of the new business unit or location is publicly disclosed by GSK. This notification shall include the address of the new business unit or location, phone number, fax number, the location's Federal health care program provider number and/or supplier number(s) (if applicable); and the name and address of each Federal health care program contractor to which GSK currently submits claims (if applicable). Each new business unit or location and all Covered Persons or Manufacturing 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, GSK proposes to sell any or all of its business units or locations that are subject to this CIA (including the terms of Appendix D), GSK shall notify OIG of the proposed sale at no

later than five days after the sale is publicly disclosed by GSK. 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, GSK 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 Board of Directors referenced in Section III.A.3;
4. the names of the DCOs required by Section III.A.4;
5. the names and positions of the Certifying Employees required by Section III.A.6;
6. a copy of GSK's Code of Conduct required by Section III.B.1;
7. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
8. (a) a copy of the letter (including all attachments) required by Section II.C.9 and III.B.2 sent to each party employing Third Party Personnel; (b) a list of all existing co-promotion and other applicable agreements between GSK and the party

employing Third Party Personnel; and (c) a description of each entity's response to GSK's letter;

9. a summary of all Policies and Procedures required by Section III.B.3 (a copy of such Policies and Procedures shall be made available to OIG upon request);

10. 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 individuals required to participate in General Training and Board Member Training, percentage of individuals 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.<sup>2</sup>

11. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; and (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A; (d) a summary and description of any and all current and prior engagements and agreements between GSK and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to GSK;

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

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

14. a certification by the Compliance Officer that the notices required by Section III.N was mailed to each HCP, HCI, and Payer, the number of HCPs, HCIs and

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<sup>2</sup>In Addition to the Implementation Report, GSK shall submit to OIG by January 30, 2013 a letter containing the information specified in Section V.A.10 as it pertains to Specific Training and Management Training as required by Section III.C.

Payers to whom or which the notice was mailed, a sample copy of the notices required by Section III.N, and a summary of the calls or messages received in response to the notices;

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

16. a list of all of GSK's locations (including locations and mailing addresses); 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 number and/or supplier number(s) (if applicable); and the name and address of any each Federal health care program contractor to which GSK currently submits claims (if applicable);

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

18. the certifications required by Section V.D.

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

Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee, the Board of Directors, the DCOs or the group of Certifying Employees described in Sections III.A.2-4 and 6;

2. a copy of the resolution by the Board required by Section III.A.3;

3. the number of individuals required to review GSK's Code of Conduct and complete the certifications required by Section III.B.1, the percentage of individuals who have completed such certifications, 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 Section II.C.9 and III.B.2 sent to each party employing Third Party Personnel; (b) a list of all existing co-promotion and other applicable agreements between GSK and the party employing Third Party Personnel; and (c) a description of each entity's response to GSK's letter;

5. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B, including any changes to the Research and Publication Practices and Authorship-Related Practices, and the reasons for such changes (e.g., change in applicable requirements);

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

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

b. the number of individuals required to complete each type of training specified in Section III.C, percentage of individuals who completed the training, 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.

7. a summary of any significant changes to the TRACER program required by Section III.D;

8. a complete copy of all reports prepared pursuant to Section III.E, and Appendices B-C along with a copy of the IRO's engagement letters;

9. GSK's response to the reports prepared pursuant to the reviews outlined in Section III.E and Appendices B-C, along with corrective action plan(s) related to any issues raised by the reports;

10. a summary and description of any and all current and prior engagements and agreements between GSK and the IRO (if different from what was submitted as part of the Implementation Report);

11. certifications from the IRO regarding its professional independence and objectivity with respect to GSK;

12. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs, FDA requirements (including CGMP Activities), or Government Reimbursed Products;

13. any changes to the process by which GSK fulfills the requirements of Section III.G regarding Ineligible Persons;

14. a summary of any changes to GSK's employee and executive incentive compensation and recoupment programs required by Section III.H and Appendix E and the information regarding Triggering Events and Recoupment Determinations required to be reported pursuant to Section E of Appendix E;

15. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.I. 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;

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

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

18. a summary of the FFMP and the results of the FFMP required by Section III.L, including 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 GSK took as a result of such determinations;

19. a summary of the Non-Promotional Monitoring Program and the results of the program described in Section III.M, including detailed description of any identified instances in which it was determined that the activities violated GSK's policies or that improper promotion of Government Reimbursed Products occurred and a description of

the action(s) GSK took as a result of such determinations;

20. a summary of the calls and messages received in response to the notices required by Section III.N and the disposition of those calls and messages;

21. a certification from the Compliance Officer that information regarding Payments has been posted on GSK's website as required by Section III.O;

22. a description of all changes to the most recently provided list of GSK's locations (including addresses) as required by Section V.A.16; the corresponding name under which each location is doing business; and the corresponding phone numbers and fax numbers;

23. a description of any additional, updated, supplemental or changed information submitted to any Compendia in accordance with Section III.B.3.t; and a description of all arrangements, processing fees, and other payments or financial support (if any) with or made to any Compendia evaluated during the annual review described in Section III.B.3.t; and

24. the certifications required by Section V.D.

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. IRO Initial Report. By March 1, 2013, GSK shall submit to OIG a report with respect to the status of, and findings regarding, the IRO Reviews for the first IRO Reporting Period (IRO Initial Report).

The IRO Initial Report shall include at a minimum:

1. a complete copy of all reports prepared pursuant to Section III.E, and Appendix B along with a copy of the IRO's engagement letters;

2. GSK's response to the reports prepared pursuant to the reviews outlined in Section III.E and Appendix B, along with corrective action plan(s) related to any issues raised by the reports;

3. a summary and description of any and all current and prior engagements and agreements between GSK and the IRO (if different from what was submitted as part of the Implementation Report);

4. certifications from the IRO regarding its professional independence and objectivity with respect to GSK;

D. Certifications.

1. Certifying Employees: In each Annual Report, GSK shall include the certifications of Certifying Employees as required by Section III.A.6;

2. Compliance Officer: In the Implementation Report, and each Annual Report, GSK shall include the following individual certification by the Compliance Officer:

a. to the best of his or her knowledge, except as otherwise described in the report, GSK is in compliance with the requirements of this CIA;

b. 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;

c. to the best of his or her knowledge, GSK has complied with its obligations under the Settlement Agreement: (1) not to resubmit to any Federal health care program Payers any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (2) not to charge to or otherwise seek payment from federal or state Payers for unallowable costs (as defined in the Settlement Agreement); and (3) to identify and adjust any past charges or claims for unallowable costs;

d. GSK'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 have been found to be in compliance with all applicable Federal health care program and FDA requirements. In addition, GSK's promotional materials containing claims or information about Government Reimbursed Products and other materials and information intended to be disseminated outside GSK have been reviewed

by competent regulatory, medical, or, as appropriate, legal counsel in accordance with applicable Policies and Procedures to ensure that legal, medical, and regulatory concerns have been addressed by GSK and brought to the attention of the appropriate individuals when required, 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 legal counsel. 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;

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

f. GSK has maintained an employee and executive incentive compensation and recoupment program in accordance with the terms set forth above in Section III.H and Appendix E.

3. Certification for the IRO Initial Report: In the IRO Initial Report, GSK shall include an individual certification by the Compliance Officer that he or she has reviewed the report and has made reasonable inquiry regarding its content and believes the information in the report is accurate and truthful.

E. Designation of Information. GSK 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. GSK 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

**GSK:** Michael L. Shaw  
Vice President & Compliance Officer  
North America Pharmaceuticals  
GlaxoSmithKline  
Three Franklin Plaza  
200 N. 16<sup>th</sup> Street  
Philadelphia, PA 19102  
Telephone: 215.751.7337  
Facsimile: 215.751.7547

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, GSK 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 GSK's or an applicable GSK Affiliate's books, records, and other documents and supporting

materials and/or conduct on-site reviews of any of GSK's locations for the purpose of verifying and evaluating: (a) GSK's or an applicable GSK Affiliate's compliance with the terms of this CIA (including Appendix D); and (b) GSK's or an applicable GSK Affiliate's compliance with the requirements of the Federal health care programs in which it participates and with all applicable FDA requirements (including CGMP Activities). The documentation described above shall be made available by GSK or the applicable GSK Affiliate 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 GSK's or the applicable GSK Affiliate'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. GSK or the applicable GSK Affiliate shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. GSK's or the applicable GSK Affiliate's employees may elect to be interviewed with or without a representative of GSK or the applicable GSK Affiliate present.

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

GSK and its Affiliates shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this CIA (including Appendix D) until the end of 2018 (or longer if otherwise required by law) from the Effective Date.

#### **IX. DISCLOSURES**

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

#### **X. BREACH AND DEFAULT PROVISIONS**

GSK is expected to fully and timely comply with all of the CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, GSK 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 GSK fails to establish and implement any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. the Board compliance obligations, including the resolution from the Board;
- d. the management accountability and certification obligations;
- e. a written Code of Conduct;
- f. written Policies and Procedures;
- g. the training of Covered Persons, Relevant Covered Persons, Management, and Board Members;
- h. a TRACER program;
- i. a Disclosure Program;
- j. Ineligible Persons screening and removal requirements;
- k. an employee and executive incentive compensation and recoupment program as required by Section III.H and Appendix E;
- l. notification of Government investigations or legal proceedings as required by Section III.I;

- m. reporting of Reportable Events as required in Section III.J;
- n. notification of written communications with FDA as required by Section III.K;
- o. a program for FFMP as required by Section III.L;
- p. a program for Non-Promotional Monitoring Program as required by Section III.M;
- q. notifications to HCPs, HCIs, and Payers as required by Section III.N; and
- r. posting of any Payments as required by Section III.O.

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 GSK fails to engage and use an IRO as required in Section III.E and Appendices A-C.

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 GSK fails to submit the Implementation Report or any Annual Report to OIG in accordance with the requirements of Section V of the CIA or of Appendix D 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 GSK fails to submit any IRO Review report (including the IRO Initial Report) in accordance with the requirements of Sections III.E and III.V and Appendices A-C.

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

- a. a GMS Compliance Officer;
- b. a GMS Compliance Committee;
- c. the Board compliance obligations, including the resolution from

the Board;

- d. a written Code of Conduct;
- e. written Policies and Procedures;
- f. the training of Manufacturing Covered Persons;
- g. cGMP Requirements;
- h. reporting of Manufacturing Reportable Events; or
- i. reporting of a recall under Section III.F of Appendix D.

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

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

8. A Stipulated Penalty of \$10,000 for each day that GSK fails to timely submit any report required under Section III.D.3.a or III.D.3.b of Appendix D.

9. A Stipulated Penalty of \$10,000 for each lot of each Covered Product for each day that GSK fails to initiate a recall for specified lots under Section III.D of Appendix D after receipt of a Final Determination.

10. A Stipulated Penalty of \$10,000 for each lot of each Covered Product for each day that GSK fails to complete a recall within a deadline established in the Final Determination for specified lots under Section III.D of Appendix D.

11. A Stipulated Penalty of \$1,000 for each day GSK or a GSK Affiliate fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to GSK or a GSK Affiliate stating the specific grounds for its determination that GSK or a GSK Affiliate has failed to comply fully and adequately with the CIA

obligation(s) at issue and steps GSK or a GSK Affiliate shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after GSK or a GSK Affiliate 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- 10 of this Section.

B. Timely Written Requests for Extensions. GSK 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 GSK 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 GSK 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 GSK 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 GSK of: (a) GSK'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, GSK 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 GSK elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until GSK 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.d, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that GSK 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 repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- b. a failure by GSK to report a Reportable Event and take corrective action as required in Section III.J of the CIA or Section III.E of Appendix D;
- c. a failure to engage and use an IRO in accordance with Section III.E and Appendices A-C;
- d. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C;
- e. a failure of the Board to issue a resolution in accordance with Section III.A.3 of the CIA or Section III.A.3 of Appendix D.
- f. a failure by GSK to timely initiate a recall of Covered Products sold in the United States pursuant to a Final Determination made under Section III.D of Appendix D after receipt of a Final Determination; or
- g. a failure by GSK to timely complete a recall of Covered Products sold in the United States as required in the Final Determination after receipt of the Final Determination under Appendix D.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by GSK constitutes an independent basis for GSK's exclusion from participation in the Federal health care programs. Upon a determination by OIG that GSK has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify GSK of: (a) GSK'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.* GSK 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. GSK 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) GSK has begun to take action to cure the material breach; (ii) GSK is pursuing such action with due diligence; and (iii) GSK has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, GSK fails to satisfy the requirements of Section X.D.3, OIG may exclude GSK from participation in the Federal health care programs. OIG shall notify GSK in writing of its determination to exclude GSK (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 GSK'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, GSK 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 GSK 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, GSK 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 GSK was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. GSK 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 GSK to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless GSK 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 GSK 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) GSK had begun to take action to cure the material breach within that period; (ii) GSK has pursued and is pursuing such action with due diligence; and (iii) GSK provided to OIG within that period a reasonable timetable for curing the material breach and GSK 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 GSK, only after a DAB decision in favor of OIG. GSK's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude GSK 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 GSK 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. GSK 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 GSK, GSK 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**

GSK and OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns, and transferees of GSK;
- 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 GSK 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.

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 GLAXOSMITHKLINE LLC**

/Deirdre Connelly/

6-28-2012

DEIRDRE CONNELLY  
President  
GlaxoSmithKline LLC

DATE

/Michael L. Shaw/

6/28/2012

MICHAEL L. SHAW  
Vice President & Compliance Officer  
North America Pharmaceuticals  
GlaxoSmithKline LLC

DATE

/Kristin Graham Koehler/

6/28/2012

PAUL E. KALB  
KRISTIN GRAHAM KOEHLER  
LAUREN K. ROTH  
Sidley Austin LLP  
Counsel for GlaxoSmithKline LLC

DATE

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

*/Gregory E. Demske/*

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*6/22/12*

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GREGORY E. DEMSKE  
Chief Counsel to the Inspector General  
Office of Inspector General  
U. S. Department of Health and Human Services

DATE

*/Mary E. Riordan/*

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*6/28/2012*

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MARY E. RIORDAN  
Senior Counsel  
Office of Inspector General  
U. S. Department of Health and Human Services

DATE

*/Christina K. McGarvey/*

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*June 28, 2012*

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CHRISTINA K. MCGARVEY  
Senior Counsel  
Office of Inspector General  
U. S. Department of Health and Human Services

DATE

## Appendix A to CIA for GlaxoSmithKline LLC

### Independent Review Organization

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

#### A. IRO Engagement.

GSK shall engage an IRO (or IRO(s)) 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 the information identified in Section V.A.11 of the CIA or any additional information submitted by GSK in response to a request by OIG, whichever is later, OIG will notify GSK if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, GSK may continue to engage the IRO.

If GSK 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, GSK shall submit the information identified in Section V.A.11 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by GSK at the request of OIG, whichever is later, OIG will notify GSK if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, GSK may continue to engage the IRO.

#### B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the IRO Reviews who have expertise in the pharmaceutical industry and have expertise in applicable Federal health care program and FDA requirements that relate to the Covered IRO Functions, including expertise relating to: i) marketing and promotional activities associated with pharmaceutical products; ii) research regarding such products; and iii) publication, authorship, and disclosure activities associated with such research). The assigned individuals shall also be experienced in risk identification and mitigation in relation to pharmaceutical product marketing and promotion. The assigned individuals also shall be knowledgeable about the general requirements of the Federal health care programs under which GSK products are reimbursed;

2. assign individuals to design and select the samples for the IRO Transactions Reviews who are knowledgeable about 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 component of each IRO 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 IRO Review;

3. if in doubt of the application of a particular Federal health care program or FDA requirement, 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 Appendices B and C to the CIA.

D. Independence and Objectivity.

The IRO must perform the IRO Reviews in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the United States Government Accountability Office.

E. IRO Removal/Termination.

1. *GSK Termination of IRO.* If GSK terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, GSK must submit a notice explaining its reasons for termination or the reason for withdrawal to OIG no later than 30 days after termination or withdrawal. GSK must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of the termination or withdrawal of the IRO.

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 GSK to engage a new IRO in accordance with Paragraph A of this Appendix. GSK must engage a new IRO within 60 days of termination of the IRO.

Prior to requiring GSK to engage a new IRO, OIG shall notify GSK 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, GSK may present additional information regarding the IRO's qualifications, independence or performance of its responsibilities. OIG will attempt in good faith to resolve any differences regarding the IRO with GSK prior to requiring GSK to terminate the IRO. However, the final determination as to whether or not to require GSK to engage a new IRO shall be made at the sole discretion of OIG.

## **Appendix B to CIA for GlaxoSmithKline LLC**

### **Independent Review Organization Reviews**

#### **I. Covered Functions Review, General Description**

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

If there are no material changes in GSK's systems, processes, policies, and procedures relating to the Covered IRO Functions, the IRO shall perform the Systems Review for the second and fifth IRO Reporting Periods. If GSK materially changes its systems, processes, policies, and procedures relating to the Covered IRO Functions, the IRO shall perform a Systems Review for the IRO Reporting Period(s) in which such changes were made in addition to conducting the Review for the second and fifth IRO 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 Transactions Review for each IRO Reporting Period of the CIA.

#### **II. IRO Systems Review**

##### **A. Description of Reviewed Policies and Procedures**

The Covered IRO Functions Systems Review shall be a review of GSK's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to certain of the Covered Functions. Where practical, GSK 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 GSK in accordance with the preceding sentence.

Specifically, the IRO shall review GSK’s systems, processes, policies, and procedures associated with the following (hereafter “Reviewed Policies and Procedures”):

1) GSK’s systems, processes, policies, and procedures applicable to the manner in which GSK field personnel (including sales personnel, marketing personnel, MSLs, HOLs, and personnel from the PPV group) and personnel from the Medical Affairs department (including MISs) handle requests or inquiries relating to information about the uses of Government Reimbursed Products (including non-FDA-approved (*i.e.*, off-label) uses of Government Reimbursed Products) and the dissemination of materials relating to the uses of these products. This review shall include:

- a) the manner in which GSK sales personnel and PPV personnel handle requests for information about off-label uses of Government Reimbursed Products (*i.e.*, by referring all such requests to Medical Affairs personnel at GSK);
- b) the manner in which Medical Affairs personnel, including those at GSK’s headquarters, handle and respond to requests for information about off-label uses of 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 Government Reimbursed Products disseminated to physicians, pharmacists, or other health care professionals (collectively “HCPs”), and health care institutions (HCIs), Payers, and formulary decision-makers by GSK;
- d) GSK's systems, processes, policies, and procedures (including the Inquiries Database) to track requests to Medical Affairs for information about off-label uses of products and responses to those requests;
- e) the manner in which GSK collects and supports information reported in any systems used to track and respond to requests to Medical Affairs for Government Reimbursed Product information, including its Inquiries Database;

- f) the processes and procedures by which Medical Affairs, the Compliance Officer, or other appropriate individuals within GSK identify situations in which it appears that off-label or other improper promotion may have occurred; and
  - g) GSK's processes and procedures for investigating, documenting, resolving, and taking appropriate disciplinary action for potential situations involving improper promotion;
- 2) GSK's systems, processes, policies, and procedures applicable to the manner and circumstances under which its Medical Affairs personnel (including MSLs, HOLs, or analogous personnel) participate in meetings or events with HCPs or HCIs (either alone or with sales representatives) regarding Government Reimbursed Products and the role of the Medical Affairs personnel at such meetings or events;
- 3) GSK's systems, processes, policies, and procedures relating to GSK's internal review of promotional materials related to Government Reimbursed Products disseminated to HCPs, HCIs and Payers and individuals or entities (*e.g.*, PBMs) acting on behalf of HCPs, HCIs or government payers;
- 4) GSK's systems, policies, processes and procedures (the "Patient First Program") relating to incentive compensation for Relevant Covered Persons who are prescriber-facing sales personnel and their direct managers, 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 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. To the extent that GSK establishes different methods of compensation for different Government Reimbursed Products, the IRO shall review each type of compensation arrangement separately;
- 5) GSK's systems, policies, processes and procedures relating to the Executive Financial Recoupment Program described in Section III.H of the CIA and in Appendix E;

- 6) GSK’s systems, processes, policies, and procedures relating to the development and review of Target Plans (as defined in Section III.B.3.j of the CIA) for 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 Target Plans based on expected utilization of Government Reimbursed Products for FDA-approved uses or non-FDA-approved uses;
- 7) GSK’s systems, processes, policies, and procedures relating to Sample Distribution Policies and Procedures (as defined in Section III.B.3.k of the CIA). 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 GSK (including, separately, from GSK sales representatives and other GSK personnel or components). It shall also include a review of whether samples of Government Reimbursed Products are distributed by GSK through sales representatives or are distributed from a central location and the rationale for the manner of distribution;
- 8) GSK’s systems (including any centralized electronic systems), processes, policies, and procedures relating to speaker programs, speaker training programs, and all events and expenses relating to such engagements or arrangements;
- 9) GSK’s systems, processes, policies, and procedures relating to engagement of “Consultants” (as defined in Section III.M.1 of the CIA) and all events and expenses associated with such activities;
- 10) GSK’s systems, processes, policies, and procedures relating to GSK’s funding, directly or indirectly, of Third Party Educational Activities for HCPs (as defined in Section II.C.8 of the CIA) and all events and expenses relating to such activities;
- 11) GSK’s systems, processes, policies, and procedures relating to the submission of information about any Government Reimbursed Product to any compendia such as Drugdex or other published source of information used in connection with the determination of coverage by a Federal health care program for the product (“Compendia”). This includes any initial submission of information to any Compendia and the submission of any

additional, updated, supplemental, or changed information, (e.g., any changes based on GSK's discovery of erroneous or scientifically unsound information or data associated with the information in the Compendia). The review shall also assess GSK's processes relating to its annual review of all arrangements, processing fees, or other payments or financial support (if any) provided to any Compendia;

12) GSK's systems, processes, policies, and procedures relating to Research and Publication Practices (as defined in Section III.B.3.u of the CIA), including the decision to provide financial or other support for such Research; the manner in which Research support is provided; the publication of information about the Research, including the publication of information about the Research results and trial outcomes, and uses made of publications relating to such research;

13) GSK's systems, processes, policies and procedures relating to authorship of any journal articles or other publications about GSK-Sponsored Research or about therapeutic areas or disease states that may be treated with Government Reimbursed Products, including, but not limited to, the disclosure of any and all financial relationships between the author and GSK, the identification of all authors or contributors (including professional writers, if any) associated with a given publication, and the scope and breadth of research results made available to each author or contributor;

14) GSK's systems, policies, processes, and procedures applicable to the manner and circumstances under which GSK personnel (including sales personnel (if any), personnel from the PPV Unit, MSLs, HOLs, or analogous personnel) participate in meetings with Payers (as defined in Section II.C.6 of the CIA) regarding Government Reimbursed Products and the role of the GSK personnel at such meetings; and

15) the form and content of information and materials disseminated by GSK to Payers and GSK's systems, policies, processes, and procedures relating to GSK's internal review and approval of information and materials related to Government Reimbursed Products disseminated to Payers by GSK.

## B. IRO 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 GSK's systems, policies, processes, and procedures relating to the items identified in Sections II.A.1-15 above, including a general description of GSK'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.1-15 above are made known or disseminated within GSK;
- 4) a detailed description of any system(s) used to track and respond to requests for information about Government Reimbursed Products (including the Inquiries Database);
- 5) findings and supporting rationale regarding any weaknesses in GSK's systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and
- 6) recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

### III. IRO Transactions Review

As described more fully below in Sections III.A-F, the Transactions Review for the second through sixth IRO Reporting Periods shall include: (1) a review of a sample of Inquiries reflected in the Inquiries Database; (2) a review of GSK's Target Plans and GSK's Target 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 GSK pursuant to Section III.O of the CIA; (5) a review of Research and Publication Practices and Authorship-Related Practices; and (6) a review of up to three additional items identified by the OIG in accordance with Section III.E.1.b of the CIA

(hereafter “Additional Items”). The IRO shall report on all aspects of its reviews in the Transactions Review Reports.

For purposes of the Transactions Review for the first IRO Reporting Period, the Transactions Review shall include a review of Items 1-3 outlined in the preceding paragraph. The Transaction Review Report for the first IRO Reporting Period shall report on Items 1-3 in accordance with Section III.G below.

A. Review of Inquiries and Inquiries Database

1) Description of Inquiries Database

As set forth in Section III.B.3.g of the CIA, GSK shall establish a database to track information relating to requests for information received by GSK about its Government Reimbursed Products (hereafter “Inquiries”). Specifically, GSK shall document and record all Inquiries received from HCPs or HCIs regarding Government Reimbursed Products in a database(s) (the “Inquiries Database”). GSK shall record in the Inquiries 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 or other individual or entity; 4) nature and topic of request (including exact language of the Inquiry if made in writing); 5) an evaluation of whether the Inquiry relates to information about an off-label indication for the product; 6) nature/form of the response from GSK (including a record of any materials provided in response to the request); and 7) the name of the GSK representative who called upon or interacted with the HCP or HCI.

2) Internal Review of Inquiries Database

On a semi-annual basis, the Compliance Officer or designee shall review the Inquiries 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 (“Inquiry Report”). The Compliance Officer or designee shall review the Inquiry 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 Compliance Officer or designee, in consultation with other appropriate GSK personnel, suspects that improper off-label promotion may have occurred in connection with any Inquiry, the

Compliance Officer or designee shall undertake a follow-up review of the Inquiry (Off-Label Review), make specific findings based on his/her Off-Label Review, and take all appropriate responsive action (including disciplinary action of the Covered Person and reporting of the conduct, including disclosing Reportable Events pursuant to Section III.J of the CIA, if applicable).

3) IRO Review of Inquiries Reflected in Inquiries Database

The IRO shall select and review a random sample of 50 Inquiries from among the Inquiries reflected in the Inquiries Database for each Reporting Period. Forty of the Inquiries reviewed by the IRO shall be Inquiries for which GSK conducted an Off-Label Review, and the other ten shall be Inquiries for which GSK did not conduct an Off-Label Review. 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 Inquiries Database for each reviewed Inquiry; and
- b) For each Inquiry for which the Compliance Officer 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 Compliance Officer as a result of the Off-Label Review; and any follow-up actions taken by GSK based on the Off-Label Review findings.

B. IRO Review of GSK's Target Plans and Target Plan Review Process

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

For each Target Plan, the IRO shall select a sample of 50 of the HCPs and HCIs included on the Target Plan. For each Target Plan, the IRO shall compare the sampled HCPs and HCIs against the criteria (e.g., medical specialty or practice area) used by GSK

in conducting its review and/or modifying the Target Plan. The IRO shall seek to determine whether GSK followed its criteria and Policies and Procedures in reviewing and modifying the Target Plan.

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

C. IRO Review of the Distribution of Samples of GSK Government Reimbursed Products

The IRO shall conduct a review and assessment of the distribution of samples of Government Reimbursed Products to HCPs and HCIs. GSK shall provide the IRO with: i) a list of Government Reimbursed Products for which GSK distributed samples during the IRO Reporting Period; ii) information about the FDA-approved uses for each such product; and iii) information about GSK's Sample Distribution Policies and Procedures, including GSK's exclusion lists showing which types of samples may not be distributed by sales personnel or other GSK personnel to HCPs and HCIs of particular medical specialties or types of clinical practices. GSK shall also provide the IRO with information about the reviews of Sample Distribution Policies and Procedures that GSK conducted during the IRO Reporting Period as set forth in Section III.B.3.k of the CIA and any modifications to the Sample Distribution Policies and Procedures or exclusion lists made as a result of GSK's reviews.

For each Government Reimbursed Product for which GSK distributed samples during the IRO Reporting Period, the IRO shall randomly select a sample of 50 separate instances in which GSK provided samples of the product to HCPs or HCIs. 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. The reviewed materials shall include materials about the following: 1) the quantity, dosage, and form of the GSK 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 GSK sales personnel or other GSK personnel provided the sample to the HCP or HCI; and 4) the manner and mechanism through which the sample was requested (e.g., sample request form, letter, or call to GSK).

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 Government Reimbursed Product approved by the FDA and whether the sample was distributed by an GSK representative in a manner consistent with GSK'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 GSK representative other than a sales personnel, 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 GSK sales representative, conversation with a GSK representative at headquarters, independent research, or knowledge of the HCP or HCI).

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 Government Reimbursed 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 Government Reimbursed Product approved by the FDA. For each such situation, the IRO shall note the process followed by GSK in determining that it was appropriate to provide a sample to such HCP or HCI and the basis for such determination. The IRO shall also note any instances in which it appears that GSK failed to follow its Sample Distribution Policies and Procedures for the Government Reimbursed Product(s) provided during the Sampling Event.

#### D. IRO Review of Physician Payment Listings

##### 1. Information Contained in Physician Payment Listings

For purposes of the IRO review as set forth in this Section III.D, each annual listing of physicians and Related Entities who received Payments (as defined in Section III.O of the CIA) from GSK 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 of the physician's practice or the Related Entity; and (iv) the aggregate value of the Payment(s) in the preceding year(s).

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 a 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 field personnel 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 IRO 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 at least 90 days prior to the end of the IRO Reporting Period, 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 the 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 GSK’s policies;
- c) Whether the aggregate value of the Payment(s) as reflected in the Listing for the sampled Physician is consistent with the

value of the Payments(s) reflected in the Control Documents;  
and

- d) Whether the Control Documents reflect that GSK'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 GSK'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 GSK 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 GSK'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 GSK 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 GSK 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. Similarly, 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 Research and Publications Practices and Authorship-Related Activities

The IRO shall conduct a review and assessment of GSK's Research and Publications Practices and Authorship-Related Activities as described in Sections III.B.3. u-v of the CIA.

Review of Research Activities: GSK shall provide the IRO with a list of all Research activities (as defined in Section III.B.3.u of the CIA) that were "active" (as classified in GSK's tracking system) during the IRO Reporting Period, and the IRO shall select a sample of 40 such activities, which sample shall include a review of each type of Research (*i.e.*, GSK-Sponsored post-marketing clinical trials, other GSK-Sponsored post-marketing studies, and post-marketing investigator-sponsored studies (ISSs).) The IRO shall review samples of each type of Research in proportion to the relative number of each type of Research that occurred during the reporting period. GSK shall provide the IRO with documents relating to the Research activities sufficient for the IRO to conduct the reviews outlined below.

For each sampled Research activity, the IRO will review whether: (i) the activity was approved consistent with GSK's standards, policies, procedures and processes regarding sponsorship or support of Research, including obtaining required approval for the Research by GSK's medical and/or research organizations and ensuring that the Research was conducted for the purpose of fostering increased understanding of scientific, clinical or medical issues; (ii) there is an executed written agreement with the Researcher that meets the requirements of GSK's standards, policies and procedures and, among other things, requires the Researcher to disclose in any publication of Research, GSK's support and any financial interest the researcher may have in GSK; and (iii) GSK's sales, marketing, or other commercial personnel did not participate in the design, conduct, or publication of the Research activity except as permitted under the limited exceptions in GSK's policies and procedures.

Review of Publication Activities:

GSK shall provide the IRO with a list of publication activities (as defined in Section III.M.3 of the CIA) that resulted in publication of data from GSK-Sponsored post-marketing clinical trials or post-marketing studies of Government Reimbursed Products that appeared during the IRO Reporting Period. The list will be broken down into two categories: (i) GSK-Sponsored post-marketing clinical trials, and (ii) other GSK-Sponsored post-marketing studies (*e.g.*, observational studies, health outcomes studies, epidemiology studies, and meta-analyses and pooled analyses.) The IRO shall select a sample from each category for review, in proportion to the relative numbers in each category (collectively, “Reviewed Publication Activities”). The IRO shall review a total of 60 Reviewed Publication Activities. GSK shall provide the IRO with copies of the publications and documents and information relating to each of the Reviewed Publication Activities sufficient for the IRO to conduct the reviews outlined below.

The IRO will assess each of the Reviewed Publication Activities to test whether the Reviewed Publication Activity was conducted in a manner consistent with GSK’s standards, policies, procedures and processes, including those that require: i) posting of summary results from all GSK-Sponsored post-marketing interventional research studies of Government Reimbursed Products on GSK’s Clinical Study Register within a specified periods of time; ii) posting of summaries of study protocols for such research studies in the GSK Clinical Study Register; iii) registration of summary results from applicable GSK-Sponsored clinical trials on the NIH sponsored website in compliance with all Federal requirements; iv) publication (or attempted publication) of the results of GSK-Sponsored post-marketing interventional Research studies in peer-reviewed journals within specified periods of times; and v) compliance with GSK’s operating practices regarding publications relating to GSK-Sponsored post-marketing interventional research studies of Government Reimbursed Products (including standards relating to appropriateness, accuracy, balance, and acknowledgement of GSK’s role as the funding source for the Research).

#### Review of Authorship-Related Activities:

For each of the Reviewed Publication Activities, the IRO shall also assess the activity to test whether the activity was conducted in a manner consistent with GSK’s standards, policies, procedures and processes relating to authorship, including those that require: i) authors of journal articles about GSK-Sponsored Research to adhere to ICMJE authorship requirements (except in instances in which a particular journal requires an alternative procedure); ii) authors of articles on GSK-Sponsored Research to disclose any GSK financial support for the study and any financial relationship with GSK; iii) authors of a GSK publication of GSK-Sponsored Research to make substantial contributions to the study and give final approval to the version of the publication ultimately published;

and iv) certifications from employees and medical writing contractors as to any GSK publication of GSK-Sponsored Research on which the individual is listed as an author or contributor.

#### F. IRO Review of Additional Items

As set forth in Section III.E.1.b of the CIA, for the second through sixth IRO Reporting Periods, the OIG at its discretion may identify up to three additional items for the IRO to review (hereafter “Additional Items”). No later than 150 days prior to the end of the applicable IRO Reporting Period, the OIG shall notify GSK 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 GSK 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 GSK’s systems, processes, policies, and procedures based on its review of each Additional Item).

GSK may propose to the OIG that its internal audit(s) be substituted, subject to the Verification Review requirements set forth below, for one or more of the Additional Items that would otherwise be reviewed by the IRO for the applicable IRO Reporting Period. The OIG retains sole discretion over whether, and in what manner, to allow GSK’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 GSK’s planned internal audit work, the results of the Transactions Review(s) during prior IRO Reporting Period(s), and GSK’s demonstrated audit capabilities to perform the proposed audit work internally. If the OIG denies GSK’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 IRO Reporting Period, GSK shall engage the IRO to perform the Review as outlined in this Section III.

If the OIG agrees to permit certain of GSK’s internal audit work for a given IRO 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 at least 20% of the sampling units reviewed by GSK in its internal audits.

#### G. Transactions Review Report

For each IRO Reporting Period, the IRO shall prepare a report based on its 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 Transactions Review.
- 2) Results to be Included in Report

Consistent with the scope of items reviewed by the IRO for the applicable IRO Reporting Period, the following results shall be included in each Transaction 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 Inquiries 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 Inquiries 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 the Compliance Officer as a result of the Off-Label Review; and any follow-up actions taken by GSK as a result of the Compliance Officer's findings;
- d) the findings and supporting rationale regarding any weaknesses in GSK's systems, processes, policies, procedures, and practices relating to the Inquiries, and the Inquiries Database, if any;
- e) recommendations for improvement in GSK's systems, processes, policies, procedures, and practices relating to the Inquiries and the Inquiries Database, if any;

(Relating to the Target Plan Reviews)

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

relating to GSK's Target Plans or the review of the Target Plans, if any;

- i) recommendations, if any, for changes in GSK's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to Target Plans or the review of the Target Plans;

(Relating to the Sampling Event Reviews)

- j) for each Government Reimbursed Product distributed during the IRO Reporting Period: i) a description of Sample Distribution Policies and Procedures (including whether sales representatives may provide samples for 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 in which it appears that the medical specialty or clinical practice of the HCPs or HCIs that received a sample during a Sampling Event was not consistent with the uses of the product approved by the FDA. This description shall include a description of the process followed by GSK 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 GSK failed to follow its Sample Distribution Policies and Procedures for the Government Reimbursed Product(s) provided during the Sampling Event;
- k) the findings and supporting rationale regarding any weaknesses in GSK's systems, processes, policies, procedures, and practices relating to GSK's distribution of samples of Government Reimbursed Products, if any;
- l) recommendations, if any, for changes in GSK'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 GSK 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 GSK's policies were followed in connection with the underlying activity reflected in the document (e.g., all required approvals were obtained); and (v) disciplinary action was undertaken in those instances in which GSK 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 Research and Publication Practices and Authorship-Related Activities)

- q) a description of each sampled Research activity reviewed, including an identification of the types of documents and information reviewed in connection with each sampled Research activity;
- r) an assessment of whether, for each sampled Research activity: (i) the activity was approved consistent with GSK's standards, policies, procedures and processes regarding sponsorship or support of Research; (ii) there is an executed written agreement with the

Researcher that meets the requirements of GSK's standards, policies and procedures; and (iii) GSK's sales, marketing, or other commercial personnel did not participate in the design, conduct, or publication of the Research Activity except as permitted under GSK's policies and procedures. If a sampled Research activity failed to meet GSK standards, policies, procedures and processes, an explanation of the deficiency;

- s) a description of each Reviewed Publication Activity assessed by the IRO, including an identification of the types of documents and information reviewed in connection with each Reviewed Publication Activity;
- t) an assessment of whether for each Reviewed Publication Activity; i) authors of journal articles about GSK-Sponsored Research adhered to ICMJE requirements; ii) authors of articles about GSK-Sponsored Research disclosed any GSK financial support for the study and any financial relationship with GSK; iii) authors of a GSK publication about GSK-Sponsored Research made substantial contributions to the study and gave final approval to the version of the publication ultimately published; and iv) GSK obtained certifications from employees, medical writing contractors, and outside authors as to any GSK publication of GSK-Sponsored Research on which the individual is listed as an author or contributor;
- u) an assessment of whether for each Reviewed Publication Activity; i) authors of journal articles about GSK-Sponsored Research adhered to ICMJE requirements; ii) authors of articles on GSK-Sponsored Research disclosed any GSK financial support for the study and any financial relationship with GSK; iii) authors of a GSK publication of GSK-Sponsored Research made substantial contributions to the study and gave final approval to the version of the publication ultimately published; and iv) GSK obtained certifications from employees, medical writing contractors, and outside authors as to any GSK publication of GSK-Sponsored Research on which the individual is listed as an author or contributor;
- v) if any Reviewed Publication Activity failed to meet GSK standards, policies, procedures and processes, an explanation of the deficiency;

- w) the IRO's findings and supporting rationale regarding any weaknesses or deficiencies in GSK's systems, processes, policies, procedures, and practices relating to GSK's Research and Publications Practices and Authorship-Related Activities, if any;
- x) recommendations, if any, for changes in GSK's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to Research and Publications Practices and Authorship-Related Activities;

(Relating to the Review of Additional Items)

- y) for each Additional Item reviewed, a description of the review conducted;
- z) for each Additional Item reviewed, the IRO's findings based on its review;
- aa) for each Additional Item reviewed, the findings and supporting rationale regarding any weaknesses in GSK's systems, processes, policies, procedures, and practices relating to the Additional Item, if any;
- bb) for each Additional Item reviewed, recommendations, if any, for changes in GSK's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the review.

**Appendix C to CIA for GlaxoSmithKline LLC**  
**IRO Reviews of GSK’s Targeted Risk Analysis and  
Compliance Evaluation Review (TRACER) Program**

I. General Description of TRACER program

GSK uses the Targeted Risk Analysis and Compliance Evaluation Review process (TRACER) as a tool to evaluate and mitigate promotional risks (hereinafter, “risks”) associated with all prescription Government Reimbursed Products that have field force support in the United States (GSK Products).

*1. Risk Identification and Evaluation*

As part of TRACER, risk information will be solicited from four key sources: (i) Copy Approval Teams; (ii) U.S. Pharma’s Monitoring Control Center of Excellence (CCoE); (iii) Deputy Compliance Officers (DCOs); and (iv) Legal department personnel.

Based on inputs from these sources, a relative risk ranking report will be produced for all GSK Products (Risk Evaluation Report). The Risk Evaluation Report will be presented to the leadership team of each U.S. Pharma commercial business unit (Leadership Team) and the U.S. Pharma Commercial Leadership Team (CLT) along with recommendations regarding which products may require enhanced risk mitigation plans.

The Risk Evaluation Report will also be used by the CCoE to inform the risk-based selection of products as required by the Field Force Monitoring Program described in CIA Section III.L.

*2. Risk Mitigation Plans*

Risk Mitigation Plans (RMPs) will be completed annually for all GSK Products. All RMPs will outline standard risk mitigation activities that will be performed and tracked for each GSK Product, regardless of the product’s relative risk ranking (Standard RMPs). Standard risk mitigation activities will consist of the monitoring activities to be conducted for each GSK Product in the upcoming year, such as monitoring of speaker programs, speaker training, advisory boards, sampling, verbatim reviews, medical information requests and ride-alongs with sales personnel.

Based on the Risk Evaluation Report, products may be selected for Enhanced RMPs by either (or both) the Leadership Teams and the CLT. These RMPs will include enhanced risk mitigation activities, in addition to the standard activities (Enhanced RMPs). Enhanced RMPs will consist of activities tailored to the risks identified during the risk ranking process. For example, such activities may include increased compliance

messaging from Leadership Teams, modifications to or limitations of promotional programs, or enhanced training requirements.

All RMPs (whether Standard or Enhanced) will be developed by brand teams, in consultation with their respective DCOs and the CCoE, on an annual basis. Each RMP will specify the: (i) risk monitoring activities; (ii) metrics by which monitoring activities and results will be evaluated and/or measured; (iii) risk mitigation action items, if necessary; (iv) metrics by which risk mitigation activities and results will be evaluated and/or measured; (v) responsible individual(s); and (vi) expected date(s) of monitoring and/or action item completion. The RMPs will be reviewed and approved by the respective business unit Leadership Teams.

### 3. *Risk Mitigation Plan Tracking*

RMP activities (including risk monitoring activities, risk mitigation activities, and risk mitigation action items) will be tracked by the CCoE and reported using a Monitoring Dashboard which will identify risk monitoring and mitigation activities and track their progress on at least a quarterly basis. The status of the RMPs will be tracked and reported to Leadership Teams and compliance personnel on at least a quarterly basis.

## II. TRACER Reviews, General Description

A. As specified more fully below, GSK shall retain an IRO to assist GSK in assessing and evaluating its systems, processes, policies, procedures, and practices relating to the TRACER program (TRACER Review). The TRACER Review shall consist of two components - a systems review (TRACER Systems Review) and a transactions review (TRACER Transactions Review) as described more fully below. GSK may engage, at its discretion, a single IRO to perform both components of the TRACER Review provided that the entity has the necessary expertise and capabilities to perform both.

B. If there are no material changes in GSK's systems, processes, policies, and procedures relating to TRACER, the IRO shall perform the TRACER Systems review for the second and fifth IRO Reporting Periods. If GSK materially changes its systems, processes, policies, and procedures relating to TRACER, the IRO shall perform a TRACER Systems Review for the IRO Reporting Period(s) in which such changes were made in addition to conducting the Systems Review for the second and fifth IRO Reporting Periods. The additional TRACER 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 TRACER Transactions Review for second through sixth IRO Reporting Periods of the CIA.

### III. TRACER Systems Review

#### A. The TRACER Systems review shall consist of the following:

1. A review of the processes by which GSK develops and evaluates Risk Evaluation Reports and develops Standard and Enhanced RMPs, including the sources of information (e.g., the individual personnel, departments or functional areas, and/or any systems involved) used to compile the Reports and RMPs; the types of underlying data and information that are considered or evaluated during the development of the Risk Evaluation Reports and the RMPs; and the timing for development of Risk Evaluation Reports and the RMPs (including modifications to the Reports or RMPs in the event of significant new developments);
2. An assessment of whether, in developing the Risk Evaluation Reports and the RMPs: i) additional or different sources of information; ii) additional or different types of data or information; and iii) additional or different timing cycles should be utilized;
3. A review of the experience and background of the brand directors responsible for development of the RMPs and an assessment of the completeness and appropriateness of the training, policies, procedures, standard operating procedures, and guidance such individuals receive regarding the development of the RMPs;
4. An assessment of whether the standard risk mitigation activities (monitoring activities) included in RMPs are designed to: (i) adequately monitor all relevant identified risks; (ii) identify any actual problems that have occurred in connection with the identified potential risk; and/or (iii) ensure that the activity associated with an identified risk does not occur in the future;
5. An assessment of whether standard risk mitigation activities (monitoring activities) that may be included in RMPs should be: (i) enhanced, revised, or refined; (ii) changed to include additional or different mitigation/monitoring options to be considered based upon specific identified risks; (iii) tracked and reviewed more frequently than prescribed by current policies to ensure that the options address all relevant risks for the specific products reviewed;

6. An assessment of whether enhanced risk mitigation activities and risk mitigation action items (and options for such activities) included in Enhanced RMPs are designed to: (i) adequately address all relevant identified risks; (ii) identify any actual problems that have occurred in connection with the identified potential risk; and/or (iii) ensure that the activity associated with an identified risk does not occur in the future;
7. An assessment of whether enhanced risk mitigation activities that may be included in RMPs should be: (i) enhanced, revised, or refined; (ii) changed to include additional or different mitigation/monitoring options to be considered based upon specific identified risks; (iii) tracked and reviewed more frequently than prescribed by current policies to ensure that the options address all relevant risks for the specific products reviewed; and
8. A review of the systems, policies, procedures, and processes (including the Monitoring Dashboard and any narrative supplements) by which GSK tracks and manages RMP activities and an assessment of whether the systems, policies, procedures and processes ensure that the RMPs are appropriately implemented (including by identifying individuals responsible for the follow-up or action items).

B. The IRO shall prepare a report based upon each Systems Review performed (System Review Report). The Systems Review Report will include the IRO's findings, recommendations, observations, and comments on items 1-8 above and, to the extent not otherwise addressed, an assessment of the following: (i) whether the Risk Evaluation Reports and RMPs identify and prioritize relevant risks; (ii) whether the risk monitoring activities, risk mitigation activities and any risk mitigation action items identified in RMPs address identified risks; (iii) whether sufficient controls exist to ensure that all risk mitigation steps (including monitoring activities and risk mitigation activities) are completed in accordance with the RMPs; iv) whether the options for risk monitoring activities and risk mitigation activities identified in the RMPs address and potentially mitigate identified risks; and (iv) whether sufficient controls exist to ensure that all agreed-upon risk monitoring activities and risk mitigation activities are completed in accordance with the RMPs.

#### IV. TRACER Transactions Review

A. At least thirty (30) days prior to the end of the second through sixth IRO Reporting Periods, GSK shall submit to OIG a list of all GSK Products for which RMPs were developed. GSK shall notify the OIG about which products had Standard RMPs and which products had Enhanced RMPs. Prior to the end of the applicable IRO

Reporting Period, OIG shall select 3 GSK Products (each a “Selected Product” and together the “Selected Products”) to be reviewed in connection with the TRACER Transactions Review.

B. For each IRO Reporting Period and for each Selected Product, the IRO shall conduct a review of: i) the applicable Risk Evaluation Report entry and RMP; ii) documents and materials related to the development of the RMP; and iii) documents and materials relating to the implementation of the RMP (including the Monitoring Dashboard and any supplements to the Scorecard). The IRO shall also interview the brand team director responsible for the development of the RMP and the individual(s) responsible for the implementation of the risk monitoring and risk mitigation activities specified in the RMP.

The objective of the IRO shall be to: (i) understand the processes followed by GSK in developing the RMP for each Selected Product, including the underlying bases for GSK’s decision to develop either a Standard RMP or an Enhanced RMP for the Selected Product; (ii) determine whether, based on the information contained in the Risk Evaluation Report, an appropriate RMP (including as to the included risk monitoring activities, risk mitigation activities, and risk mitigation action items) was developed for the Selected Product; and (iii) assess GSK’s implementation and tracking of the implementation of the RMP for the Selected Product.

C. The IRO will prepare a report based on each TRACER Transactions Review performed (Transactions Review Report). The Transactions Review Report shall include the following:

1. an identification of the 3 Selected Products and a description of the documents and information reviewed in connection with each Selected Product, including a description of whether the RMP for each Selected Product was a Standard RMP or an Enhanced RMP,
2. for each Selected Product, a description of: i) the process followed in developing the RMP; and ii) the types of identified risks associated with the Selected Product;
3. for each Selected Product, an assessment of whether it was appropriate for GSK to develop, as applicable, an Enhanced or a Standard, RMP for the product;
4. for each Selected Product, an assessment of whether, based on the information contained in the Risk Evaluation Report, an appropriate RMP was developed for the Selected Product;

5. for each Selected Product, a description of the expertise and backgrounds of the brand directors who were responsible for the development of the RMP;
6. for each Selected Product, a description of the following items set forth in the RMP: (i) risk monitoring activities; (ii) metrics by which the risk monitoring activities and results will be evaluated and/or measured; (iii) risk mitigation activities, including any risk mitigation action items; (iv) metrics by which the risk mitigation activities and results will be evaluated and/or measured; (v) responsible individual(s); (vi) expected date(s) of completion for each risk monitoring activity and risk mitigation activity; and (vii) if the RMP did not specify each of the items set forth above, a description of any deficiencies;
7. for each Selected Product, a description of whether risk monitoring activities specified in the RMP were implemented and tracked in accordance with the RMP and GSK's policies and procedures, and a description of any deficiencies;
8. for each Selected Product, a description of whether risk mitigation activities (including any action items) specified in the RMP were implemented and tracked in accordance with the RMP and GSK's policies and procedures, and a description of any deficiencies;
9. for each Selected Product a description of: (i) any recommendations made by the IRO regarding the RMP or any risk monitoring activities and risk mitigation activities included in the RMP; (ii) whether, and in what manner, GSK implemented the recommendations from the IRO; and (iii) if GSK did not implement the IRO recommendations, a description of the rationale for GSK's decision not to implement the recommendations; and
10. the IRO's findings and supporting rationale regarding any weaknesses or deficiencies in GSK's systems, processes, policies, procedures, and practices relating to the TRACER program, if any; and recommendations, if any, for changes in GSK'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 TRACER program.

## **Appendix D to CIA for GlaxoSmithKline LLC**

### **Global Manufacturing and Supply-Related Provisions**

#### **I. PREAMBLE**

Prior to the Effective Date of the CIA (as defined below), GSK and its Affiliates established a voluntary compliance program applicable to the Global Manufacturing and Supply business unit (GMS Compliance Program). GMS has responsibility for the compliance function at the manufacturing facility located in Zebulon, North Carolina (Zebulon) and at manufacturing facilities worldwide. GMS employees at Zebulon are responsible for the release and post-release management of all Covered Products (defined below in Section II.C.3) distributed in the United States that are either manufactured at the Zebulon site or manufactured at other manufacturing facilities operated by GMS and located outside of the United States.

The GMS Compliance Program includes a GMS Compliance Officer and a GMS Compliance Committee. The GMS Compliance Program also includes a Code of Conduct (as described in Section III.B.1 of the CIA), written policies and procedures, educational and training initiatives, a Disclosure Program that allows for the confidential disclosure and investigation of potential compliance violations and disciplinary procedures, screening measures for Ineligible Persons, and internal auditing procedures. GSK shall continue the GMS Compliance Program throughout the term of this Appendix and shall do so in accordance with the terms set forth below. GSK may modify its GMS Compliance Program as appropriate, but, at a minimum, GSK shall ensure that during the term of this Appendix, it shall comply with the obligations set forth in this Appendix.

#### **II. TERM AND SCOPE OF THIS APPENDIX**

A. Unless otherwise specified, the period of the compliance obligations assumed by GSK and its Affiliates under this Appendix D shall be five reporting periods, as defined below. The “Effective Date” shall be the date on which the final signatory of the CIA executes the CIA. The first Reporting Period shall be from the Effective Date through December 31, 2013. The second and subsequent Reporting Periods shall be from January 1 through December 31 of each of the subsequent four calendar years.

B. Sections III.D of this Appendix to the CIA and sections VII, X, and XI of the CIA shall expire no later than 120 days after OIG’s receipt of: (1) GSK’s final Annual Report with respect to this Appendix; or (2) any additional materials submitted by GSK pursuant to OIG’s request, whichever is later.

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

1. “Manufacturing Covered Persons” includes:

- a. President, Global Manufacturing and Supply;
- b. All members of the GMS Executive Team;
- c. Senior Vice President of GMS Quality;
- d. All members of the Quality Executive Team (QET);
- e. All “above-site” employees with a direct reporting line into a QET member, and whose responsibilities include managing GMS employees that directly support cGMP Activities at the Covered Manufacturing Facility(ies);
- f. The Site Quality Director at the Covered Manufacturing Facility(ies);
- g. All GSK employees at the Covered Manufacturing Facility(ies) who are engaged in cGMP Activities;
- h. Senior Vice President of GMS Pharma Operations;
- i. All above-site employees with a direct reporting line to the Senior Vice President of Pharma Operations whose responsibilities include managing manufacturing operations at the Covered Manufacturing Facility(ies);
- j. With respect to GMS manufacturing facilities (other than a Covered Manufacturing Facility) located in the United States that manufacture and/or release drug products for distribution in the United States, the Site Director, the Site Quality Director, and any employee who is directly responsible for authorizing the release for distribution of drug products at such GMS manufacturing facilities;
- k. With respect to GSK vaccines manufacturing facilities (other than a Covered Manufacturing Facility) located in the United States that manufacture and/or release vaccines for distribution in the United States, the Site Director, the Site Quality Director and any employee who is directly responsible for authorizing the release for distribution of vaccines at such vaccines manufacturing facilities;
- l. Any GSK employee at a distribution center located in the United States that is operated by or on behalf of GSK who is directly responsible for authorizing the release for distribution of drug products or vaccines from such distribution center; and
- m. Any contractor, subcontractor, agent or other person whose normal place of work is a Covered Manufacturing Facility(ies) and whose day-to-day responsibilities directly relate to cGMP Activities.

Notwithstanding the above, this term does not include employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per calendar year, except that any such individuals shall become “Manufacturing Covered Persons” at the point when they work more than 160 hours during the calendar year.

2. “cGMP Activities” means activities directly related to ensuring compliance with current Good Manufacturing Practice (cGMP) requirements contained in the Federal Food, Drug, and Cosmetic Act and applicable regulations (collectively “cGMP Requirements”), to submitting cGMP-related reports and information to the FDA, and/or responding to FDA inspectional observations or other correspondence, including correspondence regarding cGMP Requirements.

3. “Covered Products” means prescription drug products sold by GSK that are reimbursed by a Federal health care program and that are manufactured at a GSK facility and released by a Covered Manufacturing Facility (as defined below in Section II.C.4) or any other GSK facility for distribution into the United States. Vaccines are not Covered Products.

4. “Covered Manufacturing Facility” means the GSK facility in Zebulon, North Carolina, and subject to Section IV.A, any other GSK facility that after the Effective Date of this CIA and Appendix, manufactures, or is responsible for the release of Covered Products in the United States.

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

To the extent not accomplished prior to the Effective Date, GSK shall establish and maintain a GMS Compliance Program that includes the following elements:

#### **A. Compliance Officer and GMS Compliance Committee**

1. *Compliance Officer.* Prior to the Effective Date, GSK appointed an individual to serve as a Compliance Officer for its GMS business unit (GMS Compliance Officer) and GSK shall maintain a GMS Compliance Officer for the term of this Appendix. The GMS Compliance Officer shall be responsible for overseeing the development and implementation of policies, procedures, and practices designed to ensure compliance with the requirements set forth in this Appendix relating to cGMP Activities, with applicable Federal health care program requirements and applicable FDA requirements. The GMS Compliance Officer shall be a member of senior management of GMS, and shall report directly to the Senior Vice President for Governance, Ethics and Assurance of GlaxoSmithKline PLC, who, in turn reports to the Chief Executive Officer of GlaxoSmithKline PLC. The GMS Compliance Officer shall make periodic (at least quarterly) reports regarding GMS compliance matters related to this Appendix to the Board of Directors (or an authorized committee thereof) of GlaxoSmithKline PLC

(hereinafter, “the Board”), and shall be authorized to report on such matters to the Board at any time. The GMS Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The GMS Compliance Officer shall be responsible for oversight of the day-to-day compliance activities engaged in by GMS as well as for any reporting obligations created under this CIA. Any noncompliance job responsibilities of the GMS Compliance Officer shall be limited and must not interfere with the GMS Compliance Officer’s ability to perform the duties outlined in this CIA.

GSK shall report to OIG, in writing, any changes in the identity of the GMS Compliance Officer, or any actions or changes that would affect the GMS Compliance Officer’s ability to perform the duties necessary to meet the obligations in this Appendix, within 5 days after such a change.

2. *GMS Compliance Committee.* Prior to the Effective Date, GMS established a GMS Compliance Committee. The GMS Compliance Committee includes the GMS Compliance Officer and other members of GMS senior management necessary to meet the requirements of this Appendix. The GMS Compliance Officer shall co-chair the GMS Compliance Committee with the GMS President. The GMS Compliance Committee shall support the GMS Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the GMS’s cGMP risk areas and shall oversee monitoring of internal and external audits and investigations related to cGMP Requirements). The GMS Compliance Committee shall meet at least quarterly.

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

3. *Board of Directors Compliance Obligations.* The Board shall be responsible for the oversight of matters related to compliance with cGMP Activities, applicable Federal health care program requirements, applicable FDA requirements, and the obligations of this Appendix.

The Board shall, at a minimum, be responsible for the following:

- a. meeting at least quarterly to review and oversee GMS’s Compliance Program, including but not limited to the performance of the GMS Compliance Officer and other GMS compliance personnel;
- b. for each Reporting Period of this Appendix, adopting a resolution, signed by each member of the Board summarizing its review and oversight of GMS’s compliance with cGMP Activities, applicable Federal health care program

requirements, applicable FDA requirements, and the obligations of this Appendix.

At minimum, the resolution shall include the following language:

“The Board of Directors has made a reasonable inquiry into the operations of the GMS Compliance Program for the time period [insert time period], including the performance of the GMS Compliance Officer. The Board has concluded that, to the best of its knowledge, GSK has implemented an effective Compliance Program, including a program that is effective to meet applicable Federal health care program requirements, applicable FDA requirements, and the obligations of this Appendix D to the CIA.”

If the Board is unable to provide such a conclusion in the resolution, the Board 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 implement an effective GMS Compliance Program.

GSK shall report to the OIG, in writing, any changes in the composition of the Board, or any actions or changes that would affect the Board’s ability to perform the duties necessary to meet the obligations in this Appendix, within 15 days after such change.

**B. Written Standards**

*Code of Conduct.* Prior to the Effective Date, GSK developed and adopted a written Code of Conduct (as described in Section III.B.1 of the CIA).

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

As provided in Section III.B of the CIA, GSK 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 to Manufacturing Covered Persons within 30 days to after any revisions are finalized. Each Manufacturing 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.

1. *Policies and Procedures.* Prior to the execution of the CIA, GSK implemented written Policies and Procedures regarding the operation of its GMS Compliance Program. Within 120 days after the Effective Date, GMS shall implement written procedures regarding any additional Compliance Program requirements outlined in this Appendix D. To the extent not already accomplished, within 120 days after the Effective Date, GMS 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 of the CIA; and
- b. disciplinary policies and procedures for violations of the Company's Policies and Procedures, including policies relating to cGMP Activities and FDA requirements relating to cGMP Activities.

To the extent not already accomplished, within 120 days after the Effective Date, the Policies and Procedures shall be made available to all Manufacturing Covered Persons. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), GSK shall assess and update the Policies and Procedures, as necessary. Within 30 days after the effective date of any revisions, any such revised Policies and Procedures shall be made available to all Manufacturing Covered Persons.

### C. Training and Education

GSK represents that it provides training on a regular basis concerning a variety of topics directly related to cGMP Activities. The training required by this Appendix need not be separate and distinct from the regular training provided by GSK to Manufacturing Covered Persons. At GSK's option, the training required by this Appendix may be integrated into the regular training provided by GSK.

1. *General Training.* Within 120 days after the Effective Date, GMS shall provide at least one hour of General Training to each Manufacturing Covered Person. This training, at a minimum, shall explain:

- a. The requirements of this Appendix D to the CIA; and

- b. GMS's Compliance Program, including the Company's Code of Conduct.

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

*Board Member Training.* The training required by Section III.C.4 of the CIA shall include training on the obligations set forth in this Appendix.

2. *Certification.* Each individual who is required to receive training shall certify, in writing, or in electronic form, if applicable, that he or she has received the required training and the date upon which the training was completed. The GMS Compliance Officer (or designee) shall retain the certifications, along with all course materials.

3. *Qualifications of Trainer.* Persons providing the training shall be knowledgeable about the subject area, including about FDA requirements relating to cGMP Activities.

4. *Update of Training.* GMS shall review the content of each training program required by this Appendix annually and update the content of each training program, where appropriate, to reflect any material changes to cGMP requirements, changes to applicable Federal health care program requirements, FDA requirements, and any issues observed during internal audits.

5. *Computer-based Training.* GMS may provide the training required under this Appendix through appropriate computer-based training approaches. If GMS 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 individuals receiving such training. All applicable requirements to provide a number of "hours" of training as set forth 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. cGMP Requirements

1. In addition to existing FDA authorities and remedies, GSK agrees to certain obligations under this Appendix relating to cGMP Requirements for GSK drug products and vaccines. These provisions are in addition to other remedies available to the FDA.

2. If the Director of Compliance at FDA's Center for Drug Evaluation and Research (CDER), or in the case of a vaccine, the Director of Compliance at FDA's Center for Biologics Evaluation and Research (CBER) determines that a GSK facility (or facilities) manufacturing, processing, packing, or holding a GSK drug product or vaccine is not compliant with cGMP Requirements, FDA may so notify the OIG and recommend that OIG direct GSK to undertake a Specified Action as set forth below in section III.D.3 of this Appendix.

3. If, after reviewing FDA's notification and recommendation, OIG agrees that GSK should be directed to undertake a Specified Action as set forth in section III.D.3 of this Appendix, OIG shall notify GSK in writing of its determination and direct GSK to undertake one or more of the following actions (Specified Actions):

- a. Submit a report or information addressing the assertion of non-compliance to FDA and OIG within 10 days after the date of written notification from the OIG in accordance with the Notification provision in section III.D.4 below;
- b. In the event that OIG and/or FDA request additional or follow-up information, GSK shall submit revised, modified, or expanded report(s) or plan(s) to FDA and OIG in accordance with time frames established by the OIG and FDA; and/or
- c. Initiate a recall of the GSK drug product or vaccine in accordance with the instructions and time frames specified by OIG and FDA.

4. All notifications and reports required under this Section III.D shall be submitted to the following:

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

FDA

Division of Manufacturing and Product Quality  
HFD-320  
Center for Drug Evaluation and Research  
10903 New Hampshire Avenue  
White Oak Bldg. 51  
Silver Spring, MD 20993

GSK

Guy Wingate  
Vice President - GMS Compliance Officer  
GlaxoSmithKline  
GSK House (Mailstop BNG-15)  
980 Great West Road  
Brentford  
Middlesex  
TW8 9GS  
United Kingdom

Paul Noll  
Vice President - Associate General Counsel  
Legal Operations - Global Manufacturing and Supply  
GlaxoSmithKline  
Five Moore Drive  
Ruvane Building - Mailstop E.3334  
Research Triangle Park, NC 27709

5. Within 10 days after receiving notification from the OIG of a Specified Action to be taken, GSK shall notify OIG and FDA in writing either:
- a. that GSK is undertaking or has undertaken the Specified Action, in which event GSK also shall describe the Specified Action taken or to be taken and the schedule for completing the action; or
  - b. that GSK does not agree with the OIG's determination that it failed to comply with cGMP Requirements and/or that the Specified Action is appropriate.

6. If GSK notifies OIG and FDA that it does not agree with the determination that it failed to comply with cGMP Requirements or that the Specified Action is appropriate:

- a. GSK shall explain in writing the basis for its disagreement; in so doing, GSK also may propose specific alternative actions and specific time frames to be substituted for the Specified Action required under this Section III.D.
- b. FDA shall review GSK's notification and thereafter, in writing, make a recommendation to OIG that OIG affirm, modify, or withdraw its proposed Specified Action.

7. Based on the advice of the FDA, OIG shall decide whether the determination that GSK failed to comply with cGMP Requirements and/or the proposed Specified Action shall be affirmed, modified, or withdrawn and shall provide written notice (Final Determination) to GSK of the Specified Action to be taken or of the withdrawal of the Specified Action. GSK shall, upon receipt of the notification of Final Determination, immediately implement the Final Determination.

8. GSK's failure to implement that Specified Action shall be the basis for Stipulated Penalties and or Material Breach Penalties under Section X of the CIA.

E. Manufacturing Reportable Events

1. *Definition of Manufacturing Reportable Event.* For purposes of this Appendix, a "Manufacturing Reportable Event" means conduct related to a Covered Manufacturing Facility or Covered Product that involves:

- a. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to cGMP Activities; or
- b. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a of the CIA;

A Manufacturing Reportable Event may be the result of an isolated event or a series of occurrences. A Manufacturing Reportable Event does not include the following:

- a. Field Alert Reports submitted to FDA and related correspondence;

- b. Observations contained in FDA 483 Reports, GSK's responses to those observations and any related correspondence;
- c. Drug Quality Reporting System (DQRS) reports submitted to FDA and any related correspondence;
- d. Reports submitted to FDA relating to suspected or known counterfeit products and any related correspondence; and
- e. GSK Annual Product Reports for marketed products submitted to FDA and any related correspondence.

2. *Reporting of Manufacturing Reportable Events.* If GSK determines (after a reasonable opportunity to conduct an appropriate review or investigation) through any means that there is a Manufacturing Reportable Event, GSK shall, notify OIG in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Manufacturing Reportable Events under Section III.E.1.a-b.* For Manufacturing Reportable Events under Sections III.E.1.a-c, the report to OIG shall include:

- a. a complete description of the Manufacturing Reportable Event, including the relevant facts and persons involved and the legal authorities implicated;
- b. a description of GSK's actions taken to correct the Manufacturing Reportable Event; and
- c. any further steps GSK plans to take to address the Manufacturing Reportable Event and prevent it from recurring.

#### F. Reporting of Certain Events

If GSK voluntarily initiates a recall of a Covered Product manufactured at and/or released by either a Covered Manufacturing Facility or other GSK manufacturing facility located in the United States and that has been distributed in the United States, GSK shall notify OIG in writing within 5 days after initiating the recall.

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

Change of Status of a Covered Manufacturing Facility. In the event that, after the Effective Date, a new GSK facility located in the United States other than, or in

addition to, the Zebulon, North Carolina facility, manufacturers and/or releases for distribution in the United States Covered Products sold by GSK that are reimbursed by Federal health care programs, such facility may become a Covered Manufacturing Facility subject to the terms described below. As of the date that such new facility commences manufacture and/or release of a Covered Product, the Site Director, the Site Quality Director and all employees who are directly responsible for the release of Covered Products for distribution in the United States shall become Manufacturing Covered Persons. GSK shall have thirty (30) days to determine whether such new facility will continue to release Covered Products for distribution in the United States independently of the Zebulon, North Carolina facility. If, within the thirty (30) day period, GSK decides that such new facility will continue to release Covered Products independently of the Zebulon, North Carolina facility, then such facility shall become a Covered Manufacturing Facility and employees listed in Section II.C.1 of this Appendix shall be Manufacturing Covered Persons. If, within the thirty (30) day period, GSK determines that Covered Products manufactured at the new facility will be released under the supervision of the Zebulon, North Carolina facility, then such new facility shall not become a Covered Manufacturing Facility. In such event, the Site Director, the Site Quality Director and all employees at the facility who are directly responsible for authorizing the release of Covered Products for distribution in the United States shall be Manufacturing Covered Persons. GSK shall notify the OIG about the new Covered Manufacturing Facility in accordance with the timeframes specified in Section IV of the CIA.

## **V. IMPLEMENTATION AND ANNUAL REPORTS**

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

1. the name, address, phone number, and position description of the GMS Compliance Officer required by Section III.A of this Appendix, and a summary of other noncompliance job responsibilities the GMS Compliance Officer may have;
2. the names and positions of the members of the GMS Compliance Committee required by Section III.A.2 of this Appendix;
3. the names of the members of the Board of Directors referenced in Section III.A.3 of this Appendix;
4. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1 of this Appendix, the percentage of individuals

who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG upon request);

5. a summary of all Policies and Procedures required by Section III.B of this Appendix (copies of the Policies and Procedures shall be made available to OIG upon request);

6. the following information regarding each type of training required by Section III.C of this Appendix:

- 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 individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

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

7. A description of GSK's corporate structure as it relates to GMS and cGMP Activities; and

8. the certifications required by Section V.C of this Appendix.

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

Each Appendix Annual Report shall include, at a minimum:

1. Any change in the identity, position description, or other noncompliance job responsibilities of the GMS Compliance Officer, any changes in the membership of the GMS Compliance Committee, and any changes in the membership of the Board as described in Section III.A of this Appendix;

2. The Board resolution required by Section III.A.3 of this Appendix;

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

4. A summary of any significant changes or amendments to the Policies and Procedures required by Section III.B of this Appendix and the reasons for such changes.

5. The following information regarding each type of training required by Section III.C of this Appendix:

- a. a description of the initial and annual training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and
- b. the number of individuals required to complete the initial and annual training, the percentage of individuals who actually completed the initial and annual training, and an explanation of any exceptions.

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

6. A copy of any recall notices issued during the Reporting Period by GSK for Covered Products sold in the United States, a description of GSK's corrective action(s) taken related to the recall, and any further steps GSK plans to take related to the recall.

7. A summary of Manufacturing Reportable Events (as defined in Section III.E) identified during the Reporting Period and the status of any corrective action relating to each such Reportable Events;

8. A description of any changes to GSK's corporate structure as reported pursuant to Section V.A.7 of this Appendix D and an identification of any Covered Manufacturing Facility, if any, in lieu of or in addition to the Zebulon facility;

9. The certifications required by Section V.C.

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

C. Certifications. The Appendix Implementation Report and each Appendix Annual Report shall include a certification by the GMS Compliance Officer that:

1. to the best of his or her knowledge, except as otherwise described in the report, GMS is in compliance in all material respects with cGMP Requirements and all of the requirements of this CIA; and

2. 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.

D. Designation of Information. GSK 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. GSK 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 Appendix D 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

GSK:

Guy Wingate  
Vice President - GMS Compliance Officer  
GlaxoSmithKline  
GSK House (Mailstop BNG-15)  
980 Great West Road  
Brentford  
Middlesex  
TW8 9GS  
United Kingdom  
Telephone: +44-1833-693330  
Facsimile: +44-2080-476905

Paul Noll  
Vice President - Associate General Counsel  
Legal Operations - Global Manufacturing and Supply  
GlaxoSmithKline  
Five Moore Drive  
Ruvane Building - Mailstop E.3334  
Research Triangle Park, NC 27709  
Telephone: (919) 483-2444  
Facsimile: (919) 483-2881

Unless otherwise specified, all notifications and reports required by this Appendix 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, GSK may be required to provide OIG with an electronic copy of each notification or report required by this Appendix to the CIA in searchable portable document format (pdf), in addition to a paper copy.

## **Appendix E to CIA for GlaxoSmithKline LLC**

### **Executive Financial Recoupment Program**

**Executive Financial Recoupment Program.** Through its Existing Commitments and the New Commitments to be implemented, GSK shall establish and maintain throughout the term of the CIA a financial recoupment program that puts at risk of forfeiture and recoupment an amount equivalent to up to 3 years of annual performance pay (*i.e.*, annual bonus, plus long term incentives) for an executive who is discovered to have been involved in any significant misconduct (Executive Financial Recoupment Program). This financial recoupment program shall apply to Covered Executives, as defined below in Paragraph B, who are either current GSK employees or who are former GSK employees at the time of a Recoupment Determination.

(A) **Existing Commitments.** The annual cash bonus for each GSK employee based in the United States and the United Kingdom is at risk of forfeiture in the event of employee misconduct that is discovered by GSK before the bonus is paid. In the event of misconduct by any GSK employee worldwide, GSK also has reserved the right and full discretion to void and forfeit any unvested share options and any unvested restricted share grants under the GSK Share Option Plan, Share Value Plan and Performance Share Plan (collectively, the “LTI Plans”). If GSK discovers any employee misconduct that would implicate the forfeitures described in this paragraph, it shall evaluate the situation and make a determination about whether any forfeiture, and the terms of such forfeiture, shall be implemented.

(B) **New Commitments.** In addition to the compensation forfeiture provisions already in place with respect to annual bonuses and the LTI Plans, within 120 days after the Effective Date of the CIA, GSK shall modify and supplement its annual bonus plan and LTI Plan requirements (and any employment agreements, as appropriate) by imposing the following eligibility and repayment conditions on future bonuses and LTI Plan grants, as well as establishing the mandatory deferred annual bonus, tolling remedy, and additional remedies discussed below (collectively, “New Commitments”) to all members of GSK’s Corporate Executive Team (CET) and to any Vice Presidents and Senior Vice Presidents in Grades 0, 1, and 2 who are based in the United States (collectively “Covered Executives”). The New Commitments shall apply prospectively to Covered Executives beginning with the 2013 bonus plan year and LTI Plan grants.

(i) **Executive Bonus Eligibility and Repayment Conditions.** GSK shall implement an eligibility and repayment condition on annual bonuses designed to survive both the payment of the bonus and the separation of a Covered Executive’s employment. This will allow GSK, as a consequence of a Triggering Event as defined below in Paragraph C, to pursue repayment from the Covered Executive of all or any portion of the bonus monies paid to the Covered Executive. To the extent permitted by

controlling law, these bonus eligibility and repayment conditions will survive the payment of the Covered Executive's bonus and the separation of the Covered Executive's employment for a period of 3 years from the payment of the bonus for the plan year.

Consistent with a Recoupment Determination, as defined below in Paragraph D, GSK shall endeavor to collect repayment of any bonus from the Covered Executive through reasonable and appropriate means according to the terms of its bonus plan (or executive contract, as the case may be), and to the extent permitted by controlling law of the relevant jurisdiction. If necessary to collect the repayment, GSK shall file suit against the Covered Executive unless good cause exists not to do so. For purposes of the Executive Financial Recoupment Program, good cause shall include, but not be limited to, a financial inability on the part of the Covered Executive to repay any recoupment amount or GSK's inability to bring such a suit under the controlling law of the relevant jurisdiction.

(ii) **LTI Plans.** Prior to the Effective Date, GSK implemented a recoupment process for Covered Executives' unvested LTI share grants as discussed in Paragraph A (Existing Commitments) above. With respect to current GSK Covered Executives, GSK shall maintain these Existing Commitments and follow the Recoupment process and procedures established by the Recoupment Committee for the duration of the CIA. GSK shall also implement an eligibility and repayment condition on share grants made under LTI Plans designed to survive the separation of a Covered Executive's employment.

To the extent necessary, GSK shall implement an eligibility and repayment condition on grants made under the LTI Plans in order to clarify that, as a consequence of a Triggering Event, GSK may pursue repayment by a Covered Executive who is a former employee of all or any portion of the last 3 years' worth of share option and restricted share grants that became vested and were paid during the Covered Executive's last years of employment and following termination of employment.

To the extent permitted by controlling law, these eligibility and repayment conditions shall survive vesting and payment for a period of 3 years from the Covered Executive's employment termination date. In addition, GSK shall amend the vesting schedule in the LTI Plans so that Covered Executives who are "good leavers" (e.g., terminating employment due to retirement, death or disability) will no longer vest in, nor receive a distribution of, any unvested share options or restricted shares immediately following termination of employment; rather, these LTI Plan grants will only vest and be distributable after the first anniversary of the Covered Executive's termination of employment. Consistent with a Recoupment Determination, GSK shall endeavor to collect repayment of these LTI Plan awards from the Covered Executive through reasonable and appropriate means and to the extent permitted by controlling law of the jurisdiction in which the Covered Executive works. If necessary to collect the

repayment, GSK shall file suit against the Covered Executive unless good cause exists not to do so.

(iii) **Mandatory Deferred Annual Bonus.** GSK shall establish a deferred compensation plan that requires the deferral of ten (10%) percent of a Covered Executive's annual bonus (twenty-five (25%) percent, in the case of CET members) for a 3-year period that survives separation of the Covered Executive's employment. Bonuses deferred under the plan shall be matched on a dollar-for-dollar basis by GSK. Consistent with a Recoupment Determination, all deferred bonuses, matching contributions and any related gains thereon are subject to forfeiture and voidance as a consequence of a Triggering Event.

(iv) **Tolling Remedy.** To the extent permitting by controlling law, for the 3 years during which the bonus eligibility and repayment conditions exist, if GSK reasonably anticipates that a Triggering Event has occurred pursuant to Paragraph C, and GSK has recoupment rights remaining under Paragraphs B(i) and B(ii), GSK shall have the right to notify the Covered Executive that those rights shall be tolled and thereby extended for an additional 3 years or until the Recoupment Committee determines that a Triggering Event has not occurred, whichever is earlier, to the extent permitted by controlling law of the relevant jurisdiction.

(v) **Additional Remedies.** If, after expiration of the time period specified in Paragraphs B(i)-(iii) above, the Recoupment Committee determines that a Triggering Event occurred, GSK shall make a determination as to whether to pursue available remedies (*e.g.*, filing suit against the Covered Executive) existing under statute or common law to the extent available.

(C) **Definition of Triggering Events.** The eligibility and repayment conditions described above shall be triggered upon a Recoupment Determination that finds:

(i) significant misconduct (*e.g.*, violation of a significant GSK policy, or regulation, or law) by the Covered Executive that, if discovered prior to payment, would have made the Covered Executive ineligible for an annual bonus, bonus deferral or LTI Plan grant in that plan year or subsequent plan years; or

(ii) significant misconduct by subordinate employees in the business unit over which the Covered Executive had responsibility that does not constitute an isolated occurrence and which the Covered Executive knew or should have known was occurring that, if discovered prior to payment, would have made the Covered Executive and/or employees in question ineligible for an annual bonus, bonus deferral or LTI Plan grant in that plan year or subsequent plan years.

(D) **Administration of Recoupment Program.** GSK shall engage in a standardized, formal process to determine, in its sole discretion, whether a Triggering Event has occurred, and, if so, the extent of bonus monies, LTI Plan grants and deferred compensation that will be subject to repayment or forfeiture by the Covered Executive, and the most appropriate method for securing recoupment of relevant monies previously paid to a Covered Executive. The findings and conclusions resulting from this process shall be referred to as the “Recoupment Determination”.

(i) **Initiation.** GSK shall initiate the Recoupment Determination process upon: (1) discovery of potential significant misconduct that may rise to the level of a Triggering Event, or (2) written notification by a United States federal government agency to the Senior Vice President for Governance, Ethics, and Assurance of GlaxoSmithKline PLC of a situation that may rise to the level of a Triggering Event and either occurred in the United States or gives rise to liability relating to Federal healthcare programs. This written notification shall either identify the Covered Executive(s) potentially at issue or provide information (*e.g.*, a description of the alleged misconduct and the applicable time period) to allow GSK to identify the Covered Executive.

(ii) **Recoupment Committee.** The Recoupment Determination shall be made by a committee of senior executives headed by the Senior Vice President for Governance, Ethics, and Assurance of GlaxoSmithKline PLC (Recoupment Committee). With respect to members of the CET, a Recoupment Determination shall be subject to ratification by the Board of Directors (or appropriate committee thereof) of GlaxoSmithKline PLC.

(iii) **Timeline for Recoupment Determination Process.** GSK shall initiate the Recoupment Determination process within 30 days after discovery by GSK or notification, pursuant to Paragraph D(i), of a potential Triggering Event. Absent extraordinary reasons, GSK shall reach a Recoupment Determination within 90 days after initiation of the determination process.

In connection with making its Recoupment Determination, the Recoupment Committee or appropriate Delegate pursuant to implementing policies and procedures shall: i) undertake an appropriate and substantive review or investigation of the facts and circumstances associated with the Triggering Event or any written notifications about potential Triggering Events received pursuant to Paragraph D(i) above; ii) make written findings regarding the facts and circumstances associated with the Triggering Event and any written notifications about potential Triggering Events received pursuant to Paragraph D(i) above; and iii) set forth in writing its determinations (and the rationale for such determinations) about: 1) whether a Triggering Event occurred; 2) the extent of

bonus monies, LTI Plan grants or deferred compensation that will be subject to forfeiture and/or repayment by the Covered Executive; 3) the means that will be followed to implement the forfeiture and/or secure the recoupment of performance pay from the Covered Executive; and 4) the timetables under which GSK will implement the forfeiture and/or attempt to recoup the performance pay. For purposes of this paragraph, a “Delegate” shall refer to the GSK personnel to whom the Recoupment Committee has delegated one or more of its required tasks in furtherance of the Executive Financial Recoupment Program.

(E) **Reporting.** The Recoupment Committee shall provide annual reports to the Board of Directors (or an appropriate committee thereof) of GlaxoSmithKline PLC about: i) the number and circumstances of any Triggering Events that occurred during the preceding year and any written notifications about potential Triggering Events received pursuant to Paragraph D(i) above; ii) a description of any Recoupment Determinations made during the preceding year (including any decision to require or not require forfeiture/recoupment from any Covered Executives, the amount and type of any forfeiture/recoupment, the means for collecting any recoupment and the rationale for such decisions); and iii) a description of the status of any forfeitures and/or recoupments required under prior Recoupment Determinations that were not fully completed in prior years.

The Recoupment Committee shall also provide annual reports to the OIG about: i) the number and circumstances of any Triggering Events that occurred during the preceding year and any written notifications about potential Triggering Events received pursuant to Paragraph D(i) above; ii) a summary description of any Recoupment Determinations made during the preceding year (including any decision to require or not require forfeiture/recoupment from any Covered Executives, the amount and type of any forfeiture/recoupment, the method for collecting any recoupment, and the rationale for such decisions); and iii) a description of the status of any forfeitures and/or recoupments required under prior Recoupment Determinations that were not fully completed in prior years.

GSK commits to maintaining all of the forfeiture and recoupment commitments set forth in Paragraphs A-E above for at least the duration of the CIA, absent agreement otherwise with the OIG.