CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
SMITHKLINE BEECHAM CORPORATION D/B/A GLAXOSMITHKLINE

I. PREAMBLE

SmithKline Beecham Corporation, d/b/a GlaxoSmithKline ("GlaxoSmithKline") 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 by its officers, directors, employees, contractors, and agents 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"). Contemporaneously with this CIA, GlaxoSmithKline is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement. GlaxoSmithKline also will enter into settlement agreements with various States, and GlaxoSmithKline's agreement to this CIA is a condition precedent to those agreements.

Prior to the Effective Date of this CIA, GlaxoSmithKline initiated certain voluntary compliance measures, which include, among other things, the appointment of a Compliance Officer, the appointment of a Compliance Committee, a Disclosure Program, screening measures for Ineligible Persons, and various training and auditing programs.

GlaxoSmithKline shall continue the operation of its compliance measures in accordance with the terms set forth below for the term of this CIA. GlaxoSmithKline may modify its voluntary compliance measures as appropriate but shall, at a minimum, ensure that it complies with the compliance obligations set forth in this CIA for the term of this CIA.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by GlaxoSmithKline under this CIA shall be five years from the effective date of this CIA ("Effective Date") (unless

otherwise specified). The Effective Date shall be the date on which the final signatory of this CIA executes this agreement.

B. Sections VII, VIII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) GlaxoSmithKline's final annual report; or (2) any additional materials submitted by GlaxoSmithKline 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 employees, contractors and agents of the Managed Care Business Units within the U.S. Pharmaceuticals Division of GlaxoSmithKline ("U.S. Pharma") who have job responsibilities relating to: a) marketing or selling products to managed care entities; b) reporting of pricing information for any products that are reimbursed by Federal health care programs ("Government Reimbursed Products"), including under the Medicaid Drug Rebate Program, codified at 42 U.S.C. § 1396r-8; and c) obligations related to government contracts, including the agreements entered with the Department of HHS under the Medicaid Drug Rebate Program and the Drug Pricing Program under the Public Health Service (PHS) Act, 42 U.S.C. § 256.

b. Specifically excluded from this definition of "Covered Persons" are employees of the following groups within the Managed Care Business Units of U.S. Pharma: Professional and State Government Affairs; Trade Sales and Operations; and the Neurohealth Specialty Division. Also excluded from this definition are personnel of entities with which GlaxoSmithKline has agreements to co-promote its products and any contractor or agent retained to provide consulting or business advice and who is not engaged in the activities outlined in section II.C.1.a, above. GlaxoSmithKline shall, however, in good faith seek to obtain assurances that such persons have received appropriate training on proper promotional activities. All other personnel, apart from those acting under co-promotion agreements, who comprise U.S. Pharma's contract sales force and who report to any employees of the Managed Care Business Units

(except those specifically excluded under this sub-paragraph b) are specifically included in the definition of Covered Persons.

2. "Relevant Covered Persons" includes all Covered Persons in the Pricing, Contract Strategy and Operations Group of the Managed Care Business Units and the PBM Segment Business Analysis Manager.

3. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

III. CORPORATE INTEGRITY OBLIGATIONS

GlaxoSmithKline shall maintain a Compliance Program for U.S. Pharma that includes the following elements:

A. Compliance Officer and Committee.

1. *Compliance Officer.* GlaxoSmithKline presently has a Compliance Officer for U.S. Pharma (hereafter "Compliance Officer"), and the company shall continue to employ an individual in this capacity during the term of this CIA. The Compliance Officer is, and shall continue to be, responsible for overseeing the development of and coordinating the implementation of policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements for U.S. Pharma. The Compliance Officer is, and shall continue to be, a senior manager of U.S. Pharma. The Compliance Officer shall continue to make regular reports (at least quarterly) to the Vice President, Corporate Compliance Officer ("VP-Corporate Compliance") for GlaxoSmithKline, who in turn shall report regularly to the Audit Committee of the Board of Directors of GlaxoSmithKline and to the Risk Oversight and Compliance Council. Within 120 days after the Effective Date, the Compliance Officer shall also be authorized to report on compliance matters directly to the Audit Committee of the Board of Directors at any time. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by U.S. Pharma as well as for any reporting obligations created under this CIA.

GlaxoSmithKline shall report to OIG, in writing, any changes in the identity of or any material changes in the position description of the Compliance Officer, or any

material actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

2. *Compliance Committee.* Prior to the Effective Date, GlaxoSmithKline appointed a U.S. Pharma Compliance Committee (hereinafter "Compliance Committee"), and GlaxoSmithKline shall maintain the Compliance Committee during the term of this CIA. The Compliance Committee includes and shall, at a minimum, continue to include the Compliance Officer and other members of senior management of U.S. Pharma necessary to meet the requirements of this CIA (e.g., senior managers responsible for government contracting, sales and marketing programs, human resources, or internal audit). The Compliance Officer shall continue to be the Secretary of the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities, including assisting in the analysis of U.S. Pharma's risk areas and overseeing the results of internal and external audits and investigations.

GlaxoSmithKline shall report to OIG, in writing, any material changes in the composition of the Compliance Committee, or any material 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.

B. Written Standards.

1. *Code of Conduct.* Prior to the Effective Date, GlaxoSmithKline established a written Code of Conduct. Within 120 days after the Effective Date, GlaxoSmithKline shall redistribute its Code of Conduct with an accompanying letter to all Covered Persons and have each Covered Person certify, in writing or electronically, that he or she has received, read, understood, and shall abide by the letter and the Code of Conduct. GlaxoSmithKline shall make the promotion of, and adherence to, the Code of Conduct and the terms set forth in the letter an element in evaluating the performance of all Covered Persons. The Code of Conduct and the accompanying letter shall, at a minimum, set forth:

a. GlaxoSmithKline's commitment to full compliance with all Federal health care program requirements, including its commitment to comply with all government contracting requirements and to market and sell its Government Reimbursed Products in accordance with Federal health care program requirements;

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

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

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

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

In addition, GlaxoSmithKline shall revise and distribute its Code of Conduct, or shall establish a new code of conduct for U.S. Pharma, to all Covered Persons at the next scheduled printing of the Code of Conduct or within one year after the Effective Date, whichever is later. The revised Code of Conduct shall include, at a minimum, the topics set forth in items (a) through (e) above.

New Covered Persons shall receive the Code of Conduct and the accompanying letter 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.

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

2. *Policies and Procedures*. To the extent not already accomplished, within 120 days after the Effective Date, GlaxoSmithKline shall implement written Policies and Procedures regarding the operation of its compliance program for U.S. Pharma and its compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:

a. the subjects relating to the Code of Conduct identified in Section III.B.1;

b. the methods for gathering, calculating, verifying and reporting the data and information reported to the Centers for Medicare & Medicaid Services ("CMS") and/or the State Medicaid programs in connection with the Medicaid Drug Rebate Program;

c. promotional practices that conform with all applicable Federal health care program requirements, including the Medicaid Drug Rebate Program and the Federal Anti-kickback Statute, codified at 42 U.S.C. § 1320a-7b; and

d. the requirements of all government contracts, including those under the Medicaid Drug Rebate Program and the Drug Pricing Program.

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

At least annually (and more frequently, if appropriate), GlaxoSmithKline shall assess and update as necessary the Policies and Procedures. Within 30 days after the effective date of any material revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all individuals whose job functions relate to those Policies and Procedures. Distribution may include publishing such Policies and Procedures on GlaxoSmithKline's intranet or other internal web site available to all employees. If GlaxoSmithKline uses such an electronic method of distribution, it must notify the individuals receiving the Policies and Procedures that the Policies and

Procedures will be distributed in such a manner and it must track the distribution to ensure that all appropriate individuals received the Policies and Procedures.

C. Training and Education.

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

a. CIA requirements;

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

c. in general, the proper methods of promoting, marketing and selling products to managed care entities; the need to calculate and report accurate information in connection with Federal health care program or other requirements, including the Medicaid Rebate Program and Drug Pricing Program; and a general discussion of GlaxoSmithKline's systems for gathering relevant data, and calculating and verifying information reported to CMS for purposes of the Medicaid Drug Rebate Program.

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 training described above, each Covered Person shall receive at least one hour of general training annually.

2. *Specific Training.* Within 120 days after the Effective Date, each Relevant Covered Person shall receive at least two hours of specific training in addition to the general training required above. This specific training shall include a discussion of the following:

a. applicable legal rules and program requirements (including the sanctions for violations) relating to Government Reimbursed Products (including, but not limited to, the Anti-kickback Statute, 42 U.S.C. § 1320a-7b(1) and (2); the Civil Monetary Penalties Law, 42

U.S.C. § 1320a-7a; the Civil False Claims Act, 31 U.S.C. §§ 3729-3733; and the Medicaid Rebate Statute, 42 U.S.C. § 1396r-8);

b. the personal obligation of each individual involved in marketing and sales of Government Reimbursed Products to ensure that those products are marketed and sold in accordance with all applicable requirements of the Federal health care programs;

c. all applicable Federal health care program and other requirements relating to the Medicaid Drug Rebate Program and the Drug Pricing Program, the need to calculate and report accurate information, and a specific discussion of GlaxoSmithKline's systems for gathering relevant data, and calculating and verifying information reported to CMS for purposes of the Medicaid Drug Rebate Program;

d. the personal obligation of each individual involved to comply with the requirements of the Medicaid Drug Rebate Program and with other government contracts (such as those under the Drug Pricing Program) to ensure that all obligations associated with those programs and contracts are satisfied; and

e. examples of proper and improper sales and marketing practices, drug price reporting practices, and government contracting practices.

Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 120 days after the Effective Date, whichever is later. If any new Relevant Covered Person has responsibility for contracting for, setting policy for or supervising the marketing and sales of, or calculating and reporting the price of Government Reimbursed Products (including for purposes of the Medicaid Rebate Program or the Drug Pricing Program) prior to completing the specific training, a Relevant Covered Person who has completed the specific training shall review the untrained person's work in those areas.

After receiving the initial training described in this Section, each Relevant Covered Person shall receive at least two hours of specific training annually.

3. *Certification.* Each individual who is required to attend training shall certify, in writing or in electronic form, that he or she has received the required training.

The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

4. Training Requirements, General Description. The training and education required under this section III.C. may be provided by supervisory employees, knowledgeable staff or GlaxoSmithKline trainers and/or outside consultant trainers selected by GlaxoSmithKline. Persons providing any of the above-referenced training shall be knowledgeable about the subject areas of their training.

GlaxoSmithKline may provide the training required under this CIA through appropriate computer-based approaches. In that event, all applicable references to "hours" in this section III.C. shall mean "normative hours" as that term is used in the computer-based training industry. If GlaxoSmithKline chooses to provide computer-based training, it shall also make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the Covered Persons who are receiving such training.

GlaxoSmithKline shall annually review the training, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits or IRO audits, and any other relevant information.

To the extent that GlaxoSmithKline has provided training that satisfies the general and specific training requirements set forth above within 180 days prior to the Effective Date of this CIA, the OIG shall credit that training for purposes of satisfying part of GlaxoSmithKline's training obligations for the first year of the CIA.

D. Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Within 90 days after the Effective Date, GlaxoSmithKline shall retain an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist GlaxoSmithKline in assessing and evaluating its systems, processes, policies and practices relating to

the Medicaid Rebate Program and selected contract sales-related transactions.

Each IRO retained by GlaxoSmithKline shall have expertise in auditing and the requirements of the Federal health care programs as they related to the reimbursement, marketing/sales, and reporting of pricing information for Government Reimbursed Products (including the requirements of the Medicaid Drug Rebate Program). Each IRO shall assess, along with GlaxoSmithKline, whether it can perform the IRO review in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist.

b. Types and Frequency of IRO Reviews. The IRO shall conduct two types of review. One shall be a systems review of GlaxoSmithKline's systems, processes, policies and practices relating to the Medicaid Drug Rebate Program ("Medicaid Rebate Systems Review"). The second engagement shall address and analyze GlaxoSmithKline's systems, policies and practices with regard to specific contract sales-related transactions ("Contract Pricing Review").

If there are no material changes in GlaxoSmithKline's Medicaid Drug Rebate Program-related systems, processes, policies and practices during the term of the CIA, the IRO shall perform the Medicaid Rebate Systems Review for the first and fourth Reporting Periods. If GlaxoSmithKline materially changes its systems, processes, policies and practices, then the IRO shall perform a Medicaid Rebate Systems Review for the Reporting Period in which such changes were made in addition to conducting the Medicaid Rebate Systems Review for the first and fourth Reporting Periods. The Contract Pricing Review shall be performed annually and shall cover one quarter of each of the Reporting Periods. The IRO shall perform all components of each of the engagements.

c. Retention of Records. The IRO and GlaxoSmithKline shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those

exchanged between the IRO and GlaxoSmithKline) related to the reviews.

2. *Medicaid Rebate Systems Review.* As more fully set forth in Attachment A, the Medicaid Rebate Systems Review shall be a review that addresses GlaxoSmithKline's systems, processes, policies and practices associated with the tracking, gathering, and accounting for all relevant data for purposes of appropriately calculating the Best Price as reported under the Medicaid Rebate Program.

3. *Contract Pricing Review.* As set forth more fully in Attachment A, the Contract Pricing Review shall be a review of specific contract price transactions to determine whether those transactions were considered for purposes of determining Best Price in accordance with GlaxoSmithKline's policies and procedures and Medicaid Drug Rebate Program requirements.

4. *Review Report(s).* The IRO shall prepare a report (or reports) based upon the Medicaid Rebate Systems Review and the Contract Pricing Review performed (the "Review Report"). Information to be included in the Review Report is detailed in Appendix A.

5. *Validation Review.* In the event OIG has reason to believe that: (a) GlaxoSmithKline's Medicaid Rebate Systems Review or Contract Pricing Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Medicaid Rebate Systems Review or Contract Pricing Review complied with the requirements of the CIA and/or the findings or Review results are inaccurate ("Validation Review"). GlaxoSmithKline shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents so long as it is initiated within one year after GlaxoSmithKline's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify GlaxoSmithKline 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, GlaxoSmithKline may request a meeting with OIG to discuss the results of any Medicaid Rebate Systems Review or Contract Pricing Review submissions or findings; present any additional or relevant information to clarify the results of any of the Reviews or to correct the inaccuracy of any Review; or propose alternatives to the proposed Validation Review. GlaxoSmithKline shall provide any additional information as may be requested by OIG under this Section

in an expedited manner. OIG will attempt in good faith to resolve any Medicaid Rebate Systems Review or Contract Pricing Review issues with GlaxoSmithKline 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.

6. *Independence/Objectivity Certification.* The IRO shall include in its report(s) to GlaxoSmithKline a certification or sworn affidavit that it has evaluated its professional independence and/or objectivity, as appropriate to the nature of the engagement, with regard to the Medicaid Rebate Systems Review or Contract Pricing Review and that it has concluded that it is, in fact, independent and/or objective.

E. Disclosure Program.

GlaxoSmithKline presently has a disclosure program designed to facilitate communications relating to compliance with Federal health care program requirements and GlaxoSmithKline's policies ("the Disclosure Program"). During the term of this CIA, GlaxoSmithKline shall continue to maintain the Disclosure Program, and the program shall continue to include a mechanism (e.g., a toll-free compliance telephone line) 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 GlaxoSmithKline's policies, conduct, practices, or procedures with respect to a Federal health care program, believed by the individual to be a potential violation of criminal, civil, or administrative law. During the term of the CIA, GlaxoSmithKline shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas, including on the company's intranet or other internal web site available to all employees).

The Disclosure Program shall continue to emphasize a nonretribution, nonretaliation 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 he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, GlaxoSmithKline

shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

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

F. Ineligible Persons.

1. *Definition.* For purposes of this CIA, an "Ineligible Person" shall be an individual or entity who: (a) is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or (b) has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

2. *Screening Requirements.* The U.S. Pharma Division of GlaxoSmithKline shall not hire as an employee or engage as a contractor any Ineligible Person. To prevent hiring or engaging any Ineligible Persons, GlaxoSmithKline shall screen all prospective employees and prospective contractors prior to engaging their services by: (a) requiring such persons to disclose whether they are Ineligible Persons; and (b) appropriately querying the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://oig.hhs.gov) (these lists shall hereinafter be referred to as the "Exclusion Lists"). Nothing in this Section affects the responsibility of (or liability for) GlaxoSmithKline to refrain from billing Federal health care programs for services of the Ineligible Person.

3. *Review and Removal Requirement.* Within 120 days after the Effective Date, GlaxoSmithKline shall review its list of Covered Persons and the employees of the General Pharmaceuticals, Central Nervous System & Respiratory, and HIV Business Units (hereafter collectively "Ineligibility Relevant Covered Persons") against the Exclusion Lists. Thereafter, GlaxoSmithKline shall review its list of Ineligibility Relevant Covered Persons against the Exclusion Lists annually. In addition, GlaxoSmithKline shall require Ineligibility Relevant Covered Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes the individual an Ineligible Person.

If GlaxoSmithKline has actual notice that an Ineligibility Relevant Covered Person has become an Ineligible Person, GlaxoSmithKline shall remove such person from responsibility for, or involvement with, GlaxoSmithKline's business operations related to the Federal health care programs and shall remove such person from any position for which the person's compensation or the items or services rendered, ordered, or prescribed by the 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 person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions*. If GlaxoSmithKline has actual notice that an Ineligibility Relevant Covered Person is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment, involvement, or contract term, GlaxoSmithKline shall take all appropriate actions to ensure that the responsibilities of that person have not and shall not adversely affect the accuracy of any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, GlaxoSmithKline shall notify OIG, in writing, of any ongoing investigation known to GlaxoSmithKline or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that GlaxoSmithKline 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. GlaxoSmithKline 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 proceedings, if any.

H. Reporting of Reportable Events.

1. *Definition of Reportable Event*.

For purposes of this CIA, a "Reportable Event" means anything that involves a matter, brought to the attention of senior management at GlaxoSmithKline's corporate headquarters, 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. A Reportable Event may be the result of an isolated event or a series of occurrences.

2. *Reporting of Reportable Events*. (a) If GlaxoSmithKline determines through any means that there is a Reportable Event, GlaxoSmithKline shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:

i. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

ii. a description of GlaxoSmithKline's actions taken to correct the Reportable Event; and

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

(b) GlaxoSmithKline 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.G, above.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, GlaxoSmithKline establishes or acquires new business units engaged in contracting with managed care entities or in functions relating to the Medicaid Drug Rebate Program or the Drug Pricing Program, GlaxoSmithKline shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of such establishment or acquisition. This notification shall include the address of the new business unit, phone number, fax number, Federal health care provider number (if any), and the corresponding contractor's name and address that has issued each Federal health care program provider number. All Covered Persons at each such business unit shall be subject to the applicable requirements in this CIA (e.g., completing certifications and undergoing training).

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the Effective Date, GlaxoSmithKline shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA. This Implementation Report shall include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, 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;

3. a copy of GlaxoSmithKline's Code of Conduct and the accompanying letter required by Section III.B.1;

4. a copy of all Policies and Procedures required by Section III.B.2;

5. a copy of all training materials used for the training required by Section III.C, a description of such training, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;

6. a certification by the Compliance Officer that:

   a. the Policies and Procedures required by Section III.B have been developed, are being implemented, and have been distributed to all appropriate Covered Persons;

   b. all Covered Persons have completed the Code of Conduct and accompanying letter certification required by Section III.B.1; and

   c. all Covered Persons have completed the applicable training and executed the certification(s) required by Section III.C.

The documentation supporting this certification shall be available to OIG, upon request.

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

8. the identity of the IRO(s), a summary/description of all engagements between GlaxoSmithKline and the IRO, including, but not limited to, any outside financial audits or reimbursement consulting, and the proposed start and completion dates of the Medicaid Rebate Systems Review and the Contract Pricing Review;

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

10. a summary of personnel actions (other than hiring) taken pursuant to Section III.F.;

11. except for home offices, a list of all of GlaxoSmithKline's locations (including locations and mailing addresses) that house Covered Persons; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; and, if applicable each location's Federal health care program provider identification number(s), and the name and address of the Federal health care program contractor to which GlaxoSmithKline submits claims;

12. a description of GlaxoSmithKline's corporate structure, including identification of any parent and/or sister or subsidiary companies, and their respective lines of business; and

13. the certification required by Section V.C.

B. Annual Reports. GlaxoSmithKline shall submit to OIG Annual Reports with respect to the status of, and findings regarding, GlaxoSmithKline's compliance activities for each of the five Reporting Periods.

Each Annual Report shall include:

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 described in Section III.A;

2. the certification set forth in Attachment B to the CIA, and a certification by the Compliance Officer that:

a. all Covered Persons have completed any Code of Conduct certifications required by Section III.B.1; and

b. all Covered Persons have completed the applicable training and executed the certification(s) required by Section III.C.

The documentation supporting this certification shall be available to OIG, upon request.

3. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in Federal health care program requirements) and copies of any compliance-related Policies and Procedures;

4. a copy of all training materials used for the training required by Section III.C (to the extent it has not already been provided as part of the Implementation Report), a description of such training conducted during the Reporting Period, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;

5. a complete copy of all reports prepared pursuant to the IRO's Medicaid Rebate Systems Review and Contract Pricing Review, including a copy of the methodology used, along with a copy of the IRO's engagement letter(s);

6. GlaxoSmithKline's response and corrective action plan(s) related to any issues raised by the IRO(s);

7. a revised summary/description of all engagements between GlaxoSmithKline and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, if different from what was submitted as part of the Implementation Report;

8. a certification from the IRO regarding its professional independence and/or objectivity with respect to GlaxoSmithKline;

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

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

11. a description of any personnel actions (other than hiring) taken by GlaxoSmithKline as a result of the obligations in Section III.F, and the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F., and the actions taken in response to the obligations set forth in that Section;

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

13. a description of all changes to the most recently provided list (as updated) of GlaxoSmithKline's locations (including addresses) as required by Section V.A.11, the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, and, if applicable, each location's Federal health care program provider identification number(s), and the contractor name and address that issued each provider number;

14. a description of the co-promotion agreements that GlaxoSmithKline has with other firms, including the number of such agreements in existence

during the Reporting Period and a summary of the assurances GlaxoSmithKline has received regarding the training of co-promotion personnel, as referenced Section II; and

15. the certification required by Section V.C.

The first Annual Report shall be received by OIG no later than 90 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that: (1) to the best of his or her knowledge, except as otherwise described in the applicable report, GlaxoSmithKline is in compliance with all of the requirements of this CIA; and (2) the Compliance Officer has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information is accurate and truthful.

D. Designation of Information. GlaxoSmithKline 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. GlaxoSmithKline 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, D.C. 20201

Telephone: 202.619.2078
Facsimile: 202.205.0604

GlaxoSmithKline:

Arjun Rajaratnam
Vice President & Compliance Officer - Global Pharmaceuticals
GlaxoSmithKline
Five Moore Drive
P.O. Box. 13398
Research Triangle Park, NC 27709-3398
Telephone: 919.483.9938
Facsimile: 919.483.8746

With a copy to:

Thomas H. Lee, II, Esq.
Dechert LLP
4000 Bell Atlantic Tower
1717 Arch Street
Philadelphia, PA 19103-2793
Telephone: 215.994.2994
Facsimile: 215.994.2222

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.

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 GlaxoSmithKline's books, records, and other documents and supporting materials (to the extent such items are not protected under appropriately asserted legal privilege) and/or conduct on-site reviews of any of GlaxoSmithKline's locations for the purpose of verifying and evaluating: (a) GlaxoSmithKline's compliance with the terms of this CIA; and (b) GlaxoSmithKline's compliance with the applicable requirements of the Federal

health care programs in which it participates. The documentation described above shall be made available by GlaxoSmithKline 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 GlaxoSmithKline'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. GlaxoSmithKline's employees, contractors and agents shall have the right to be represented by counsel and any such individual may, at his or her option, be accompanied by counsel for GlaxoSmithKline and/or personal counsel at any interview by the OIG. GlaxoSmithKline shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Notwithstanding such arrangement, the OIG recognizes that individuals have the right to refuse to submit to interviews, and GlaxoSmithKline shall not be obligated to require such individuals to submit to interviews. If any individual decides not to submit to an interview, such refusal shall not constitute a breach of this CIA. GlaxoSmithKline's employees may elect to be interviewed with or without a representative of GlaxoSmithKline present.

VIII. DOCUMENT AND RECORD RETENTION

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

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 GlaxoSmithKline prior to any release by OIG of information submitted or made available by GlaxoSmithKline pursuant to its obligations under this CIA and identified upon submission by GlaxoSmithKline as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, GlaxoSmithKline shall have the rights set forth at 45 C.F.R. § 5.65(d). The OIG shall provide the pre-disclosure notice required pursuant to 45 C.F.R. § 5.65(d) to the Compliance Officer at the address provided in Section VI. Nothing in this CIA or any communication or report made pursuant to this CIA shall constitute or be construed as a waiver by GlaxoSmithKline of its attorney-client, work product or other applicable privileges. Notwithstanding that fact, the

existence of any such privilege does not affect GlaxoSmithKline's obligation to comply with the provisions of the CIA.

X. BREACH AND DEFAULT PROVISIONS

GlaxoSmithKline is expected to fully and timely comply with all of its CIA obligations. A breach of this CIA does not constitute a breach of the Settlement Agreement between GlaxoSmithKline and the United States or the settlement agreements with the individual States referred to in the Preamble. Any breach of the terms of those agreements does not constitute a breach of this CIA, except to the extent that such a breach independently also constitutes a breach of this CIA. Section X of this CIA specifies all of the remedies available to the OIG if GlaxoSmithKline fails to satisfy its obligations under this CIA. The remedies available to the OIG under this section X do not preempt or limit any actions that individual States may take against GlaxoSmithKline under appropriate authorities.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, GlaxoSmithKline and OIG hereby agree that failure to comply with certain obligations 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 GlaxoSmithKline fails to have in place any of the obligations described in Section III:

a. a Compliance Officer with the authorities referenced in Section III.A;

b. a Compliance Committee;

c. a written Code of Conduct and the accompanying letter referenced in Section III.B ;

d. written Policies and Procedures;

e. a requirement that Covered Persons be trained; and

f. a Disclosure Program.

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 GlaxoSmithKline fails to retain an IRO, as required in Section III.D.

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 GlaxoSmithKline fails to meet any of the deadlines for the submission of the Implementation Report or the Annual Reports to OIG.

4. A Stipulated Penalty of $2,000 (which shall begin to accrue on the date the failure to comply began) for each day GlaxoSmithKline employs or contracts with an Ineligible Person as an Ineligibility Relevant Covered Person and that person: (a) has responsibility for, or involvement with, GlaxoSmithKline's business operations related to the Federal health care programs; or (b) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (the Stipulated Penalty described in this Subsection shall not be demanded for any time period during which GlaxoSmithKline can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in Section III.F) as to the status of the person).

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

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

7. A Stipulated Penalty of $1,000 for each day GlaxoSmithKline fails to comply fully and adequately with any obligation of this CIA. In its notice to GlaxoSmithKline, OIG shall state the specific grounds for its determination that GlaxoSmithKline has failed to comply fully and adequately with the CIA obligation(s) at issue and steps GlaxoSmithKline shall take to comply with the CIA. (This Stipulated

Penalty shall begin to accrue 10 days after GlaxoSmithKline receives notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-6 of this Section.

B. Timely Written Requests for Extensions. GlaxoSmithKline 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 GlaxoSmithKline 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 GlaxoSmithKline 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 GlaxoSmithKline 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 GlaxoSmithKline of: (a) GlaxoSmithKline's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter"). Such Demand Letter shall specifically state the conduct that the OIG contends constitutes the basis for imposing the Stipulated Penalty.

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, GlaxoSmithKline 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 GlaxoSmithKline elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until GlaxoSmithKline 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 certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in Section VI.

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

D. Exclusion for Material Breach of this CIA.

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

a. a failure by GlaxoSmithKline to report a Reportable Event and take corrective action as required in Section III.H.;

b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;

c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or

d. a failure to retain and use an IRO in accordance with Section III.D.

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

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, GlaxoSmithKline fails to satisfy the requirements of Section X.D.3, OIG may exclude GlaxoSmithKline from participation in the Federal health care programs. OIG shall notify GlaxoSmithKline in writing of its determination to exclude GlaxoSmithKline (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 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, GlaxoSmithKline 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 GlaxoSmithKline 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, GlaxoSmithKline 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 Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether GlaxoSmithKline was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. GlaxoSmithKline 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 GlaxoSmithKline to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless GlaxoSmithKline 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 Chapter 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 GlaxoSmithKline 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) GlaxoSmithKline had begun to take action to cure the material breach within that period; (ii) GlaxoSmithKline has pursued and is pursuing such action with due diligence; and (iii) GlaxoSmithKline provided to OIG within that period a reasonable timetable for curing the material breach and GlaxoSmithKline 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 GlaxoSmithKline, only after a DAB

decision in favor of OIG. GlaxoSmithKline's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude GlaxoSmithKline 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 GlaxoSmithKline 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. GlaxoSmithKline 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 GlaxoSmithKline, GlaxoSmithKline 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

Consistent with the provisions in the Settlement Agreement pursuant to which this CIA is entered, and into which this CIA is incorporated, GlaxoSmithKline and OIG agree as follows:

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

B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;

C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA;

D. The undersigned GlaxoSmithKline 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.

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

Larry J. Goldberg

Larry J. Goldberg
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

4/15/03
DATE

ON BEHALF OF SMITHKLINE BEECHAM CORPORATION D/B/A GLAXOSMITHKLINE

Arjun Rajaratnam
Vice President & Compliance Officer -
Global Pharmaceuticals

4/14/03
DATE

Geoffrey E. Hobart, Esq.
Holland & Knight, L.L.P.
Counsel for SmithKline Beecham Corporation
d/b/a GlaxoSmithKline

4/15/03
DATE

Thomas H. Lee, II, Esq.
Dechert, LLP
Counsel for SmithKline Beecham Corporation
d/b/a GlaxoSmithKline

4/15/03
DATE

Attachment A to CIA between SmithKline Beecham Corporation d/b/a GlaxoSmithKline and Office of Inspector General

Medicaid Rebate and Contract Pricing Reviews

IRO Reviews, General Description

As specified more fully below, GlaxoSmithKline ("GSK") shall retain an Independent Review Organization ("IRO") to perform reviews to assist GSK in assessing and evaluating its systems, processes, policies and practices related to the Medicaid Drug Rebate Program. The IRO shall perform two types of review, a systems review of GSK's systems, processes, policies and practices relating to the Medicaid Drug Rebate Program ("Medicaid Rebate Systems Review") and a review of specific contract price transactions to determine whether those transactions were considered for purposes of determining Best Price in accordance with GSK's policies and procedures and Medicaid Drug Rebate Program requirements ("Contract Pricing Review").

The Medicaid Rebate Systems Review shall be a review of GSK's systems, processes, policies and practices (including the controls on those systems, processes, policies and practices) as they relate to the Medicaid Drug Rebate Program. If there are no material changes in GSK's systems, processes, policies and practices during the term of the CIA, then the IRO shall perform the Medicaid Rebate Systems Review covering the first and fourth Reporting Periods. If GSK materially changes its systems, processes, policies and practices as they relate to the Medicaid Drug Rebate Program, then the IRO shall perform a Medicaid Rebate Systems Review covering the Reporting Period in which such changes were made in addition to conducting the Medicaid Rebate Systems Review for the first and fourth Reporting Periods.

The Contract Pricing Review shall consist of two parts: (1) a review of all contract prices for a sample of 20 GSK Customers for the quarter under review; and (2) a review of all prices in any contract lower than the reported Best Price for the five (5) NDCs for which GSK paid the largest amount of rebates in the quarter under review. The term "GSK Customer" shall mean any customer with whom GSK contracts directly. The Contract Pricing Review shall be conducted annually for a randomly selected quarter of each Reporting Period.

A. Medicaid Rebate Systems Review

1. General Description of Medicaid Rebate Systems Review

For at least the first and fourth Reporting Periods, the IRO shall review GSK's systems, processes, policies and practices associated with the

tracking of, gathering of, and appropriate accounting for all data relevant for purposes of calculating the Best Prices reported to the Centers for Medicare and Medicaid Services ("CMS").

In general terms, the IRO shall review the following:

(a) what systems, processes, policies, and practices are in place to track, gather, and appropriately account for contract price terms with GSK Customers that are relevant to the Medicaid Rebate Program. Specifically, this includes a review of:

(1) the process used to determine whether discounts or rebates in GSK Customer contracts are included in the determination of the Medicaid Best Price for any product (this includes: (a) a review of the data or information flow process by which relevant contract price terms are evaluated for purposes of determining the Medicaid Best Price; and (b) a review of any GSK inquiries to CMS regarding Medicaid Best Price and any responses to those inquiries);

(2) the computer or other relevant systems used to calculate the Medicaid Best Price; and

(b) the policies and practices of the Government Contracts/Pricing Programs Group to examine system reports for variations that require critical evaluation (including a review of the basis upon which variations are identified and the follow-up activities taken to identify the cause of the variations).

2. Medicaid Rebate Systems Review Report

For each relevant Reporting Period, the IRO shall prepare a report based upon the Medicaid Rebate Systems Review. Each report shall include the following items:

(a) a description of the systems, processes, policies, and practices in place to track, gather, and appropriately account for those contract price terms with GSK Customers that are relevant to the Medicaid Rebate Program, including, but not limited to:

(1) the computer or other relevant systems used to calculate the Medicaid Best Price;

(2) what information is input into GSK's relevant computer or other systems and whether appropriate information is input into the system;

(3) the system logic or decisional rationale used to determine whether discounts or rebates in GSK Customer contracts are included in the determination of the Medicaid Best Price; and

(4) the policies and practices of the Government Contracts/ Pricing Programs Group in examining system reports for variations that require critical evaluation.

(b) a description of all documentation, information, and systems reviewed including a description of GSK's inquiries to CMS regarding Medicaid Best Price and any responses to those inquiries and a summary of interviews with personnel (if any interviews were conducted); and

(c) observations, findings, and recommendations on possible improvements to GSK's systems, processes, policies, and practices, including the IRO's assessment of whether GSK's systems, processes, policies and practices result in the inclusion of all appropriate and relevant contract price terms in the determination of the Medicaid Best Price.

B. Contract Pricing Review

1. General Description of Contract Pricing Review

GSK's Policies and Procedures (referenced in Section III.B.2 of the CIA) include policies and procedures which GSK follows in gathering, calculating and reporting prices under the Medicaid Drug Rebate Program. In addition to the Medicaid Rebate Systems Review, the IRO will review a sample of GSK Customers from a randomly selected quarter during the Reporting Period. This review shall determine whether GSK's processes and systems are correctly capturing the prices specified in each contract for each NDC in the sample and whether each price has been appropriately considered for purposes of determining a Best Price for the NDC at issue in

accordance with GSK policies and procedures and Medicaid Drug Rebate Program requirements.

2. Initial Review

The Contract Pricing Review shall consist of two parts as follows:

(a) Part One

At the end of each Reporting Period, the IRO shall randomly select the quarter for review. The IRO will then obtain a listing of all GSK Customers to whom sales of products were made at contracted prices during the relevant quarter of the Review Period. The IRO will randomly select a sample of 20 GSK Customers using the following methodology. The IRO will aggregate the number of NDCs for each GSK Customer and will categorize each GSK Customer as large or small based on the total number for NDCs for that GSK Customer for the Reporting Period quarter selected. The IRO shall coordinate with the OIG to develop a stratification system whereby the chance for selection in the large GSK Customer pool is greater than the chance for selection in the small GSK Customer pool. The IRO shall randomly select 15 GSK Customers from the large GSK Customer pool and 5 GSK Customers from the small GSK Customer pool. For each GSK Customer selected, the IRO will identify all contracts with GSK and all corresponding NDCs for which the GSK Customer had a contract price with GSK. The IRO will then verify for each GSK Customer that each contract price for each NDC number was accurately reflected in GSK's contract tracking system and that the contract price for the NDC was appropriately considered for purposes of determining GSK's Best Price in accordance with GSK's policies and procedures and Medicaid Drug Rebate Program requirements.

(b) Part Two

The IRO will obtain the following information:

(1) the five NDCs for which GSK paid the largest amount (e.g., total dollars) of rebates in the quarter under review; and

(i) for each of the five NDCs, any price reflected anywhere in GSK's systems where an

actual sale was recorded in the quarter under review at which the recorded price was lower than the Best Price reported by GSK for that NDC for that quarter.

(ii) For each of the five NDCs, the IRO will review each of those lower prices and determine if each was properly excluded from the determination of Best Price for that NDC in the quarter under review in accordance with GSK's policies and procedures and the Medicaid Drug Rebate Program requirements.

3. Additional Investigation

If the IRO determines that any of the prices reviewed either in Part One or Part Two of the Contract Pricing Review were not accurately reflected in GSK's systems and/or were not appropriately included in or excluded from GSK's Best Price determination in accordance with GSK's policies and procedures and Medicaid Drug Rebate Requirements, then the IRO shall conduct such additional investigation as may be necessary to determine the root cause of why any such price was not accurately reflected in GSK's systems. For example, the IRO may need to review additional documentation and/or conduct interviews with appropriate personnel to identify the root cause of the error. In the event the IRO finds more than one such price for the quarter under review, the IRO will perform a second Contract Pricing Review. The second Contract Pricing Review shall consist of the IRO: (i) reviewing a random selection of an additional five GSK Customers from the large GSK Customer pool, and (ii) reviewing the next five NDCs with the highest amounts of rebates (total dollars) paid by GSK.

4. Contract Pricing Review Report

The IRO shall annually prepare a report based upon each Contract Pricing Review performed. Each report shall be broken into two sections to reflect Part One and Part Two of the Review. The report shall include the following general elements pertaining to Part One and Part Two of the Review:

(a) Elements to Be Included in Both Part One and Part Two of the Report:

(1) Contract Pricing Review Objectives: A clear statement of the objectives intended to be achieved by the review;

(2) Review Protocol: A detailed narrative description of: (i) the procedures performed, (ii) sampling unit; and (iii) the universe from which the sample was selected; and

(3) Sources of Data: A full description of documentation (and/or other information) relied upon by the IRO when performing the Contract Pricing Review.

(b) Results to Be Included for Part One of Contract Pricing Review

The following results shall be included in the section of the report for Part One of the Contract Pricing Review:

(1) a list of the 20 GSK Customers reviewed under Part One of the Review, the number of contracts associated with each GSK Customer, the NDCs reviewed, the contract prices for each NDC reviewed; and a list of any supporting documentation reviewed;

(2) for each of GSK Customer, a description of the steps taken to verify that the contract price for each NDC reviewed was accurately reflected in GSK's systems;

(3) for each GSK Customer, the IRO's determination of whether each NDC contract price was accurately reflected in the system, and, if it was not, include the correct price;

(4) a detailed description of any additional investigation or review undertaken with regard to any price not accurately reflected in GSK's systems and the results of any additional investigation or reviews undertaken with respect to any such price;

(5) for each GSK Customer, a description of the steps taken to determine that each NDC's contract price was appropriately included or excluded in GSK's determination of Best Price for that NDC;

(6) for each GSK Customer, a list of any price inappropriately included in or excluded from GSK's Best Price determination for that quarter;

(7) a detailed description of any additional investigation or review undertaken with regard to any price not accurately included or excluded in GSK's Best Price determination for that quarter, and the results of any additional investigation or reviews undertaken with respect to any such price; and

(8) the IRO's recommendations for changes in GSK's policies and procedures to correct or address any weaknesses or deficiencies uncovered during the Review.

(c) Results to Be Included for Part Two of Contract Pricing Review

The following results shall be included in the section of the report for Part Two of the Contract Pricing Review:

(1) a narrative list of the five NDCs with the highest rebates paid by GSK for the quarter under review and the Best Price reported by GSK to the Medicaid Drug Rebate Program for each such NDC for the quarter under review;

(2) a list of all prices and the corresponding GSK Customer for which a sale was made for the five NDCs in the quarter under review where the contract price was lower than the Best Price reported to CMS for that quarter;

(3) a description of the steps and the supporting documentation reviewed to determine that each such lower price was appropriately evaluated for that NDC for purposes of determining the Best Price;

(4) a list of any prices not appropriately included or excluded in GSK's Best Price determination for that quarter;

(5) a detailed description of any additional investigation undertaken with regard to any prices that were not accurately included or excluded in GSK's Best Price determination for the quarter under review and the results of any additional investigation or reviews undertaken with respect to any such price; and

(6) The IRO's recommendations for changes in GSK's policies and procedures to correct or address any weaknesses or deficiencies uncovered during the review.

Attachment B to
CIA between the Office of Inspector General and
SmithKline Beecham Corporation d/b/a GlaxoSmithKline

CERTIFICATION

In accordance with the Corporate Integrity Agreement ("CIA") entered between GlaxoSmithKline and the OIG, the undersigned hereby certifies the following to the best of my knowledge, information and belief:

1) GlaxoSmithKline has in place policies and procedures describing in all material respects the methods for gathering, calculating, verifying and reporting the data and information reported to the Centers for Medicare and Medicaid Services ("CMS") and/or the State Medicaid programs in connection with the Medicaid Drug Rebate program ("Medicaid Rebate Policies and Procedures");

2) the Medicaid Rebate Policies and Procedures have been designed to ensure compliance with GlaxoSmithKline's obligations under the Medicaid Drug Rebate Program; and,

3) GlaxoSmithKline's Medicaid Rebate Policies and Procedures were followed in all material respects in connection with the calculation of Best Price for GlaxoSmithKline's products for each of the following four quarters: [identify each specific quarter.]

_____

Arjun Rajaratnam
Vice President & Compliance Officer

_____

Date