CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
ASTRAZENECA PHARMACEUTICALS LP
AND ASTRAZENECA LP

I. PREAMBLE

AstraZeneca Pharmaceuticals LP and AstraZeneca LP hereby enter 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 their officers, employees, agents and Contractors (as defined herein) (collectively "AstraZeneca"), 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, AstraZeneca is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement. Contemporaneously with this CIA, AstraZeneca is also entering or will enter into settlement agreements with various States, and AstraZeneca's agreement to this CIA is a condition precedent to those agreements.

Prior to the effective date of this CIA, AstraZeneca established a voluntary compliance program, which includes a corporate compliance officer and compliance committee, a Code of Conduct for all employees, written policies and procedures, educational and training initiatives, review and disciplinary procedures, a confidential disclosure program, and internal review procedures designed, as represented by AstraZeneca, to promote compliance with applicable laws and the promotion of high ethical standards. AstraZeneca agrees to continue the operation of its compliance measures in accordance with the terms set forth below for the term of this CIA. AstraZeneca may modify its voluntary compliance measures as appropriate, but, at a minimum, AstraZeneca will ensure that, during the term of this CIA, it shall comply with the integrity obligations enumerated in this CIA.

II. TERM AND SCOPE OF THE CIA The period of the compliance obligations assumed by AstraZeneca under this CIA shall be 5 years from the effective date of this CIA (unless otherwise specified). The effective date ("Effective Date") of this CIA shall be the date on which the final signatory of this CIA executes this CIA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

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

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

1. "Contractor" is any individual who, pursuant to the terms of any contract or written agreement with AstraZeneca for the provision of services (excluding legal services), sells or markets Government Reimbursed Products on behalf of AstraZeneca; calculates or reports prices; and/or negotiates, implements, or reports information related to, government contracts relating to Federal health care programs, including Medicare and the Medicaid Rebate program (codified at 42 U.S.C. § 1396r-8 et seq.), or contracts with the United States Department of Defense.

2. "Covered Products" means the AstraZeneca products listed in Appendix A for which AstraZeneca will report Average Sale Prices in accordance with section III.D below.

3. "Government Reimbursed Products" means AstraZeneca products for which Federal health care programs provide reimbursement.

4. "Covered Persons" includes all Contractors (as defined above) of AstraZeneca located in the United States. "Covered Persons" also includes all officers, employees, and agents of AstraZeneca located in the United States whose job responsibilities relate to: (1) sales and marketing activities for Government Reimbursed Products; (2) the calculation and reporting of prices for purposes of Federal health care programs, including, but not limited to, Medicare and the Medicaid Rebate Program; or (3) the

negotiation, implementation, and any reporting of information related to, government contracts.[1]

III. CORPORATE INTEGRITY OBLIGATIONS

AstraZeneca hereby agrees to maintain a Compliance Program that includes the following elements:

A. Compliance Officer and Committee.

1. *Compliance Officer.* AstraZeneca presently has a Compliance Officer and AstraZeneca shall continue to employ an individual to serve as its Compliance Officer during the term of this CIA. The Compliance Officer shall 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. The Compliance Officer is, and shall continue to be, a member of senior management of AstraZeneca, shall make periodic (at least semi-annual) reports regarding compliance matters directly to the AstraZeneca Leadership Team (AZLT) and shall make at least annual reports regarding compliance matters to the Board of Directors of AstraZeneca PLC.[2] In addition, the Compliance Officer shall provide a copy of the CIA and the Annual Reports relating to the CIA to the Board of Directors and shall annually report to the Board about AstraZeneca's compliance with the terms of this CIA. The Compliance Officer shall be authorized to report on compliance matters to the Board of Directors at any time. The Compliance Officer, with assistance from the Senior Director of Corporate Compliance, shall be responsible for monitoring the day-to-day compliance activities engaged in by AstraZeneca as well as for any reporting obligations created under this CIA.

AstraZeneca shall report to the 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

1 Specifically excluded from the definition of "Covered Persons" are the marketing, sales or other personnel of entities with which AstraZeneca has agreements to co-promote its products. AstraZeneca shall, however, in good faith seek to obtain assurances that such personnel have received appropriate training on proper marketing and sales techniques. The term "Covered Persons" specifically includes all other personnel, apart from those acting under co-promotion agreements, who comprise AstraZeneca's contract sales force, if any.

2 AstraZeneca PLC is a pharmaceutical company headquartered in England, of which AstraZeneca Pharmaceuticals LP and AstraZeneca LP are indirect subsidiaries.

the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

2. *Business Compliance Committee.* Prior to the Effective Date, AstraZeneca established a Business Compliance Committee. It shall maintain the Business Compliance Committee during the term of this CIA. The Compliance Committee includes, and shall continue to include (at a minimum), 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 Sales and Marketing, Internal Audit, Human Resources). The Compliance Officer shall continue to chair the Business Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of AstraZeneca's risk areas and shall oversee monitoring of internal and external audits and investigations).

AstraZeneca shall report to OIG, in writing, any material changes in the composition of the Business Compliance Committee, or any material actions or changes that would affect the Business Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change. Notwithstanding this notice, AstraZeneca is authorized to modify the structure or function of the Business Compliance Committee consistent with the terms of the CIA.

B. Written Standards.

1. *Code of Conduct.* Prior to the Effective Date, AstraZeneca established a written Code of Conduct. Within 120 days after the Effective Date, AstraZeneca 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. AstraZeneca may distribute the Code of Conduct and the accompanying letter to each individual Covered Person either electronically or in hard-copy form. AstraZeneca shall continue to make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

a. AstraZeneca's commitment to full compliance with all Federal health care program requirements, including its commitment to report prices for and market and sell its Government Reimbursed

Products in accordance with Federal health care program requirements;

b. AstraZeneca's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with AstraZeneca's own Policies and Procedures as implemented pursuant to section III.B.2 (including the requirements of this CIA);

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

d. the possible consequences to both AstraZeneca and Covered Persons of failure to comply with all Federal health care program requirements and with AstraZeneca's own Policies and Procedures or of failure to report such non-compliance; and

e. the right of all individuals to use the Disclosure Program described in section III.F, and AstraZeneca's commitment to maintain confidentiality, as appropriate, and non-retaliation with respect to such disclosures.

AstraZeneca shall revise and distribute its Code of Conduct 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 shall complete the required certification within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later.

AstraZeneca shall annually 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 will

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, AstraZeneca shall implement written policies and procedures regarding the operation of its compliance program 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 calculation and reporting of accurate prices for Government Reimbursed Products to certain entities, including the Centers for Medicare & Medicaid Services ("CMS"), the State Medicaid programs, and the drug price reporting services on which government agencies now rely (i.e., First DataBank Inc., the Red Book, etc.) or shall rely in the future;

c. the proper calculation and reporting of all data and information reported to CMS and/or the State Medicaid programs in connection with the Medicaid Drug Rebate program, codified at 42 U.S.C. § 1396r-8;

d. the proper uses and tracking of drug samples in accordance with all applicable requirements, including, but not limited to, the Prescription Drug Marketing Act, codified in 21 U.S.C. §§ 331, 333 and 353; and

e. measures designed to promote marketing and sales practices that conform with all statutes, regulations and requirements applicable to Government Reimbursed Products. The Policies and Procedures shall specify that AstraZeneca shall comply with the Federal anti-kickback statute, codified at 42 U.S.C. §§ 1320a-7b(1) & (2), and other applicable statutes, regulations or requirements.

Within 120 days after the Effective Date, to the extent not already accomplished, the relevant portions of the Policies and Procedures shall be distributed to all Covered Persons whose job functions are related to those Policies and Procedures. Distribution may include publishing such Policies and Procedures on AstraZeneca's intranet or other internal web site available to all employees. If AstraZeneca 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. Appropriate and knowledgeable staff should be available to explain the Policies and Procedures.

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

C. Training and Education.

1. *Training Requirements, General Description.* The training and education required under section III.C of this CIA may be provided by supervisory employees or outside consultant trainers selected by AstraZeneca and/or through electronic or any other effective means. Persons providing the training must be knowledgeable about the subject areas of their training. AstraZeneca 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 AstraZeneca 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.

AstraZeneca 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, or any other relevant information.

New Covered Persons shall receive the training outlined below in sections III.C.2 and III.C.3 within 60 days after becoming Covered Persons or within 120 days

after the Effective Date, whichever is later. An AstraZeneca employee who has completed the training shall review a new Covered Person's work, to the extent that the work relates to the marketing or sales of Government Reimbursed Products; the calculating or reporting of prices for Government Reimbursed Products; or the fulfillment of any responsibilities relating to the Medicaid Drug Rebate program until such time as the new Covered Person completes the applicable training.

2. *Training Provided to Covered Persons.* Within 120 days after the Effective Date, AstraZeneca shall provide at least four hours of training to each Covered Person. This training, at a minimum, shall explain:

a. AstraZeneca's CIA requirements;

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

c. proper methods of marketing and selling Government Reimbursed Products in accordance with all applicable statutes, regulations and requirements, including, but not limited to, the Federal anti-kickback statute and the Prescription Drug Marketing Act (to the extent such Covered Person's responsibilities involve handling drug samples);

d. 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;

e. all applicable legal rules (including the sanctions for violations) relating to marketing and sales of Government Reimbursed Products (including, but not limited to, the Federal anti-kickback statute; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the civil False Claims Act, 31 U.S.C. §§ 3729-3733; the Medicaid Drug Rebate statute, and the Prescription Drug Marketing Act (to the extent such Covered Person's responsibilities involve handling drug samples); and

f. examples of proper and improper marketing and sales practices.

After receiving the initial training described above, each Covered Person shall annually receive at least three hours of training on the topics outlined above.

To the extent that AstraZeneca has provided training that satisfies the requirements set forth above within 180 days prior to the Effective Date, the OIG shall credit that training for purposes of satisfying, in part, AstraZeneca's training obligations as set forth in this Section III.C.2 for the first year of the CIA.

3. *Additional Training for Certain Covered Persons*. In addition to the training outlined in section III.C.2 above, within 120 days after the Effective Date, AstraZeneca shall provide 90 minutes of additional training (the "Additional Training") to those Covered Persons: 1) whose job responsibilities include complying with any requirements of the Medicaid Drug Rebate program; or 2) who are involved in the calculation or reporting of any pricing data or other related information for Government Reimbursed Products. To the extent that AstraZeneca has provided training that satisfies the Additional Training requirements set forth below within 180 days prior to the Effective Date, the OIG shall credit that training for purposes of satisfying AstraZeneca's Additional Training obligations for the first year of the CIA.

This Additional Training shall include a discussion of:

a. the calculation and reporting of accurate pricing data and other information to CMS, the State Medicaid programs and drug price reporting services for Government Reimbursed Products (i.e., currently First DataBank, Inc., the Red Book);

b. the calculation and reporting of accurate pricing data and other information as required by the Medicaid Drug Rebate program;

c. the personal obligation of each individual involved in the calculation or reporting of drug pricing data or other information to ensure that prices are accurately calculated and reported;

d. all applicable legal rules (including the sanctions for violations) relating to proper calculation and reporting of drug pricing data for

Government Reimbursed Products (including, but not limited to, the Federal anti-kickback statute; the Civil Monetary Penalties Law; the civil False Claims Act; and the Medicaid Drug Rebate statute); and

e. examples of proper and improper drug price calculation and reporting practices.

After receiving the initial training described in this section, every Covered Person required to receive Additional Training shall receive at least one hour of Additional Training annually.

4. *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.

D. Reporting Requirements.

1. *General Statement of Purpose and Intent.*

On a quarterly basis, AstraZeneca shall report to the entities identified below in section III.D.2.b certain pricing information, as specified below in section III.D.2.a, for the purpose of furnishing those entities with pricing information that accurately reflects prices at which actual purchasers buy the Covered Products sold by AstraZeneca. Such information shall be provided to the OIG subject to section IX and other conditions of this CIA, and AstraZeneca shall comply with section V.D in providing the data. The OIG agrees that, consistent with the provisions in section III.D.2.d below, if, and when, it shares the confidential pricing information with government agencies other than the OIG, it will encourage that the information not be used in a way that would competitively disadvantage AstraZeneca in relation to any of its competitors.

2. *Specific Reporting Requirements.*

a. *Average Sale Price Defined*

For purposes of this CIA, "Average Sale Price" means, with respect to each dosage form, strength and volume of the Covered Products identified in Appendix A (without regard to any special packaging, labeling, or identifiers on the dosage form or product or package) the average of all final sales prices charged by AstraZeneca for the product in the United States to all purchasers, excluding those sales exempt from inclusion in the calculation of "Best Price" for Medicaid Drug Rebate purposes, pursuant to 42 U.S.C. § 1396r-8, and excluding identifiable direct sales to hospitals. (Those purchasers for which the sales are included in the calculation of Average Sale Price are hereafter referred to as the "Relevant Purchasers.") The prices identified in the calculation of the Average Sale Price should be net of all the following: volume discounts; prompt pay discounts; cash discounts; chargebacks; short-dated product discounts; free goods; rebates;[3] and all other price concessions provided by AstraZeneca to any Relevant Purchaser that result in a reduction of the ultimate cost to the purchaser. Notwithstanding the foregoing, the Average Sale Price shall not include the value of bona fide charity care or bona fide grants.

AstraZeneca shall report the Average Sale Price by National Drug Code ("NDC") for each Covered Product by AstraZeneca's NDC. The Average Sale Price reported shall be properly weighted to reflect the volume of sales at each sale price, i.e., for each NDC, the price reported shall be an average per unit price determined by dividing the sum of all final prices charged by AstraZeneca to a Relevant Purchaser, net of all price reductions identified above, for a Covered Product in a quarter by the total number of units of that product sold in that quarter.

b. *Reporting Obligations for Covered Products*

Except as otherwise noted below, 45 days after the last day of each calendar quarter, AstraZeneca shall report, in accordance with section III.D.2.a above, the Average Sale Prices for the Covered Products identified in Appendix A by AstraZeneca's NDC to: 1) the Medicaid programs of those States who have executed a state settlement agreement with AstraZeneca; 2) to First DataBank Inc.[4] solely for the purpose of

[3] The term "rebate" as used in this paragraph does not include any payments made by AstraZeneca to the States pursuant to the Medicaid Drug Rebate program (42 U.S.C. § 1396r-8).

[4] If appropriate to reflect changes in the sources from which the State Medicaid programs receive their pricing information, AstraZeneca agrees that, upon the receipt of a written request by any of the States, it will report the required information to a drug pricing reporting source other than, and in addition to, First DataBank Inc., subject to reasonable provisions equivalent to those agreed to by First DataBank Inc. to ensure the confidentiality of that

reporting pricing information based on those Average Sale Prices to the Medicaid programs of those States that have executed a state settlement agreement; 3) to CMS; and 4) to the OIG. The first report of Average Sale Prices shall be made no later than 45 days after the end of the first full calendar quarter following the Effective Date. The Average Sale Price reporting obligations of this CIA may be subject to modification consistent with a change in federal statutory or regulatory requirements pertaining to the submission of price information by pharmaceutical manufacturers.

c. *Certification Requirement*

In connection with each report of Average Sale Price, AstraZeneca shall also provide the OIG, CMS, and the applicable States a detailed description of the methodology used to calculate the Average Sale Prices. An appropriate employee or agent of AstraZeneca will certify that the Average Sale Prices reported are calculated in accordance with the described methodology. Said certifications shall be made in the form attached hereto as Attachment A. AstraZeneca agrees that this certification by an appropriate employee or agent of AstraZeneca constitutes a certification by AstraZeneca. To the extent that AstraZeneca's methodology involves accruing for the impact of future events, AstraZeneca shall include a description of its accrual methodology, including underlying assumptions, with its certification, and shall, on a quarterly basis, evaluate such accrual methodology in light of its actual experience and make any appropriate adjustments.

d. Confidentiality and Use of Reported Information

AstraZeneca and the OIG (on behalf of itself and CMS) acknowledge that the pricing information provided by AstraZeneca under this section III.D is considered to be confidential commercial information and proprietary trade secrets that if disclosed may cause substantial injury to the competitive position of AstraZeneca. On behalf of itself and CMS, the OIG agrees to afford the pricing information disclosed by AstraZeneca the maximum degree of confidentiality permitted by law. CMS has been advised by the OIG of the purpose and use of the pricing information provided by AstraZeneca. Without surrendering any legal right to contest the use of this information, AstraZeneca acknowledges that this information may be relied upon by CMS in establishing

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information.

reimbursement rates for AstraZeneca products, provided however that CMS will not change reimbursement rates for any AstraZeneca product based on this information without conducting meaningful review for all government-reimbursed therapeutically-similar products. Similarly, without surrendering any legal right to contest the use of this information, AstraZeneca acknowledges that the pricing information may be relied upon by State Medicaid programs in establishing reimbursement rates for AstraZeneca's products, subject to the provisions of the settlement agreements entered between AstraZeneca and various States as referenced in the Preamble to this CIA.

e. *Document Retention*

AstraZeneca shall retain all supporting work papers and documentation relating to the Average Sale Price of its Government Reimbursed Products for six years after the Effective Date and, to the extent not protected by appropriately asserted privileges, shall make such documentation available for inspection by the OIG or its duly authorized representative(s) in accordance with the provisions set forth more fully below in section VII of this CIA. However, the existence of any such privilege does not affect AstraZeneca's obligation to comply with the provisions of the CIA.

E. Review Procedures.

1. General Description.

During the term of the CIA, AstraZeneca shall retain either its own internal audit department or an independent review organization (IRO) to perform two types of reviews. The first relates to reported prices (Best Price and Average Sale Price) and the second relates to sales and marketing practices. Each type of review has two associated components – a systems review and sampling review of particular transactions. Generally speaking, the system reviews shall be conducted by the IRO for two Reporting Periods of the CIA. With one exception, the sampling reviews shall be conducted annually by the internal audit department.

a. Internal CIA Audit.

As set forth more fully in Attachment B, AstraZeneca may direct its Group Internal Audit ("GIA") to annually perform certain procedures to assist the company in assessing and evaluating its practices relating to the determination and reporting of Best Price for

purposes of the Medicaid Drug Rebate program ("Medicaid Rebate Review") and its sales and marketing practices ("Sales and Marketing Review"). Any reviews conducted by the GIA will be subject to verification by the Independent Review Organization (IRO) as set forth in Attachment C.

b. Retention of Independent Review Organization.

Within 120 days after the Effective Date, AstraZeneca shall retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter "IRO"), to perform procedures as set forth in Attachment C to assist AstraZeneca in assessing and evaluating its drug price reporting systems and practices and its sales and marketing systems and practices. Each IRO must have expertise in auditing and in the requirements of the Federal health care programs as they relate to the reporting for, reimbursement of, and marketing/sales of Government Reimbursed Products. Each IRO shall assess, along with AstraZeneca, whether it can perform the engagements in a professionally independent and/or objective fashion, taking into account any other business relationships or other engagements that may exist.

c. *Types and Frequency of IRO Reviews.*

As specified more fully in Attachment C, AstraZeneca shall retain an Independent Review Organization ("IRO") to perform reviews to assist AstraZeneca in assessing and evaluating its systems, processes, policies and practices related to: 1) the determination of Best Price for purposes of the Medicaid Drug Rebate Program ("Medicaid Rebate Systems Review"); 2) the methodology for calculating Average Sale Price ("Average Sale Price Systems Review"); and 3) its sales and marketing activities ("Sales and Marketing Systems Reviews").

If, during the term of the CIA, there are no material changes in AstraZeneca's systems, processes, policies and practices relating to the determination of Best Price, the calculation of Average Sale Price, or its sales and marketing activities, then the IRO shall perform the Systems Reviews outlined above to cover the first and fourth Reporting Periods. If AstraZeneca materially changes its systems, processes, policies or practices, then the IRO shall perform the applicable additional Systems Review(s) covering the Reporting Period(s) in which such changes were made in addition to conducting the Systems Reviews for the first and fourth Reporting Periods.

In addition to the Systems Reviews outlined above, for at least the first two years of the CIA, the IRO shall conduct the Average Sale Price Review outlined in Section D of Attachment C. After the IRO performs the Average Sale Price Review for the first two Reporting Periods of the CIA, AstraZeneca may, at its option, request the OIG to permit the Average Sale Price Review to be conducted by the GIA subject to verification by the IRO. The OIG retains sole discretion over whether to permit the Average Sale Price Review to be conducted by the GIA (subject to IRO verification) for subsequent years. In making its decision, the OIG will consider, among other factors, the results of the Average Sale Price Reviews for the first two Reporting Periods and AstraZeneca's demonstrated audit capabilities to perform the Average Sale Price Review internally. If the OIG denies AstraZeneca's request to shift the audit responsibilities, AstraZeneca agrees to engage the IRO to perform the remaining Average Sale Price Reviews.

d. Retention and Submission of Records.

For each year of the CIA, a complete copy of each of the GIA's and the IRO's Review Reports shall be included in AstraZeneca's Annual Reports to OIG. The GIA, the IRO and AstraZeneca shall retain and make available to the OIG upon request all work papers, supporting documentation, correspondence, and draft reports (those that are exchanged between the GIA and the IRO and AstraZeneca) relating to the engagements.

e. Submission of workplans

Prior to conducting their reviews, the GIA and IRO shall submit their workplan(s) to the OIG for comment. However, any comments or recommendations made by the OIG in connection with a review of the submitted workplan(s) will not preclude the OIG from making further comments or recommendations for future workplan(s) after reviewing the reports from the various reviews.

2. Validation Review.

In the event that the OIG has reason to believe that: (a) any of AstraZeneca's IRO or GIA Reviews fails to conform to the requirements of this CIA, or (b) the findings or reports from these Reviews are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Review in question complies with the requirements of the CIA and/or the reported findings for the Review are inaccurate ("Validation Review"). AstraZeneca shall pay for the reasonable cost of any such review performed

by the OIG or any of its designated agents so long as it is initiated within one year after AstraZeneca's final submission (as described in section II) is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify AstraZeneca of its intent to do so and provide an explanation of why the OIG believes such a review is necessary. To resolve any concerns raised by the OIG, AstraZeneca may request a meeting with the OIG to discuss the results of any Review submissions or findings; present any additional or relevant information to clarify the results of the Review or to correct any inaccuracies; or propose alternatives to the proposed Validation Review. AstraZeneca shall produce any additional information as may be requested by the OIG under this section in an expedited manner. The OIG will attempt in good faith to resolve any IRO or GIA Review issues with AstraZeneca prior to conducting a Validation Review. However, the final determination as to whether to proceed with a Validation Review shall be made at the sole discretion of the OIG.

3. *Independence Certification.*

The IRO shall include in its reports to AstraZeneca a certification or sworn affidavit that it has evaluated its professional independence and/or objectivity, as appropriate to the nature of the engagement, and that it has concluded that it is, in fact, independent and/or objective. The first such certification shall be included in the Implementation Report.

F. Disclosure Program.

AstraZeneca presently has a Disclosure Program designed to facilitate communications relating to compliance with the law and AstraZeneca's policies. During the term of the CIA, AstraZeneca shall maintain its Disclosure Program, which includes a mechanism (the toll-free Code of Conduct Ethics 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 AstraZeneca'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. AstraZeneca shall continue to appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a non-retribution, non-retaliation policy, and shall continue to include a reporting mechanism for anonymous, confidential communications. Upon receipt of a disclosure associated with AstraZeneca's policies, conduct, practices or procedures with respect to any Federal health care program or Federal health care program requirement ("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, AstraZeneca 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.

G. Ineligible Persons.

1. *Definition.* For purposes of this CIA, an "Ineligible Person" shall be any 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 non-procurement programs; or (b) has been convicted of a criminal offense that is governed by 42 U.S.C. § 1320a-7(a) related to the provision of health care items or services, but has not yet been excluded, debarred, suspended or otherwise declared ineligible.

2. *Screening Requirements.* AstraZeneca has a policy to not hire or engage as a Covered Person any Ineligible Person, and it shall maintain that policy during the term of the CIA. To prevent hiring or engaging any Ineligible Person, AstraZeneca shall screen all prospective Covered Persons prior to engaging their services by: (a) requiring applicants 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 will hereinafter be referred to as the "Exclusion Lists").

3. *Review and Removal Requirement.* Within 120 days after the Effective Date, to the extent not already accomplished, AstraZeneca shall review its list of current Covered Persons against the Exclusion Lists. Thereafter, AstraZeneca shall review the list annually. In addition, AstraZeneca shall require Covered Persons to disclose immediately any debarment, exclusion, suspension or other event that makes the individual an Ineligible Person.

If AstraZeneca has actual notice that a Covered Person has become an Ineligible Person, AstraZeneca shall remove such person from responsibility for, or involvement with, AstraZeneca's business operations related to the Federal health care programs and shall remove such person from any 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 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 AstraZeneca has actual notice that a 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 or contract, AstraZeneca shall take all appropriate actions to ensure that the Covered Person's continued performance of his or her responsibilities shall not adversely affect the accuracy of any claims submitted to any Federal health care program.

H. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, AstraZeneca shall notify OIG, in writing, of any ongoing investigation known to AstraZeneca or any legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that AstraZeneca has committed a crime or has engaged in fraudulent activities in the United States. 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. AstraZeneca shall also provide written notice to OIG within 30 days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

I. 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 AstraZeneca'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.* If AstraZeneca determines through any means that there is a Reportable Event, AstraZeneca shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to the 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 AstraZeneca's actions taken to correct the Reportable Event; and

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

3. AstraZeneca shall not be required to report any Reportable Event that is the subject of an ongoing investigation or legal proceeding by a government entity or its agents previously disclosed under section III.H. above.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, AstraZeneca establishes or acquires new business units engaged in the contracting for, marketing, sales or price reporting of Government Reimbursed Products, AstraZeneca shall notify OIG of this fact as soon as possible, but no later than within 30 days of the date of the establishment or acquisition. This notification shall include the location of the new operation(s), phone number, fax number, Federal health care program provider number(s) (if any), and the corresponding contractor's name and address that has issued each provider number. All new Covered Persons at such business units 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 120 days after the Effective Date, AstraZeneca 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, position description of the Compliance Officer required by section III.A.1, and summary of other non-compliance job responsibilities the Compliance Officer may have;

2. the names and positions of the members of the Business Compliance Committee required by section III.A.2;

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

4. to the extent not already provided, a copy of all Policies and Procedures required by section III.B.2;

5. to the extent not already provided, a copy of all training materials used for the training required by section III.C, a description of such training programs including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, and 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.2 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;

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.F;

8. a summary/description of all reviews to be completed by GIA and the proposed start and completion date of the first reviews; the identity of the IRO(s); a summary/description of all engagements between AstraZeneca and the IRO, including, but not limited to, any outside financial audits or other audits, and the proposed start and completion dates of the first IRO reviews;

9. a certification from the IRO regarding its professional independence and/or objectivity from AstraZeneca;

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

11. except for home offices, a list of all of AstraZeneca's locations (including locations and mailing addresses) at which Covered Persons work, 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's name and address that issued each provider identification number;

12. to the extent not already furnished to OIG, or if modified, a description of AstraZeneca's corporate structure, including identification of any parent and sister companies, subsidiaries and their respective lines of business; and

13. the certification required by section V.C.

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

Each Annual Report shall include:

1. as described in section III.A, any change in the identity, position description, or other non-compliance job responsibilities of the Compliance Officer and any change in the membership of the Business Compliance Committee;

2. a certification by the Compliance Officer that:

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

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

c. AstraZeneca's Policies and Procedures and its templates for the standardized contracts and other similar documents have been reviewed by competent legal counsel and have been found to be in compliance with the requirements of the Federal anti-kickback statute, the Prescription Drug Marketing Act, and other applicable laws. 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.

To the extent that the Compliance Officer cannot certify to these items in their entirety, the Compliance Officer shall provide an explanation of any deficiencies and a timetable for their remedy.

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 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), a description of such training conducted during the Reporting Period, including a list of 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 GIA's and IRO's Reviews required by this CIA, including, to the extent not already provided, a copy of the methodologies used, along with a copy of the IRO's engagement letter;

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

7. a revised summary/description of all engagements between AstraZeneca and the GIA and IRO, as described in section V.A.8, if different than what was submitted as part of the Implementation Report; for the second and subsequent Reporting Periods, a certification from the IRO regarding its professional independence and/or objectivity from AstraZeneca.

8. a summary of the Disclosures in the Disclosure log required by section III.F;

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

10. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to section III.H. 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;

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

12. a description of the co-promotion agreements that AstraZeneca has with other firms, including the number of such agreements in existence during the Reporting Period and a summary of the assurances AstraZeneca has received regarding the training of co-promotion personnel, as referenced in Section II;

13. a description of all changes to the most recently provided list (as updated) of AstraZeneca's locations except home offices 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 identification number; and

14. the certification required by section V.C.

The first Annual Report shall be submitted to the OIG no later than 90 days after the end of the first Reporting Period. Each subsequent Annual Report shall be submitted to OIG no later than 90 days after the end of each subsequent Reporting Period.

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, AstraZeneca 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 therein is accurate and truthful.

D. Designation of Information.

AstraZeneca shall clearly identify any portions of any of its submissions under this CIA 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. AstraZeneca 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 of this CIA, 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, SW
Washington, DC 20201
Phone: (202) 619-2078
Fax: (202) 205-0604

AstraZeneca:

Glenn M. Engelmann
Vice President, General Counsel and Compliance Officer
AstraZeneca Pharmaceuticals LP
1800 Concord Pike
PO Box 15437
Wilmington, DE 19850-5437
Phone: (302) 886-3244
Fax: (302) 886-1578

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, messenger delivery (such as Federal Express, or its equivalent), 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 AstraZeneca'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 AstraZeneca's locations for the purpose of verifying and evaluating: (a) AstraZeneca's compliance with the terms of this CIA; and (b) AstraZeneca'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 AstraZeneca 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 AstraZeneca's Covered Persons 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. AstraZeneca shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. AstraZeneca's employees may elect to be interviewed with or without a representative of AstraZeneca present. AstraZeneca employees shall have the right to be represented by counsel and any such employee may, at his or her option, be accompanied by counsel for AstraZeneca and/or their personal counsel at any interview by the OIG.

Notwithstanding such arrangement, the OIG recognizes that individuals have the right to refuse to submit to interviews, and AstraZeneca 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.

VIII. DOCUMENT AND RECORD RETENTION

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

IX. DISCLOSURES

The OIG shall follow all applicable Federal laws concerning privacy and confidentiality, including the Federal Privacy Act, 5 U.S.C. § 552a, to the greatest extent allowed by law. Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify AstraZeneca prior to any release by OIG of information submitted by AstraZeneca pursuant to its obligations under this CIA and identified upon submission by AstraZeneca as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, AstraZeneca 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 AstraZeneca of AstraZeneca's attorney-client, work product or other applicable privileges. Except as otherwise stated herein, the existence of any such privilege does not affect AstraZeneca's obligation to comply with the provisions of the CIA.

X. BREACH AND DEFAULT PROVISIONS

AstraZeneca 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 or Plea Agreement between AstraZeneca and the United States executed contemporaneously herewith 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 AstraZeneca 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 AstraZeneca under appropriate authorities not specified in this CIA.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, AstraZeneca 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 AstraZeneca fails to have in place any of the following obligations described in section III:

a. a Compliance Officer;

b. a Business 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 AstraZeneca fails to direct the GIA or to retain an IRO as required in section III.E.

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 AstraZeneca 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 failure to comply began) for each day AstraZeneca engages as a Covered Person an Ineligible Person and that person: (i) has responsibility for, or involvement with, AstraZeneca's business operations related to the Federal health care programs; or (ii) 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 paragraph shall not be demanded for any time period during which AstraZeneca can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.G) as to the status of the person).

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

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

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

B. Timely Written Requests for Extensions.

AstraZeneca may, in advance of the due date, submit a timely written request for an extension of time to perform any act or submit 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 AstraZeneca 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 submit the notification or report shall not begin to accrue until three business days after AstraZeneca 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 AstraZeneca 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 AstraZeneca in writing of: (a) AstraZeneca's failure to comply; and (b) the 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, AstraZeneca 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 AstraZeneca elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until AstraZeneca 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 AstraZeneca 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 AstraZeneca to report a Reportable Event and take corrective action as required by Section III.I;

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 direct or retain and use the GIA and IRO in accordance with section III.E.

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

4. *Exclusion Letter.* If at the conclusion of the 30-day period, AstraZeneca fails to satisfy the requirements of section X.D.3, OIG may exclude AstraZeneca from participation in the Federal health care programs. OIG will notify AstraZeneca in writing of its determination to exclude AstraZeneca (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 non-procurement programs. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, AstraZeneca wishes to apply for reinstatement, AstraZeneca must submit 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 AstraZeneca 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, AstraZeneca 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

AstraZeneca was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. AstraZeneca shall have the burden of proving its full and timely compliance with the obligations at issue 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 AstraZeneca to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless AstraZeneca 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 AstraZeneca 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) AstraZeneca had begun to take action to cure the material breach within that period; (ii) AstraZeneca has pursued and is pursuing such action with due diligence; and (iii) AstraZeneca provided to OIG within that period a reasonable timetable for curing the material breach and AstraZeneca 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 AstraZeneca, only after a DAB decision in favor of OIG. AstraZeneca's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude AstraZeneca upon the issuance of an ALJ's decision in favor of the OIG. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that AstraZeneca 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. AstraZeneca shall waive its right to notice of such exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of AstraZeneca, AstraZeneca shall be reinstated effective on the date of the original exclusion.

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, AstraZeneca and OIG agree as follows:

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

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 AstraZeneca signatory represents and warrants that he is 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 ASTRAZENECA PHARMACEUTICALS LP AND ASTRAZENECA LP

Glenn Engelmann
Vice President, General Counsel
and Compliance Officer
On behalf of AstraZeneca Pharmaceuticals LP and
AstraZeneca LP

DATE 6/4/03

Kathleen M. Sanzo
John C. Dodds
Morgan, Lewis & Bockius LLP

DATE 6/4/03

ON BEHALF OF ASTRAZENECA PHARMACEUTICALS LP AND ASTRAZENECA LP

_____

Glenn Engelmann
Vice President, General Counsel
and Compliance Officer
On behalf of AstraZeneca Pharmaceuticals LP and
AstraZeneca LP

DATE

Kathleen M. Sanzo

Kathleen M. Sanzo
John C. Dodds
Morgan, Lewis & Bockius LLP

DATE June 4, 2003

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

May 19, 2003
DATE

Attachment A to CIA between AstraZeneca and Office of Inspector General

CERTIFICATION

In accordance with the Corporate Integrity Agreement ("CIA") entered between AstraZeneca Pharmaceuticals LP and AstraZeneca LP (collectively "AstraZeneca") and the OIG, the undersigned hereby certifies that the attached Average Sale Price information has been provided to First DataBank Inc. (and/or other price reporting entity as specified in the CIA); to the State Medicaid programs of those States which executed settlement agreements with AstraZeneca; to the OIG; and to CMS; and that the average sale price has been calculated in accordance with the methodology described generally in the CIA and more specifically in the attached document.

_____

Name
Title

_____

Date

Appendix A to CIA between AstraZeneca and Office of Inspector General

List of Covered Products

1. Cefotan
2. Elavil Injection *
3. Faslodex
4. Foscavir
5. Merrem
6. Tenormin Injection
7. Xylocaine Injection
8. Zolodex

Following the Effective Date of the CIA, the list of Covered Products for which AstraZeneca is required to report Average Sale Price in accordance with Section III.D of the CIA shall include the above-listed products and all other newly developed injectible products primarily marketed and sold by AstraZeneca to individual medical practitioners/clinics for in-office administration and directly billed by the practitioners/clinics to health care insurers, including Federal health care programs.

* As of February 2003, AstraZeneca no longer makes or sells Elavil Injection. Consequently, AstraZenca may be limited or unable to report Average Sale price for this product in the future.

Attachment B to CIA between AstraZeneca and Office of Inspector General

Audit Workplan for Group Internal Audit (GIA)

As specified more fully below, AstraZeneca shall direct its Group Internal Audit ("GIA") to perform reviews to assist the company in determining the accuracy of Best Price reported for purposes of the Medicaid Drug Rebate Program ("Medicaid Rebate Review"). AstraZeneca shall also direct its GIA to perform reviews to assist the company in assessing and evaluating its systems, processes, policies and practices related to Sales and Marketing ("Sales and Marketing Review").

The GIA shall perform the Medicaid Rebate Review for one randomly selected quarter of each Reporting Period. The GIA shall perform the Sales and Marketing Review annually for each Reporting Period.

A. Medicaid Rebate Review

1. General Description of Medicaid Rebate Review

   AstraZenca's Policies and Procedures (referenced in Section III.B.2 of the CIA) include policies and procedures which the company follows in gathering, calculating and reporting prices for purposes of the Medicaid Drug Rebate Program. The GIA will review a sample of the Best Prices reported to CMS for 50 11–digit NDCs during a randomly selected quarter during the Reporting Period.

2. Medicaid Rebate Review Methodology

   The Medicaid Rebate Review shall consist of two parts as follows:

   (a) Part One – Review of Samples

   At the end of each Reporting Period, the GIA shall randomly select one quarter for review. The GIA will then obtain a listing of all 11-digit NDCs for which Best Price was reported during the quarter under review. The GIA will identify the five 11-digit NDCs for which AstraZeneca paid the largest amount (e.g., total dollars) of rebates to the States under the Medicaid Drug Rebate program in the quarter under review. From the listing, the GIA will also randomly select another 45 11-digit NDCs for review.

For each of the 50 11-digit NDCs included in the Medicaid Rebate Review, the GIA will:

(1) select all prices identified in the AstraZeneca Top Contracts Report and all manual price adjustments within AstraZeneca's government pricing system(s) where an actual sale was recorded in the quarter under review at a price lower than the Best Price reported by AstraZeneca for the NDC for the quarter[1]; and

(2) analyze each of the lower prices and determine, based on AstraZeneca's policies and procedures and the Medicaid Drug Rebate Program requirements, if each price was properly excluded from the determination of Best Price.

(b) Part Two - Additional Investigation

For purposes of additional investigation, an error shall be defined to be any instances in which: 1) contract price terms for the 11-digit NDCs under review which were not appropriately included in or excluded from AstraZeneca's Best Price determination; or 2) the reported Best Price for any 11-digit NDC was incorrectly reported. If the GIA discovers either type of error, then the GIA shall conduct an additional investigation, as may be necessary, to determine the root cause of the error (*e.g.*, review additional documentation and/or conduct interviews with appropriate personnel to identify the root cause of the error.)

In the event the GIA finds more than one error as defined in the preceding paragraph, the GIA will perform a second Medicaid Rebate Review. The second Medicaid Rebate Review shall consist of the GIA randomly selecting and reviewing (in accordance with the steps outlined in section A.2.a above) an additional five 11-digit NDCs for which AstraZeneca paid Medicaid rebates in the quarter under review.

3. IRO Verification Review

The IRO shall conduct a verification review, which shall evaluate at least 15 of the same 11-digit NDCs reviewed by the GIA. The IRO will independently obtain

1 The review of the AstraZeneca Top Contracts Report and all manual price adjustments will result in a review of all contract prices within AstraZeneca's government pricing system where an actual sale was made at a price lower than the Best Price reported by AstraZeneca for the NDCs for the quarter.

source documentation relating to the 15 11-digit NDCs and will independently conduct the steps outlined contained in section A.2.a above. After the IRO has conducted its verification review and made its independent determinations, it shall: 1) obtain the GIA's findings with regard to each of the 15 11-digit NDCs; 2) compare its own findings to those of the GIA; 3) identify any discrepancies between the two sets of findings; and 4) explain potential reasons for the discrepancies.

If the IRO identifies errors in any of AstraZeneca's findings, the IRO shall conduct a verification review of at least an additional 5 of the 11-digit NDCs reviewed by the GIA. If the IRO identifies any AstraZeneca errors in this additional review, AstraZeneca and the IRO shall notify the OIG to discuss appropriate additional steps to be taken (*e.g.*, additional reviews or a requirement that an IRO, rather than the GIA, conduct all or part of future reviews).

The IRO shall prepare a report based upon its review ("IRO Verification Report"). The IRO Verification Report shall contain, for each NDC reviewed: (i) the IRO's findings; (ii) a detailed description of any discrepancies between the IRO's findings and those of the GIA; and (iii) the IRO's explanation of the possible reasons for the discrepancies. In addition, if the IRO conducted any additional verification review(s) (beyond the initial review of the 15 NDCs), the IRO Verification Report shall contain a detailed description of the results of that review, including the IRO's findings. The IRO Verification Report shall be provided to the OIG.

4. Medicaid Rebate Review Report

The GIA shall annually prepare a report based upon the Medicaid Rebate Review performed. The report shall include the following general elements and information:

(a) Review Objective: A clear statement of the objective(s) intended to be achieved by the review;

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

(c) Sources of Data: A full description of documentation (and/or other information) relied upon by the GIA when performing the Medicaid Rebate Review;

(d) a narrative list of the five 11-digit NDCs with the highest rebates paid by AstraZeneca for the quarter under review and the associated Best Price reported by AstraZeneca to CMS and a narrative list of the 45 randomly selected 11-digit NDCs and the associated Best Price reported by AstraZeneca to CMS;

(e) for each 11-digit NDC under review, a list of all contract price terms and the corresponding AstraZeneca customer to which a sale was made at a price lower than the Best Price reported to CMS for that quarter;

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

(g) for each NDC under review, a list of any prices not appropriately included in AstraZeneca's Best Price determination for that quarter;

(h) a detailed description of any additional investigation undertaken with regard to any prices that were not accurately included or excluded in AstraZeneca'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

(i) the GIA's recommendations for changes in AstraZeneca's policies and procedures to correct or address any weaknesses or deficiencies uncovered during the review.

B. Sales and Marketing Review

1. General Description of Sales and Marketing Review

The Sales and Marketing Review shall be conducted for three of AstraZeneca's Business Centers annually and shall cover all therapy areas handled by the respective Business Center. The Sales and Marketing review shall consist of two parts: (1) interviews with Pharmaceutical Sales Specialists (PSSs), contract sales representatives, District Sales Managers (DSMs) and other supervisory personnel at the Business Center; and (2) a review of a sample of Control Documents, as defined below, completed by personnel at the Business Center in connection with sales and marketing activities.

AstraZeneca's Policies and Procedures (referenced in section III.B.2 of the CIA), including its Business Policies (hereafter collectively "AstraZeneca's Policies"), set forth certain requirements relating to control type documents used in connection with the following types of activities (hereafter, collectively "Sales and Marketing Related Activities" or "Activities"):

(a) provision of Access Tools (*e.g.*, meals, refreshments, other items) to healthcare professionals (HCPs) or others;

(b) engagement of HCPs, institutions, organizations for contracted services (*e.g.*, consulting, advisory, speaking and other fee-for-service arrangements);

(c) sponsorship of promotional education programs (*e.g.*, speakers programs, convention/symposia exhibits; case study programs, *etc.*);

(d) provision of grants (*e.g.*, educational and other grants);

(e) expenditures for third party advice about reimbursement or claims submissions for Government Reimbursed Products, if any;

(f) provision of customer assistance programs, if any;

(g) provision of drug samples; and

(h) provision of any or all other activities identified in AstraZeneca's Policies and used in connection with Sales and Marketing Activities.

For purposes of this Sales and Marketing Review, "Control Documents" is defined mean all documents associated with the above-referenced Sales and Marketing Related Activities. For instance, Control Documents include Expense Reports, Purchase Orders, and Vendor Invoices, among others.

2. Interviews of Personnel from Business Centers

For each Business Center under review, the GIA shall annually interview at least 5% of the PSSs and their corresponding supervisory DSMs, and shall interview at least three contract sales representatives and one supervisory contract DSM associated with the Business Center. The interviews shall be designed to evaluate the PSSs', the contract sale representatives', and the DSMs' knowledge of and adherence to AstraZeneca's Policies relating to the Sales and Marketing Related

Activities and the extent to which the PSSs and contract sale representatives have engaged in various types of Sales and Marketing Related Activities. The 5% of the PSSs interviewed shall be judgmentally selected from among the PSSs assigned to each Business Center in a manner designed to ensure that PSSs from each therapy area, territory and different experience levels associated with the Business Center are selected for interview.

The GIA shall also identify the therapy area in the applicable Business Center with the highest dollar amounts of budgeted expenditures per PSS for Sales and Marketing Related Activities during the Reporting Period. The GIA shall then conduct interviews with an additional number of PSSs from the identified high-expenditure therapy area. The number of additional PSSs to be interviewed from the high-expenditure therapy area shall be equal to at least 50% of the aggregate number of PSSs selected for the initial interviews (as described above) in the Business Center. The contract sales representatives interviewed shall be randomly selected.

3. GIA Review of Control Documents

For each Reporting Period and for each Business Center, the GIA shall review at least four Expense Reports and other Control Documents, selected from the 12-month period proceeding the review, for each of the PSSs and contract sales representatives selected for interview. At a minimum, GIA shall review 158 Expense Reports annually. In addition, GIA shall review a minimum of 54 non-Expense Report Control Documents associated with the PSSs and contract sales representatives selected for interview. To the extent the GIA cannot identify at least 54 non-Expense Report Control Documents associated with the PSSs and contract sales representatives interviewed, the GIA shall select the 54 non-Expense Report Control Documents for other personnel at the Business Center.

The GIA shall evaluate and review the Control Documents to determine:

(a) whether the Control Documents were completed in accordance with the requirements set forth in the AstraZeneca's Policies;

(b) whether the Control Documents reflect that all required written approvals were obtained in accordance with AstraZeneca's Policies; and

(c) for each Control Document reviewed, whether all supporting documentation (*e.g.,* receipts) and follow-up documentation (*e.g.,* progress and final reports produced in connection with grants) exists in appropriate

files in accordance with AstraZeneca's Policies.

Any Control Document that does not satisfy the criteria set forth above shall be considered an exception and shall be noted by the GIA. The GIA will consider a Control Document to have a Material Error if either of the following is identified:

(a) all the appropriate and required Control Documents do not exist and no corrective action has been taken prior to the GIA review; or

(b) information or data is omitted from key fields in the Control Documents that prevents the GIA from understanding the nature of the expenditure and/or assessing compliance with AstraZeneca's Policies.

4. Additional Review of Material Errors Are Discovered

If the GIA finds any Material Errors, it shall conduct an additional review of the expenditures or activities reflected in the Control Documents at issue. The GIA shall perform this additional review in a manner designed to determine the root cause of the Material Errors. For instance the GIA may need to review additional documentation and/or conduct interviews with appropriate personnel to identify the root cause of the Material Error.

5. IRO Verification Review

The IRO shall conduct a verification review which shall evaluate least 20% of the same Expense Reports and 20% of the non-Expense Report Control Documents reviewed by the GIA. The IRO will independently obtain source documentation relating to the Control Documents under review and will independently conduct the steps outlined in section B.3 above. After the IRO has conducted its verification review and made its independent determinations, it shall: 1) obtain the GIA's findings with regard to each of the Control Documents; 2) compare its own findings to those of the GIA; 3) identify any discrepancies between the two sets of findings; and 4) explain potential reasons for the discrepancies.

If the IRO identifies errors in any of AstraZeneca's findings, the IRO shall conduct a verification review of at least an additional 10% of the Expense Reports and 10% of the non-Expense Report Control Documents reviewed by the GIA. If the IRO identifies any AstraZeneca errors in this additional review, AstraZeneca and the IRO shall notify the OIG to discuss appropriate additional steps to be taken (*e.g.*, additional reviews or a requirement that an IRO, rather than the GIA, conduct all or part of future reviews).

The IRO shall prepare a report based upon its review ("IRO Verification Report").

The IRO Verification Report shall contain, for each Control Document: (i) the IRO's findings; (ii) a detailed description of any discrepancies between the IRO's findings and those of the GIA; and (iii) the IRO's explanation of the possible reasons for the discrepancies. In addition, if the IRO conducted any additional verification review(s) (beyond the 20% initial review), the IRO Verification Report shall contain a detailed description of the results of that review, including the IRO's findings. The IRO Verification Report shall be provided to the OIG.

6. Sales and Marketing Review Report

The GIA shall annually prepare a report based upon each Sales and Marketing Review performed ("Sales and Marketing Review Report"). Each Sales and Marketing Review Report shall include the following elements/information:

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

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

(c) Sources of Data: A full description of the documentation (and/or other information) relied upon by the GIA when performing the Sales and Marketing Review.

(d) a summary of the interviews with the PSSs, contract sales representatives, and DSMs, including the GIA's assessment of: (i) whether the PSSs, contract sales representatives and DSMs received adequate training relating to the Sales and Marketing Activities; (ii) the frequency with which personnel at the Business Center engaged in each type of Activity; and (iii) a detailed description of instances in which the training appeared inadequate and/or the Business Center personnel failed to follow AstraZeneca's Policies.

(e) for each sample unit, the GIA shall state its findings and supporting rationale as to whether: a) the Control Document was completed in accordance with all requirements set forth in the AstraZeneca's Policies; b) the Control Document reflects that all written approvals were obtained in accordance with AstraZeneca's Policies; and c) all supporting documentation and follow-up documentation exists in accordance with AstraZeneca's Policies;

(f) for each sample unit reviewed, the GIA shall identify all exceptions and

Material Errors discovered. For the exceptions, the GIA shall describe in general terms what the errors were. The GIA shall describe those situations when corrective action was taken prior to the GIA review, including a description of the circumstances requiring corrective action and the nature of the corrective action;

(g) if any Material Errors were discovered for any sample unit, the GIA shall describe the Material Error and the additional review procedures it performed, and shall state its findings as to the root cause of the Material Errors; and

(h) the GIA's recommendations for changes in AstraZeneca's Policies in order to correct or address any weaknesses or deficiencies uncovered during the review.

Attachment C to CIA between AstraZeneca and Office of Inspector General

Independent Review Organization (IRO) Reviews

As specified more fully below, AstraZeneca shall retain an Independent Review Organization ("IRO") to perform reviews to assist AstraZeneca in assessing and evaluating its systems, processes, policies and practices related to: 1) the determination of Best Price for purposes of the Medicaid Drug Rebate Program ("Medicaid Rebate Systems Review"); 2) the methodology for calculating Average Sale Price ("Average Sale Price Systems Review"); and 3) its sales and marketing activities ("Sales and Marketing Systems Reviews").

If, during the term of the CIA, there are no material changes in AstraZeneca's systems, processes, policies and practices relating to the determination of Best Price, the calculation of Average Sale Price, or its sales and marketing activities, then the IRO shall perform the Systems Reviews listed above to cover the first and fourth Reporting Periods. If AstraZeneca materially changes its systems, processes, policies or practices, then the IRO shall perform the applicable additional Systems Review(s) covering the Reporting Period(s) in which such changes were made in addition to conducting the Systems Reviews for the first and fourth Reporting Periods.

As specified in section III.E of the CIA, for at least the first two years of the CIA, AstraZeneca shall also retain the IRO to conduct the Average Sale Price Review outlined below in Section D. Each Average Sale Price Review shall cover one randomly-selected quarter of the 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 and evaluate AstraZeneca's systems, processes, policies and practices associated with the tracking of, gathering of, and appropriate accounting for all data relevant for purposes of determining the Best Prices reported to the Centers for Medicare and Medicaid Services ("CMS").

In general terms, the IRO shall evaluate the following:

(a) the systems, processes, policies, and practices that are in place to track, gather, and appropriately account for contract price

terms that are relevant to the Medicaid Rebate Program. Specifically, this includes a review of:

(1) the processes, policies and procedures used to determine whether contract price terms are appropriately 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 AstraZeneca inquiries to CMS regarding Medicaid Best Price and any responses to those inquiries); and

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

(b) AstraZeneca's policies and practices for identifying outliers (*i.e.*, reported Best Prices that, according to AstraZeneca's policies, would require further scrutiny), the reasons for any identified outliers, and the identification and correction of any erroneous Best Price reported.

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

(1) the computer or other relevant system(s) used to determine the Medicaid Best Price;

(2) what information is input into AstraZeneca's relevant computer or other system(s) and whether this information is appropriate and comprehensive;

(3) the system logic or decision rationale used to determine whether relevant contract price terms are included in the determination of the Medicaid Best Price; and

(4) AstraZeneca's policies and practices for identifying outliers, the reasons for any identified outliers, and the identification and correction of any erroneous Best Price reported.

(b) a full description of all documentation, information, and systems reviewed, including but not limited to, a description of AstraZeneca's inquiries to CMS regarding Best Price, 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 AstraZeneca's systems, processes, policies, and practices, including the IRO's assessment of whether AstraZeneca's systems, processes, policies and practices result in the inclusion of appropriate and relevant contract price terms in the determination of the Medicaid Best Price.

B. Average Sale Price Systems Review

1. General Description of Average Sale Price Systems Review

For at least the first and fourth Reporting Periods, the IRO shall review and evaluate AstraZeneca'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 Average Sale Prices reported pursuant Section III.D of the CIA.

In general terms, the IRO shall evaluate the following:

(a) the systems, processes, policies, and practices that are in place to track, gather, and appropriately account for price terms that are relevant for purposes of the Average Sale Price. Specifically, this includes a review of:

(1) the process, policies, and procedures used to determine whether particular transactions reflecting final sales prices are included in or excluded from the calculation of the Average Sale Price for any product (this includes: (a) a review of the decision rationale by which sales to certain types of customers are included in or excluded from the calculation of Average Sale Price; (b) a review of the decision rationale by which certain transactions are included in or excluded from the calculation of Average Sale Price; and (c) the relevant data or information flow process by which relevant price terms are evaluated for purposes of determining the Average Sale Price);

(2) the computer or other relevant system(s) used to calculate the Average Sale Prices; and

(b) AstraZeneca's policies and practices for identifying outliers (*i.e.*, reported Average Sale Prices that, according to AstraZeneca's policies, require further scrutiny), the reasons for any identified outliers, and the identification and correction of any erroneous Average Sale Price reported.

2. Average Sale Price Systems Review Report

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

(a) a full description of the systems, processes, policies, and practices in place to track, gather, and appropriately account for price terms relevant for purposes of the Average Sale Price including, but not limited to:

(1) the computer or other relevant systems used to calculate the Average Sale Price;

(2) what information is input into AstraZeneca's relevant computer or other system(s) and whether this information is appropriate and comprehensive;

(3) the system logic or decision rationale used to determine whether certain transactions are included in or excluded from the calculation of the Average Sale Price; and

(4) AstraZeneca's policies and practices of identifying outliers, the reasons for any identified outliers, and the identification and correction of any erroneous Average Sale Price reported.

(b) observations, findings, and recommendations on possible improvements to AstraZeneca's systems, processes, policies, and practices, including the IRO's assessment of whether AstraZeneca's systems, processes, policies and practices result in the inclusion of appropriate and relevant price terms in the determination of the Average Sale Price.

C. Sales and Marketing Systems Review

1. General Description of Sales and Marketing Systems Review

For at least the first and fourth Reporting Periods, the IRO shall review AstraZeneca's systems, processes, policies and practices associated with the following types of activities (hereafter collectively "Sales and Marketing Related Activities" or "Activities"):

a) provision of Access Tools (*e.g.*, meals, refreshments, other items) to healthcare professionals (HCPs) or others;
b) engagement of HCPs, institutions, organizations for contracted services (*e.g.*, consulting, advisory, speaking and other fee-for-service arrangements);
c) sponsorship of promotional education programs (*e.g.*, speakers programs,

convention/symposia exhibits; case study programs, *etc.*);
d) provision of grants (*e.g.*, educational and other grants);
e) expenditures for third party advice about reimbursement or claims submissions for Government Reimbursed Products, if any;
f) provision of gifts, if any;
h) provision of customer assistance programs, if any;
i) provision of debt forgiveness, debt reduction, or other like assistance to customers, if any; and
j) provision of drug samples.

For each of the Sales and Marketing Related Activities, the IRO shall determine the following:

(a) whether AstraZeneca has instituted control and accountability systems (*e.g.*, documentation and approval requirements, tracking mechanisms) and written policies regarding the Activity;
(b) whether the control and accountability systems and the written policies are adequate and appropriate;
(c) the manner in which the control and accountability systems and the written policies are made known or disseminated within AstraZeneca;
(d) what disciplinary measures AstraZeneca has established for failure to comply with the control and accountability systems and written policies; and
(e) the number of instances and the circumstances in which AstraZeneca took disciplinary actions for failure to comply with the systems and policies.

2. Sales and Marketing Systems Review Report

For each relevant Reporting Period, the IRO shall prepare a report based upon the Sales and Marketing Systems Review. Each report shall include the following items for each of the Sales and Marketing Related Activities:

(a) a description of the documentation reviewed and any personnel interviewed;
(b) a general description of AstraZeneca's control and accountability systems and written policies and actual practices and the IRO's

assessment about their adequacy and appropriateness;
(c) a description of the manner in which the control and accountability systems and written policies are disseminated or made known within AstraZeneca;
(d) a general description of the disciplinary measures AstraZeneca has established for failure to comply with the control and accountability systems and written policies;
(e) a description of the number of instances and a description of the circumstances in which AstraZeneca undertook disciplinary actions for failure to comply with the systems and policies;
(f) the findings and supporting rationale regarding any weaknesses in AstraZeneca's sales and marketing related systems, policies and practices; and
(g) any recommendations to improve any of AstraZeneca's sales and marketing related systems, policies or practices.

D. Average Sale Price Review

1. General Description of Average Sale Price Review

Section III.D of the CIA requires AstraZeneca to calculate and report Average Sale Prices for Covered Products. The IRO shall randomly select five 11-digit NDCs for which Average Sale Prices were reported during the quarter of the Reporting Period under review. The IRO shall then randomly select 50 transactions (defined to be final sale prices) associated with each of the five 11-digit NDCs. This review shall determine, in accordance with AstraZeneca's policies and procedures and the CIA requirements, whether: 1) each transaction is supported by source documentation; and 2) whether each transaction has been appropriately considered (*i.e.*, included or excluded) for purposes of determining an Average Sale Price for the 11-digit NDC under review.

2. Average Sales Price Review Methodology

The Average Sale Price Review shall consist of two parts as follows:

(a) Part One – Review of Samples

At the end of each Reporting Period, the IRO shall randomly select one quarter for review. The IRO will then randomly select 5 11-digit NDCs for which Average Sale Price was reported during the quarter under review. From that listing, the IRO will randomly select for review 50 transactions associated with each of the five 11-digit NDCs.

For each of the five 11-digit NDCs included in the Average Sales Price Review, the IRO will:

(1) obtain information about all transactions reflected anywhere in AstraZeneca's systems relating to the calculation of Average Sale Price for the 11-digit NDC under review; and

(2) for each of the five 11-digit NDCs, the IRO will review a sample of 50 randomly selected transactions to determine whether: 1) each transaction is supported by source documentation; and 2) each transaction was properly included in or excluded from the calculation of Average Sale Price.

(b) Part Two - Additional Investigation

For purposes of additional investigation, an error shall be defined to be any transaction that was: 1) not supported by source documentation; or 2) not appropriately included in or excluded from AstraZeneca's Average Sale Price calculation. If the IRO discovers either type of error, then the IRO shall conduct an additional investigation (*e.g.*, conduct interviews and/or review additional documentation) as may be necessary to determine the root cause of the error.

3. Average Sale Price Review Report

The IRO shall annually prepare a report based upon the Average Sale Price Review performed. The report shall include the following general elements and information:

(a) Review Objectives: A clear statement of the objective(s) intended to be achieved by the review;

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

(c) Sources of Data: A full description of documentation (and/or other information) relied upon by the IRO when performing the Average Sale Price Review.

(d) a narrative list of the five 11-digit NDCs for which AstraZeneca reported Average Sale Price for the quarter under review and the associated Average Sale Price reported for each;

(e) for each NDC under review, a list of all transactions reviewed and a description of all documentation supporting the transaction;

(f) for each NDC under review, a description of the steps and the supporting documentation reviewed to determine that each transaction was appropriately included or excluded for purposes of determining the Average Sale Price;

(g) for each NDC under review, a list of any transactions not appropriately included in or excluded from AstraZeneca's Average Sale Price determination for that quarter;

(h) a detailed description of any additional investigation undertaken with regard to any identified error and the results of any additional investigation or reviews undertaken with respect to any such error; and

(i) the IRO's recommendations for changes in

AstraZeneca's policies and procedures to correct or address any weaknesses or deficiencies uncovered during the review.