CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND BAYER CORPORATION

I. PREAMBLE

Bayer Corporation ("Bayer") hereby enters into this Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to promote compliance by officers, directors, employees, contractors (subject to Bayer's control) and agents of the Bayer Pharmaceutical Division who are involved in the contracting for, or marketing, selling or reporting the price of products that are reimbursed by Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a7b(f)) (hereinafter collectively referred to as the "Federal health care programs") with the requirements of those Federal health care programs. All persons identified in the preceding sentence shall collectively be referred to as the "Covered Persons."[1] If during the term of this CIA, any Bayer division or affiliate (defined as an entity controlled by Bayer) besides, or in addition to, the Pharmaceutical Division becomes involved in the contracting for,

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[1] Specifically excluded from the definition of "Covered Persons" are the marketing, sales or other personnel of firms with which Bayer has agreements to co-promote its products. Bayer 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 Bayer's contract sales force.

marketing, selling or reporting the price of pharmaceutical or biological products that are reimbursed by Medicare, Medicaid or other Federal health care programs, the term Covered Persons shall also include the individuals in that division or affiliate, and all references to the Pharmaceutical Division in this CIA shall also be construed to also include that other Bayer division or affiliate.

Contemporaneously with this CIA, Bayer is entering into a Settlement Agreement with the United States and this CIA is incorporated by reference into that Settlement Agreement, subject to the terms of Section X below. Contemporaneously with this CIA, Bayer is also entering settlement agreements with various other states, and Bayer's agreement to this CIA is a condition precedent to those agreements.

II. TERM OF THE CIA

The period of the compliance obligations assumed by Bayer under this CIA shall be five (5) years from the Effective Date of this CIA (unless otherwise specified). The Effective Date of this CIA will be the date on which the final signatory to this CIA executes this CIA (the "Effective Date").

Sections VII, VIII, IX, X and XI shall remain in effect until the OIG has completed its review of the final Annual Report and any additional materials submitted by Bayer pursuant to the OIG's request.

III. CORPORATE INTEGRITY OBLIGATIONS

Bayer hereby agrees to establish a Compliance Program that includes the following elements:

A. **Compliance Officer and Committee.** Within sixty (60) days of the Effective Date of this CIA, Bayer Pharmaceutical Division shall appoint an individual to serve as its Compliance Officer. That person shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with the requirements of the Federal health care programs. The Compliance Officer shall be a member of senior management of the Bayer Pharmaceutical Division, shall make periodic (at least quarterly) reports regarding compliance matters directly to the President of the Pharmaceutical Division and shall be authorized to report on such matters to the Chief Executive Officer and the Board of Directors of Bayer at any time. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Bayer Pharmaceutical Division as well as any reporting obligations created under this CIA.

Any change in the identity or position description of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, must be reported to OIG, in writing, within fifteen (15) days of such a change.

Bayer Pharmaceutical Division shall also appoint a Compliance Committee within sixty (60) days of the Effective Date of this CIA. The Compliance Committee shall, at a minimum, include the Compliance Officer and any other members of senior management of the Pharmaceutical Division necessary to meet the requirements of this CIA (e.g., senior executives of each major department, such as Contracting, Sales, Marketing,

Human Resources and Internal Audit). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the Pharmaceutical Division's risk areas and shall oversee monitoring of internal and external compliance audits and investigations).

Any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, must be reported to OIG, in writing, within fifteen (15) days of such a change.

B. Written Standards.

1. ***Code of Conduct.*** Within ninety (90) days of the Effective Date of this CIA, Bayer Pharmaceutical Division shall establish a Code of Conduct. The Code of Conduct shall be distributed to all Covered Persons within one-hundred-twenty (120) days of the Effective Date of this CIA. Bayer Pharmaceutical Division shall 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. Bayer Pharmaceutical Division's commitment to full compliance with all Federal health care program requirements, including its commitment to report prices for and market its drug and biologic products for which the Federal health care programs provide reimbursement ("Government

Reimbursed Products") in accordance with Federal health care program requirements;

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

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

d. the potential consequences to both Bayer and to Covered Persons of failure to comply with all Federal health care program requirements and with Bayer Pharmaceutical Division's own Policies and Procedures or of failure to report such noncompliance; and

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

Within one-hundred twenty (120) days of the Effective Date of the CIA, each Covered Person shall certify, in writing or in electronic form, that he or she has received, read, understood, and will abide by Bayer Pharmaceutical Division's Code of Conduct. New Covered Persons shall receive and complete the required certification within two (2) weeks after becoming a Covered Person or within one-hundred twenty (120) days of the Effective Date of the CIA, whichever is later.

Bayer Pharmaceutical Division will 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 thirty (30) days of finalizing such changes. Covered Persons shall certify that they have received, read, understood and will abide by the revised Code of Conduct within thirty (30) days after distribution of such revisions.

2. ***Policies and Procedures***. Within one-hundred twenty (120) days of the Effective Date of this CIA, Bayer Pharmaceutical Division shall implement written Policies and Procedures regarding the operation of its compliance program and its compliance with all of the Federal health care program requirements. At a minimum, the Policies and Procedures shall specifically address: 1) the subjects relating to the Code of Conduct identified in Section III.B.1; 2) the need to report accurate prices, including proper accrual determinations (based on reasonable assumptions that are regularly reviewed and for which appropriate adjustments are made, if necessary) for Government Reimbursed Products to the Health Care Financing Administration ("HCFA"), the State

Medicaid programs and all drug price reporting services on which government agencies rely; and 3) the requirements for marketing, selling and distributing Government Reimbursed Products in accordance with all applicable requirements of the Federal health care programs.

Within one-hundred twenty (120) days of the Effective Date of the CIA, the relevant portions of the Policies and Procedures shall be distributed to all Covered Persons. Bayer Pharmaceutical Division shall make available appropriate and knowledgeable staff to explain the Policies and Procedures.

At least annually (and more frequently if appropriate) Bayer Pharmaceutical Division shall assess and update as necessary the Policies and Procedures. Within thirty (30) days of 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. ***General Training.*** Within one-hundred twenty (120) days of the Effective Date of this CIA, Bayer Pharmaceutical Division shall make its best efforts to provide at least three (3) hours of general training to each Covered Person. In the event that the Pharmaceutical Division is unable to complete the training within one hundred and twenty (120) days of the Effective Date of this CIA, it shall complete such training by no later than one hundred and fifty (150) days of the Effective Date. If any Covered Person has not completed the general training within this time period, a Covered Person

who has completed the general training shall review all of the untrained person's work in the area of contracting for, marketing, selling or reporting the price of products that are reimbursed by Federal health care programs until that untrained person receives training. This general training shall explain:

a. Bayer's Corporate Integrity Agreement requirements;

b. Bayer Pharmaceutical Division's Compliance Program (including the Policies and Procedures as they pertain to general compliance issues);

c. the proper methods of marketing and selling Government Reimbursed Products in accordance with applicable requirements of Federal heath care programs;

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 of the Federal health care programs; and

e. applicable legal rules (including the sanctions for violations) relating to Government Reimbursed Products (including, but not limited to, the Anti-kickback Statute, 42 U.S.C. § 1320a-7b(1) and (2); the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Civil False Claims Act, 31 U.S.C. §§ 3729-3733; and the Medicaid Rebate Statute, 42 U.S.C. § 1396r-8)).

New Covered Persons shall receive the general training described above within thirty (30) days of becoming a Covered Person or within one-hundred twenty (120) days after the Effective Date of this CIA, whichever is later. If any new Covered Person has responsibility for contracting for, marketing, selling or reporting the price of Government Reimbursed Products prior to completing the general training, a Covered Person who has completed the general training shall review the untrained person's work in those areas. After receiving the initial training described above, each Covered Person shall receive at least one hour of general training annually.

2. ***Specific Training.*** Within one-hundred twenty (120) days of the Effective Date of this CIA, each Covered Person who has direct responsibility for establishing or reporting prices for Government Reimbursed Products or sets policy for or supervises the marketing and sales of Government Reimbursed Products ("Relevant Covered Persons") shall receive at least two hours of specific training in addition to the general training required above. This training shall include a discussion of:

a. the reporting of accurate pricing information to HCFA, the State Medicaid Programs and drug price reporting services for Government Reimbursed Products;

b. the personal obligation of each individual involved in the drug price reporting process to ensure that prices are accurately reported; and

c. examples of proper and improper drug price reporting and marketing/sales practices.

Relevant Covered Persons shall receive this specific training within thirty (30) days of becoming a Relevant Covered Person or within one hundred twenty (120) days of the Effective Date of this CIA, whichever is later. If a new Relevant Covered Person has any responsibility for the reporting of drug pricing information or the marketing/sales of Government Reimbursed Products prior to completing this specific training, a Relevant Covered Person who has completed the specific training shall review all of the untrained person's work in these areas.

After receiving this initial training described in this section, every Relevant Covered Person shall receive at least two (2) hours of specific training annually.

3. ***Certification.*** Each individual who is required to attend training shall certify, in writing (or in electronic form if the training is computerized) 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 his or her designee) shall retain the certifications, along with specific course materials. These shall be made available to OIG upon request.

4. ***Training Methodology.*** Persons designing and providing all training required under this section III.C. must be knowledgeable about the subject areas of the training. Bayer Pharmaceutical Division may provide the training required under this CIA through appropriate web-based approaches. In that event, all references to "hours" in this section III.C. shall mean "normative hours" as that term is used in the computer-based training industry. If Bayer Pharmaceutical Division chooses to provide web-based

training, it shall also make available appropriately qualified and knowledgeable staff to answer questions or provide additional information to the Covered Persons who are receiving such training.

D. Reporting Requirements.

1. *General Statement of Purpose and Intent.* On a quarterly basis, Bayer Pharmaceutical Division 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 true pricing information that accurately reflects prices at which actual purchasers buy the Government Reimbursed Products sold by Bayer. Bayer understands that this information may be relied upon by State government entities in establishing Medicaid reimbursement rates for the Government Reimbursed Products.

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 drug or biologic product (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 Bayer for the drug or biologic product in the United States to all purchasers, excluding those sales exempt from inclusion in the calculation of "Best Price" for Medicaid Rebate purposes, pursuant to 42 U.S.C. § 1396r-8, and direct sales to hospitals. 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,[2] and all other price concessions provided by Bayer to any relevant purchaser, as earlier defined in this paragraph, 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 grants.

Bayer Pharmaceutical Division shall report the average sale price by National Drug Code ("NDC") for each Government Reimbursed Product identified by Bayer'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 Bayer, net of all price reductions identified above, for a drug or biologic product in a quarter by the total number of units of that drug or biologic product sold in that quarter.

b) ***Reporting Obligations for Government Reimbursed Products:***

Except as otherwise noted below, thirty (30) days after the last day of each calendar quarter, Bayer Pharmaceutical Division shall report, in accordance with Section III.D.2.a above, the average sale prices of each of its Government Reimbursed Products identified by Bayer's NDC to: 1) the Medicaid programs of those States who have executed a state settlement agreement with Bayer; 2) to First DataBank Inc.[3] solely for the

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

[3] If appropriate to reflect changes in the sources from which the State Medicaid programs

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purpose of reporting pricing information based on those average sale prices to the Medicaid Programs of those States that have executed a state settlement agreement; 3) and to the OIG. The first such report of average sale prices shall be made by February 28, 2001, or fifteen (15) days after the Effective Date of this CIA, whichever is later. With respect to the Qui Tam Drugs,[4] Bayer Pharmaceutical Division shall not report an Average Wholesale Price ("AWP") to First DataBank, or any other reporting service, to be used for purposes of setting Medicaid reimbursement prices for the Qui Tam Drugs and Bayer shall expressly inform such reporting services to this effect. This restriction shall not limit Bayer's ability to report AWP information for the Qui Tam Drugs to any price reporting service for uses unrelated to Medicaid, or Bayer's ability to report AWP information for any purposes for drugs or biologic products other than the Qui Tam Drugs.

c) ***Certification Requirement:***

In connection with each report of average sale price, Bayer Pharmaceutical Division shall also provide the OIG and the applicable States a detailed description of the

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received their pricing information, Bayer 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, subject to reasonable provisions equivalent to those agreed to by First Data Bank to ensure the confidentiality of that information.

[4] The Qui Tam Drugs, as defined in the Settlement Agreement incorporated herein by reference, are: Koate-HP Antihemophilic Factor (Human), Kogenate Antihemophilic Factor (Recombinant), Konyne-80 Factor IX Complex (Human), Gamimune N, 5% Immune Globulin Intravenous (Human 5%), Gamimune N, 10% Immune Globulin Intravenous (Human, 10%), and Thrombate III (Antithrombin III, Human).

methodology used to calculate the average sale prices. A high managerial agent of Bayer Pharmaceutical Division will certify that the average sale prices reported with the certification are calculated in accordance with the described methodology. Said certifications shall be made in form attached hereto as Attachment A and shall include an acknowledgment that the average sale prices reported will be filed with and used in the administration of the Medicaid programs. To the extent that Bayer's methodology involves accruing for the impact of future events, Bayer shall include a description of its accrual methodology, including underlying assumptions, in 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 of Reported Information:***

It is understood that Bayer considers the average sale price information and the methodology by which it is calculated to be confidential commercial information and proprietary trade secrets that if disclosed would cause substantial injury to the competitive position of Bayer.

e) ***Document Retention:***

Bayer Pharmaceutical Division shall retain all work papers and supporting documentation relating to the average sale price of its drugs for six years after the Effective Date of this CIA and 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.

E. Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Bayer shall retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform procedures to assist Bayer in assessing and evaluating its drug price reporting and compliance practices pursuant to this CIA. Each Independent Review Organization must have expertise in auditing and the requirements of the Federal health care programs as they relate to the reimbursement and marketing/sales of Government Reimbursed Products. The Independent Review Organization(s) must be retained to conduct the engagements described below for the first year within ninety (90) days of the Effective Date of this CIA. Each IRO shall assess, along with Bayer, whether it can perform the IRO engagements in a professionally independent fashion taking into account any other business relationships or other engagements that may exist.

b. Types of and Frequency of Engagements. The Independent Review Organization(s) will conduct two separate engagements. One engagement shall be to conduct procedures with regard to Bayer Pharmaceutical Division's drug price reporting practices ("Drug Price Reporting Engagement"). The second engagement will be to conduct procedures with regard to whether Bayer is in compliance with this CIA

("Compliance Engagement"). The Drug Price Reporting Engagement shall be performed annually and shall cover each of the one-year periods beginning with the Effective Date of the CIA. The Compliance Engagement shall be performed by the IRO for the first one-year period beginning with the Effective Date of the CIA.

c. Retention and Submission of Records. A complete copy of the Independent Review Organization's Drug Price Reporting Report for each year of the CIA and, for the first year of the CIA only, the IRO's Compliance Engagement Report, shall be included in Bayer's Annual Reports to OIG. The IRO and Bayer shall retain and make available to the OIG upon request all work papers, supporting documentation, correspondence, and draft reports that are exchanged between the IRO and Bayer relating to the engagements.

2. *Drug Price Reporting Engagement.* The Drug Price Reporting Engagement, shall be composed of two separate sets of procedures, "Reported Prices Procedures" and "Systems Procedures", both of which are described in detail in Attachment B to the CIA. Prior to conducting the Drug Price Reporting Engagement, the IRO may submit its workplan(s) to the OIG for comment. However, any comments or recommendations made by the OIG in connection with a review of the workplan will not preclude the OIG from making further comments or recommendations after reviewing the Drug Price Reporting Engagement Report.

3. *Compliance Engagement.* The IRO shall conduct an engagement regarding Bayer's compliance activities under which it shall perform procedures designed to assist in determining Bayer's compliance with the obligations set forth in sections I through

VIII of this CIA. The IRO shall prepare a report based upon the Compliance Engagement performed (the "Compliance Engagement Report"), which shall include the IRO's findings, supporting rationale, and a summary of such findings and rationale regarding Bayer's compliance with the terms sections I through VIII of the CIA, as applicable.

4. ***Verification/Validation.*** In the event that the OIG has reason to believe that: (a) Bayer's Drug Price Reporting or Compliance Engagement fails to conform to the requirements of this CIA, or (b) the findings of the reports from these engagements are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Drug Price Reporting Engagement and Compliance Engagement comply with the requirements of the CIA and/or the reported findings are inaccurate. Bayer agrees to 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 before one year after the Final Annual Report or any additional materials requested by the OIG as described in section II. Prior to proceeding with such an independent review, the OIG shall notify Bayer of its intent to do so and its reasons for believing such a review is necessary, and shall in good faith attempt to resolve any Drug Price Reporting or Compliance Engagement issues without proceeding with an independent review. However, it shall remain in the sole discretion of the OIG to proceed with an independent review as described above.

5. ***Independence Certification.*** The IRO(s) shall include in its report(s) to Bayer a certification or sworn affidavit that it has: 1) evaluated its professional independence with regard to the Drug Price Reporting and Compliance Engagements (in accordance

with the independence standards of its industry/profession); and 2) concluded that it was, in fact, independent.

F. Confidential Disclosure Program. Within one-hundred twenty (120) days after the Effective Date of this CIA, Bayer Pharmaceutical Division shall establish a Confidential Disclosure Program, which must include a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Bayer's policies, practices or procedures with respect to any Federal health care programs, believed by the individual to be a potential violation of criminal, civil or administrative law. Bayer Pharmaceutical Division shall publicize the existence of the confidential disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Confidential Disclosure Program shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous, confidential communications. Upon receipt of a disclosure, 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, Bayer

Pharmaceutical Division 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 his or her designee) shall maintain a confidential disclosure log, which shall include a record and summary of each allegation received, the status of the respective investigations, and any corrective action taken in response to the internal reviews. The confidential disclosure log shall be available to the 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, suspended, debarred 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 falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, or otherwise declared ineligible.

2. ***Screening Requirements.*** Bayer Pharmaceutical Division shall not hire or engage as a Covered Person any Ineligible Person. To prevent hiring or engaging any Ineligible Person, Bayer Pharmaceutical Division shall screen all prospective Covered Persons prior to engaging their services by: (a) requiring applicants to disclose whether they are Ineligible Persons, and (b) reviewing the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://www.arnet.gov) and the HHS/OIG List of Excluded Individuals/Entities (available

through the Internet at http://www.hhs.gov/oig) (these lists will hereinafter be referred to as the "Exclusion Lists").

3. ***Review and Removal Requirement.*** Within one hundred twenty (120) days of the Effective Date of this CIA, Bayer Pharmaceutical Division will review its list of current Covered Persons against the Exclusion Lists. Thereafter, Bayer Pharmaceutical Division shall review its list of Covered Persons against the Exclusion Lists once annually. In addition, Bayer Pharmaceutical Division shall require Covered Persons to disclose immediately any debarment, exclusion or other event that makes the individual an Ineligible Person.

If Bayer Pharmaceutical Division has notice that a Covered Person has become an Ineligible Person, it will remove such person from responsibility for, or involvement with, Bayer Pharmaceutical Division'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 any 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 Bayer Pharmaceutical Division has 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 engagement, Bayer Pharmaceutical Division shall take all appropriate

actions to ensure that the responsibilities of that individual shall not adversely affect the accuracy of any claims for reimbursement submitted to any Federal health care program.

H. Notification of Government Investigation or Legal Proceedings. Within thirty (30) days of discovery, Bayer shall notify OIG, in writing, of any ongoing investigation or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that Bayer Pharmaceutical Division has committed a crime or has engaged in fraudulent activities or that Bayer has committed a crime or engaged in fraudulent activities relating to the Federal health care programs. 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. Bayer shall also provide written notice to OIG within thirty (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.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date of this CIA, Bayer changes locations or purchases or establishes new business units engaged in the contracting for, marketing, sales or price reporting of Government Reimbursed Products, Bayer shall notify OIG of this fact as soon as possible, but no later than within thirty (30) days of the date of change of location, purchase or establishment. This notification shall include the location of 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 such provider number. All Covered Persons at such locations shall be subject

to the applicable requirements in this CIA (e.g., completing certifications and undergoing training). Bayer shall use its best efforts to implement the requirements of this CIA in new business units or locations that participate in any Federal health care program as soon as practicable. Notwithstanding any other provisions to the contrary, the price reporting requirements of Section III.D of this CIA shall not become effective for new business units or locations until six (6) months after the purchase or establishment of such new business units or locations.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report.

Within one hundred and fifty-five (155) days after the Effective Date of this CIA, Bayer shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA. This Implementation Report shall include:

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

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

3. a copy of the Code of Conduct required by section III.B.1;

4. a summary of the Policies and Procedures required by section III.B.2;

5. a copy of training materials used for the training required by section III.C, a description of such training programs, and a summary of the

activities undertaken in furtherance of these programs, including a schedule and topic outline of the training sessions;

6. a certification by the Compliance Officer that:

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

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

   c. all Covered Persons have completed the applicable training and executed the certification required by section III.C.

   d. In the event 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 when the deficiencies will be remedied.

7. a description of the Confidential Disclosure Program required by section III.F;

8. the identity of the IRO(s); a summary/description of all current engagements between Bayer and the IRO; and a summary/description of all engagements between Bayer and the IRO relating to the work of or issues examined by the IRO in connection with the Drug Price Reporting Engagement or the Compliance Engagement; and the proposed start and

completion dates of the first Drug Price Reporting Engagement and Compliance Engagement;

9. a certification from the IRO regarding its professional independence from Bayer as required by section III.E.5;

10. a summary of personnel action (other than hiring), if any, taken pursuant to section III.G;

11. a list of all of Bayer Pharmaceutical Division locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Medicare provider identification number(s) (if any) 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 Bayer'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.

Bayer shall submit to OIG Annual Reports with respect to the status and findings regarding its compliance activities for each of the five one-year periods beginning on the Effective Date of the CIA. (The one-year period covered by each Annual Report shall be referred to as "the Reporting Period").

Each Annual Report shall include:

1. any change in the identity or position description of the Compliance Officer and/or members of the Compliance Committee described in section III.A;

2. a certification by the Compliance Officer that:

   a. when required, Covered Persons have completed the annual Code of Conduct certification required by section III.B.1; and

   b. all Covered Persons completed the applicable training and executed the certification required by section III.C.

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

3. a summary of any significant changes or amendments to the Policies and Procedures required by section III.B.2 and the reasons for such changes (e.g., change in Federal health care program requirements);

4. a copy of the training materials used for the training required by section III.C. (to the extent not already provided), and description of the training required by section III.C conducted during the Reporting Period, including a schedule, topic outline of training sessions, and list of attendees;

5. a complete copy of the reports prepared pursuant to the IRO's Drug Price Reporting and Compliance Engagements, including a copy of the methodology used and a copy of the IRO's engagement letter;

6. Bayer's response/corrective action plan to any issues raised by the IRO;

7. a revised summary/description of all engagements between Bayer and the IRO as described in section V.A.8, if different from what was submitted as part of the Implementation Report;

8. a summary of the disclosures in the confidential disclosure log required by section III.F that relate to Federal health care programs;

9. a description of any personnel actions (other than hiring) taken by Bayer Pharmaceutical Division as a result of the obligations in section III.G, and the name, title, and responsibilities of any person who falls within the ambit of section III.G.4, 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 description of any and all changes to the most recently provided list (as updated) of Bayer's locations (including locations and mailing addresses) as required by section V.A.11, the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Federal health care program provider

identification numbers(s) (if any), and the contractor names and address that issued each provider identification number;

12. a description of the co-promotion agreements that Bayer has with other firms, including the number of such agreements in existence during the Reporting Period and a summary of the assurances Bayer has received regarding the training of co-promotion personnel, as referenced in Footnote 1; and

13. the certification required by section V.C.

The first Annual Report shall be received by the OIG no later than one year and seventy-five (75) days after the Effective Date of this CIA. Subsequent Annual Reports shall be submitted no later than the anniversary date of the due date of the first Annual Report.

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

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing subsequent to the Effective Date of this CIA, all notifications and reports required under this CIA shall be submitted to the entities listed below:

OIG:

Civil Recoveries Branch - Compliance Unit
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

Bayer:

Compliance Officer
c/o Bayer Corporation Pharmaceutical Division
400 Morgan Lane
West Haven, CT 06516
Phone: 203.812.2647
Fax : 203.812.3143

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

VII. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine Bayer Pharmaceutical Division's books, records, and other documents and supporting materials subject to any properly asserted legal privilege, and/or conduct on-site reviews at reasonable times of any relevant Bayer location for the purpose of verifying and evaluating: (a) Bayer's compliance with the terms of this CIA; and (b) Bayer Pharmaceutical Division's compliance with applicable requirements of the Federal health care programs. The documentation described above shall be made available 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 Bayer's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Bayer agrees to assist OIG or its duly authorized representatives(s) in contacting and arranging interviews with such individuals upon OIG's reasonable request. Bayer's employees may elect to be interviewed with or without a representative of Bayer present. If an employee, consistent with his or her rights and privileges, refuses to be interviewed based upon an individual decision, Bayer will not be in breach of this CIA if the interview does not occur.

VIII. DOCUMENT AND RECORD RETENTION

Bayer shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs or to compliance with this CIA for six (6) years from the Effective Date of this CIA (or longer if otherwise required by law).

IX. DISCLOSURES AND PRIVILEGES

When Bayer submits any information to the OIG pursuant to its obligations under this CIA, it shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore exempt from disclosure under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. The OIG shall follow all applicable Federal laws concerning privacy and confidentiality, including the Federal Privacy Act, 5 U.S.C. § 522a, to the greatest extent allowed by law. Consistent with HHS's Freedom of Information Act ("FOIA") procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify Bayer prior to any release by the OIG of information submitted by Bayer pursuant to its obligations under this CIA and identified upon submission by Bayer as trade secrets, commercial or financial information, or privileged and confidential under the FOIA rules. With respect to such releases, Bayer shall have the rights set forth at 45 C.F.R. § 5.65(d). Bayer shall refrain from identifying any information as exempt from release if that information does not meet the criteria for exemption from disclosure under FOIA. 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 Bayer of Bayer's attorney-client, work product or other applicable privileges. Notwithstanding that fact, the existence of any such privilege does not affect Bayer's obligation to comply with the provisions of the CIA.

X. BREACH AND DEFAULT PROVISIONS

Bayer is expected to fully and timely comply with all of its CIA obligations. The remedies available to the OIG under this Section X do not preempt or limit any actions that individual States may take against Bayer under appropriate authorities not specified in this CIA. A breach of this CIA does not constitute a breach of the Settlement Agreement with the United States or the settlement agreements with the individual states. A breach of the terms of those settlement 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 Bayer fails to satisfy its obligations under this CIA.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Bayer 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 Bayer Pharmaceutical Division fails to have in place any of the following:

a. a Compliance Officer and Committee as described by section III.A;

b. a written Code of Conduct as described by section III.B.1;

c. written Policies and Procedures as described by section III.B.2;

d. a training program as described by section III.C; and

e. a Confidential Disclosure Program as described by section III.F.

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 Bayer Pharmaceutical Division fails to retain an Independent Review Organization as required by 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 Bayer fails meet any of the deadlines to submit the Implementation Report or the Annual Reports to the OIG.

4. A Stipulated Penalty of $2,000 (which shall begin to accrue ten (10) days after the date the failure to comply began) for each day Bayer Pharmaceutical Division employs or engages an Ineligible Person as a Covered Person (the Stipulated Penalty described in this paragraph shall not be demanded for any time period during which Bayer 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 the status of the person).

5. A Stipulated Penalty of $1,500 for each day Bayer 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 Bayer fails to grant access.)

6. A Stipulated Penalty of $1,000 (which shall begin to accrue ten (10) days after the date that OIG provides notice to Bayer of the failure to comply) for each day Bayer fails to comply fully and adequately with any obligation of this CIA not already covered in sections X.A.1-5. In its notice to Bayer, the OIG shall state the specific grounds for its determination that the Bayer has failed to comply fully and adequately with the CIA obligation(s) at issue and the steps Bayer must take to comply with the CIA. The OIG shall not seek to impose the Stipulated Penalties discussed in this section X.A.6 if Bayer cures the identified deficiency within the ten (10) day period.

B. Timely Written Requests for Extensions. Bayer may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Bayer fails to meet the revised deadline set by the OIG. Notwithstanding any other provision in this section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until two (2) business days after Bayer 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 (5) 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 Bayer has failed to comply with any of the obligations described in section X.A and determining that Stipulated Penalties are appropriate, OIG shall notify Bayer of (a) Bayer'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").

2. *Response to Demand Letter.* Within ten (10) days of the receipt of the Demand Letter, Bayer shall either: (a) cure the breach to the OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute the OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section X.E. In the event Bayer elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Bayer cures, to the 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.4.b these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for the OIG's determination that Bayer has materially breached this CIA, which decision shall be made at the OIG's discretion and governed by the provisions in section X.D, below.

D. Exclusion for Material Breach of this CIA.

1. *Notice of Material Breach and Intent to Exclude.* The parties agree that a Material Breach of this CIA, as defined below, by Bayer constitutes an independent basis for Bayer's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Bayer has materially breached this CIA and that exclusion should be imposed, the OIG shall notify Bayer of: (a) Bayer's Material Breach; and (b) OIG's intent to exercise its right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

2. *Opportunity to Cure.* Bayer shall have thirty (30) days from the date of receipt of the Notice of Material Breach and Intent to Exclude Letter to demonstrate to the OIG's satisfaction that:

a. Bayer is not in Material Breach of this CIA;

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) Bayer has begun to take action to cure the Material Breach; (ii) Bayer is pursuing such action with due diligence; and (iii) Bayer has provided to the OIG a reasonable timetable for curing the Material Breach.

3. *Exclusion Letter.* If at the conclusion of the thirty (30) day period, Bayer fails to satisfy the requirements of section X.D.2, OIG may exclude Bayer from participation in the Federal health care programs. In order to effectuate such exclusion, OIG will notify Bayer in writing of its determination to exclude Bayer (this letter shall be referred to hereinafter as the "Exclusion Letter"). Unless Bayer exercises its review rights set forth in the Dispute Resolution provisions in section X.E, below, the exclusion shall go into effect thirty (30) days after the date of the Exclusion Letter. The exclusion shall have national effect and will 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, Bayer wishes to apply for reinstatement, Bayer must submit a written request for reinstatement pursuant to the provisions at 42 C.F.R. §§ 1001.3001-.3004.

4. *Definition of Material Breach.* A Material Breach of this CIA means:

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

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

c. a failure to retain and use an Independent Review Organization for review purposes in accordance with section III.E.

E. Dispute Resolution.

1. *Review Rights.* Upon the OIG's delivery to Bayer of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under the obligation of this CIA, Bayer 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. § 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, the OIG's determination to demand payment of Stipulated Penalties or 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 ten (10) days of receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within twenty five (25) days of 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 Bayer was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. Bayer shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the

ALJ finds that Bayer breached this CIA and orders Bayer to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable twenty (20) days after the ALJ issues such a decision unless Bayer 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 the OIG, the Stipulated Penalties shall become due and payable twenty (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 Bayer was in Material Breach of this CIA; (b) whether such breach was continuing on the date of the Exclusion Letter; (c) whether the alleged Material Breach could not have been cured within the thirty (30) day period, but that: (i) Bayer had begun to take action to cure the Material Breach within that period, (ii) Bayer has pursued and is pursuing such action with due diligence, and (iii) Bayer provided to OIG a reasonable timetable for curing the Material Breach and Bayer has followed the timetable.

4. For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision that is favorable to the OIG, or if the ALJ rules for Bayer, only after a DAB decision in favor of OIG. Bayer's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude Bayer upon the issuance of the ALJ's decision. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect twenty (20) days after the ALJ issues such a

decision, notwithstanding that Bayer 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 twenty (20) days after the DAB decision.

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, Bayer and OIG agree as follows:

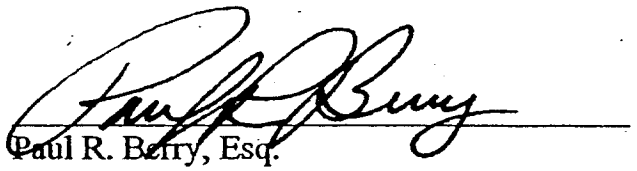
A. This CIA shall be binding on the successors, assigns and transferees of Bayer;

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; and

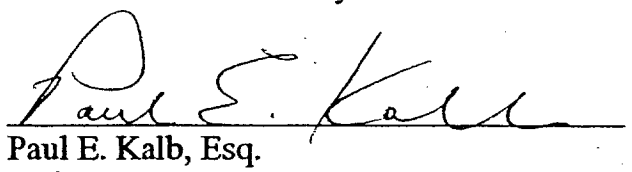
D. The undersigned Bayer signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

ON BEHALF OF BAYER CORPORATION



Paul R. Berry, Esq.
Vice President and Assistant
General Counsel for Bayer

1/19/01
DATE



Paul E. Kalb, Esq.
I. Scott Bass, Esq.
Robert Fabrikant, Esq.
Sidley & Austin
Counsel for Bayer

1/21/01
DATE

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

D. McCarty Thornton
Chief Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services

1/23/01
DATE

Attachment A

CERTIFICATION

The undersigned, a high managerial agent of _____, hereby certifies that the attached average sale price information has been communicated to First DataBank and to the State Medicaid programs indicated below and that it has been calculated in accordance with the methodology described herein. I further acknowledge that the average sale prices so reported will be filed with and used in the administration of the _____ State Medicaid program(s).

_____
Signature

_____
Title

_____
Date

Attachment B

A. **Reported Prices Procedures.** The IRO shall perform Reported Prices Procedures to assist in assessing whether the average sale prices for Government Reimbursed Products reported pursuant to section III.D. of this CIA during the one year period covered by the Drug Price Reporting Engagement were determined and reported in accordance with the provisions set forth in that section of the CIA.

As described below, the IRO shall conduct the Reported Prices Procedures by testing samples of transactions (consisting of sales and sales-related activities with purchasers specifically included in or excluded from the average sale price calculation, as defined in section III.D.2.a. above, including cash disbursements to purchasers (hereafter "Transactions"))[1]. The IRO will test the samples of Transactions in accordance with the guidelines set forth in section A.1 of this Attachment B to the CIA.

In accordance with section A.2 of this Attachment B, the IRO will also test samples of the estimated rebate amounts used in the calculation of average sale prices in order to test whether Bayer followed its accrual methodologies as described in the certification referenced in section III.D.2.c. of the CIA.

1. Statistical Testing of Transactions

The IRO shall begin these procedures by grouping all like-kind Transactions that occurred during the twelve-month period covered by the Drug Price Reporting Engagement. The sum of all the Transactions in all the universes combined shall

[1] For example, Transactions as used in this CIA would include, but not be limited to: sales; volume discounts; prompt pay discounts; cash discounts; chargebacks; short-dated product discounts; free goods; rebates paid to customers or credited to customers' accounts; replacement goods; cash disbursements to purchasers; and all other price concessions or incentives provided by Bayer to any relevant purchaser.

equal the sum of all Transactions which occurred during the twelve-month period covered by the Drug Price Reporting Engagement.

Each group of like-kind Transactions will be considered a separate universe from which the IRO will test a statistically valid random probe sample and, if required as set forth below, a statistically valid random full sample of Transactions. With regard to all groupings of like-kind Transactions except Rebate Transactions[2], the IRO will test the statistically valid random samples in order to determine whether: 1) the correct prices for the Transactions were input into Bayer's system (e.g. - whether the Transaction prices are supported by source documents); and 2) Bayer properly included or excluded each Transaction in the calculation of average sale price under the definition of that term as set forth in section III.D.2.a. With regard to the groupings of like-kind Rebate Transactions, the IRO will test statistically valid random samples to determine whether: 1) the correct prices for the Transactions were input into Bayer's system (e.g. - whether the Transaction prices are supported by source documents); and 2) the rebate Transaction amount calculated by Bayer was supported by Bayer's contract with the customer, the customer's purchasing history and Bayer's rebate policy.

Each full sample shall consist of a statistically valid sample of Transactions that can be projected to the corresponding universe of like-kind Transactions for the relevant period. The sample size for each of the full samples shall be determined through the use of a probe sample. A separate probe sample, comprised of at least 30 sampling units, shall be used for each universe. The variable that will be tested in both the probe and full sample will be dollars that were improperly included/excluded in the calculation of average sale price. At a minimum, the full samples will be designed with the objective of providing a statistical extrapolation

[2] As used herein, Rebate Transactions shall be defined to be those reductions in price the value of which is not known at the time of the sale.

of the results of the testing with a ninety (90) percent confidence level and a precision level of twenty-five (25) percent. In other words, each of the full samples will be designed with the objective of containing a sufficient number of items so that if the dollars included or excluded in error, if any, identified for each of the full samples were projected to the universe of all like-kind Transactions from which each full sample was drawn, the projection would provide a 90% confidence level and a maximum relative precision (i.e., semi-width of the confidence interval) of plus or minus 25% of the point estimate.

Both the probe samples and the full samples must be selected through use of the random number generator contained in OIG's Office of Audit Services Statistical Sampling Software, also known as "RAT-STATS." which is available through the Internet at www.hhs.gov/oas/ratstat.html. The number of Transactions to be tested in each full sample will be based on the results of each probe sample. The IRO shall use RAT-STATS to estimate the sample size for each full sample.

For each universe of like-kind Transactions described above, the IRO shall test a probe sample of at least thirty (30) Transactions. If no variances are noted in the initial probe sample, a second probe sample, of at least thirty (30) sampling units, will be randomly selected and tested. If no variances are found in the second probe sample, then no further testing of the universe of like-kind Transactions being tested will be required and the results of the two probe samples will be reported in lieu of the testing of the related full sample when preparing and submitting the Drug Price Reporting Engagement Report.

The IRO will have the option of selecting initial probe samples with at least fifty (50) sampling units for each universe of like-kind Transactions described above. If no variances are found in the 50-item probe sample, no further testing of the universe of like-kind Transactions from which the 50-item probe sample was

selected will be required and the results of the 50-item probe sample will be reported in lieu of the testing of the related full sample when preparing and submitting the Drug Price Reporting Engagement Report.

2. Testing of Estimated Rebate Amounts Used in Calculating Average sale price

In order to test the estimated rebate amounts used in calculations of average sale price, the IRO shall randomly select a sample of the estimated rebate amounts determined through Bayer's accrual methodology and used in the calculation of average sale price for the lesser of thirty (30) NDCs (11 digits) from, or ten percent (10%) of, the universe of NDCs (11 digits) reported for Government Reimbursed Products. For each of those sampled units, the IRO will determine whether Bayer: 1) made assumptions about those rebate amounts that were based upon commercial arrangements and supported by source documentation; 2) tested those assumptions in light of actual experience; and 3) made adjustments in light of actual experience.

B. Systems Procedures. The IRO shall also perform procedures with regard to Bayer's price calculation and reporting systems as they relate to Government Reimbursed Products and Bayer's obligations under the CIA ("the Systems Procedures"). The Systems Procedures shall consist of thorough inquiries, including queries of the client, analysis of relevant Bayer policies and procedures, and analysis of all other appropriate documentation of the following:

1. Bayer's systems and operations relating to the calculation of average sale price and other information as required by the CIA, including, but not limited to, the computation of the average sale price in accordance with the specifications outlined in section III.D.2.a of the CIA;

2. Bayer's systems and operations relating to the reporting of average sale price and other information as required by the CIA, including, but not limited to, the transcription and reporting of the calculated average sale prices to the required entities;

3. Bayer's systems and operations relating to the identification and correction of any inaccurate pricing information, if any, provided to the State Medicaid Programs, the OIG, and all drug price reporting services on which government agencies rely; and

4. the steps Bayer has represented it has or is taking to bring its operations into compliance or to correct any problems identified by the most recent previous Drug Price Reporting Engagement.

C. **Drug Price Reporting Engagement Report.** The following information shall be included in each annual Drug Price Reporting Engagement Report:

1. **Elements to Be Included:**

a. Engagement Objectives: A clear statement of the objectives intended to be achieved by the Drug Price Reporting Engagement. A separate objective should be stated for each universe of like-kind Transactions; the testing of estimated rebate amounts used in calculating average sale price; and for each element of the Systems Procedures.

b. Procedures Protocol: A detailed description of how the Drug Price Reporting Engagement was conducted, the specific procedures performed, and a description of each sampling unit and universe utilized in performing the procedures. The protocol should also include a detailed description of how the procedures were performed for each universe of like-kind Transactions and for each system.

c. Sources of Data: A full description of the types of information sources upon which the IRO based the findings of the Drug Price Reporting

Engagement, including, but not limited to, the professional standards applied and the documents, pricing and sales data, and/or any applicable contracts utilized in performing the procedures conducted pursuant to the Drug Price Reporting Engagement.

2. Results of Drug Price Reporting Engagement. The following results shall be included in each Drug Price Reporting Engagement Report:

a. for each universe of like-kind Transactions, the IRO shall state the findings, a description of the procedures performed, and the basis for the findings as to whether correct Transaction prices were input into Bayer's systems;

b. for each universe of like-kind Transactions except the Rebate Transactions, the IRO shall state the findings, a description of the procedures performed, and the basis for the findings as to as to whether the Transactions were properly included in or excluded from the calculations of average sale prices in accordance with the provisions of section III.D. of this CIA. If any sample Transaction was not properly calculated into the average sale price, the findings should also identify the dollar amount included or excluded in error for each such sample Transaction;

c. for each universe of like-kind Rebate Transactions, the IRO shall state the findings, a description of the procedures performed, and the basis for the findings as to whether the rebate amount calculated by Bayer was supported by Bayer's contract with the customer, the customer's purchasing history and Bayer's rebate policy;

d. for the sampled estimated rebate amounts included in the calculation of average sale price, the findings, a description of the procedures performed, and the basis for the findings as to whether Bayer: 1) made assumptions about those estimated rebate amounts that were based upon commercial

arrangements and supported by source documentation; 2) tested those assumptions in light of actual experience; and 3) made adjustments in light of actual experience;

e. the findings, a description of the procedures performed, and the basis for the findings as to Bayer's systems and operations relating to the calculation of average sale price information as required by the CIA;

f. the findings, a description of the procedures performed, and the basis for the findings as to Bayer's systems and operations relating to the reporting of average sale price information as required by the CIA;

g. the findings, a description of the procedures performed, and the basis for the findings as to Bayer's systems and operations relating to the identification and correction of any inaccurate pricing information provided to the State Medicaid Programs, to OIG and all drug price reporting services on which government agencies rely;

h. the findings, a description of the procedures performed, and the basis for the findings as to the steps Bayer has represented it has or is taking to bring its operations into compliance or to correct any problems identified by the most recent previous Drug Price Reporting Engagement; and

i. observations, as a result of the procedures performed with regard to Bayer's practices and systems for the reporting of average sale prices and other drug price information as defined in and required by the CIA (including, but not limited to, observed weaknesses, if any, in the operations of these practices and systems and Bayer's internal controls for such systems and any recommendations, if any, the IRO may have to improve any of these operations, practices, systems and related internal controls).

ADDENDUM TO CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
BAYER CORPORATION

I. PREAMBLE

Bayer Corporation hereby enters into this Addendum to its Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") that became effective January 23, 2001. Contemporaneously with this Addendum, Bayer Corporation is entering into a Settlement Agreement with the United States, and the CIA and this Addendum are incorporated by reference into that Settlement Agreement. Bayer Corporation shall also enter into related settlement agreements with various States, and Bayer Corporation's agreement to the CIA and this Addendum is a condition precedent to those agreements.

In early 2003, Bayer Corporation reorganized its business. The functions and operations of the Bayer Pharmaceutical Division (referenced in the CIA) now reside with Bayer Pharmaceuticals Corporation and the Biological Products Division of Bayer HealthCare LLC. Each and every reference to the Bayer Pharmaceutical Division in the CIA shall now refer to the Bayer Pharmaceuticals Corporation and the Biological Products Division of Bayer HealthCare LLC (collectively hereafter "Bayer").

For purposes of the CIA and this Addendum, the term "Covered Persons" shall continue to refer to officers, directors, employees, contractors (subject to Bayer's control) and agents of Bayer who are involved in the contracting for, or marketing, selling or reporting the price of products that are reimbursed by Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. §1320a-7b(f)).[1] If during the term

[1] Specifically excluded from the definition of "Covered Persons" are the marketing, sales or other personnel of firms with which Bayer has agreements to co-promote its products. Bayer 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,

of this Addendum, any Bayer division or affiliate (defined as an entity controlled by Bayer Corporation or its parent) besides, or in addition to, Bayer Pharmaceuticals Corporation or the Biological Products Division of Bayer HealthCare LLC becomes involved in the contracting for, marketing, selling or reporting the price of pharmaceutical or biological products that are reimbursed by Federal health care programs, the term Covered Persons shall also include the individuals in that division or affiliate, and all references to Bayer in this Addendum shall also be construed to include that other division or affiliate.

For purposes of the CIA and this Addendum, references in the CIA to HCFA ("Health Care Financing Administration") shall be construed to refer to the Centers for Medicare and Medicaid Services ("CMS").

II. TERM AND SCOPE OF THE CIA AND ADDENDUM

Unless otherwise specified herein, Bayer shall continue all of the obligations assumed under the CIA, and the period of the additional compliance obligations agreed to by Bayer under this Addendum shall be six years from the Effective Date of this Addendum. The Effective Date of this Addendum shall be January 23, 2003.

III. CORPORATE INTEGRITY OBLIGATIONS

A. Compliance Officer and Committee.

The terms of Section III.A of the CIA remain in effect and Bayer shall continue its obligations under Section III.A through the term of this Addendum.

B. Written Standards.

1. *Code of Conduct.* The terms of Section III.B.1 of the CIA remain in effect and Bayer shall continue its obligations under Section III.B.1 through the term of this Addendum.

2. *Policies and Procedures.* The terms of Section III.B.2 of the CIA remain in effect and Bayer shall continue its obligations under Section III.B.2 as amended herein

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who comprise Bayer's contract sales force.

through the term of this Addendum. To the extent not already accomplished, Bayer shall amend its Policies and Procedures to address the requirements of government contracts, including those entered into between Bayer and the HHS under the Medicaid Drug Rebate Program, 42 U.S.C. § 1396r-8, and the Drug Pricing Program under the Public Health Service (PHS) Act, 42 U.S.C. § 256b. Within 120 days of the date of the last signature on this Addendum ("Signing Date"), to the extent not already accomplished, Bayer shall distribute the relevant portions of its amended Policies and Procedures to all Covered Persons.

C. Training and Education.

1. *General Training.* The terms of Section III.C.1 of the CIA remain in effect and Bayer shall continue its obligations under Section III.C.1 through the term of this Addendum.

2. *Specific Training.* Section III.C.2 of the CIA shall be amended to read as follows and shall remain in effect through the term of this Addendum.

Within 120 days of the Signing Date of this Addendum, to the extent not already accomplished, each Covered Person who has direct responsibility for establishing or reporting pricing information for Government Reimbursed Products (including prices established and reported for purposes of the Medicaid Drug Rebate Program or the Drug Pricing Program) or sets policy for or supervises the marketing and sales of Government Reimbursed Products (hereafter collectively "Relevant Covered Persons") shall receive at least two hours of specific training in addition to the general training required above. This specific training shall include a discussion of:

a. the reporting of accurate pricing information to CMS, the State Medicaid Programs and drug price reporting services for Government Reimbursed Products (including a discussion of Bayer's systems for gathering relevant data and calculating, verifying and reporting Average Sale Price and information relating to the Medicaid Drug Rebate Program and the Drug Pricing Program);

b. the personal obligation of each individual involved in the drug price reporting process to ensure that prices are accurately reported;

c. all applicable Federal health care program requirements relating to the Medicaid Drug Rebate Program and the Drug Pricing Program;

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

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

New Relevant Covered Persons shall receive this specific training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 120 days after the Signing Date, whichever is later. If a new Relevant Covered Person has any responsibility for establishing or reporting pricing information for, or setting the policy for or supervising the marketing/sales of, Government Reimbursed Products prior to completing this specific training, a Relevant Covered Person who has completed the specific training shall review all of the untrained person's work in these areas. After receiving the initial specific training described in this section, every Relevant Covered Person shall receive at least two hours of specific training annually.

3. *Certification.* The terms of Section III.C.3 of the CIA remain in effect and Bayer shall continue its obligations under Section III.C.3 through the term of this Addendum.

4. *Training Methodology.* The terms of Section III.C.4 of the CIA remain in effect and Bayer shall continue its obligations under Section III.C.4 through the term of this Addendum.

D. Reporting Requirements.

The terms of Section III.D of the CIA (including the certification set forth in Attachment A to the CIA) remain in effect and Bayer shall continue its obligations under Section III.D through the original term of the CIA.

E. Review Procedures.

Section III.E of the CIA shall be amended to read as follows and shall remain in effect through the term of this Addendum, except as specified below.

1. *General Description.*

a. Retention of Independent Review Organization. Bayer shall continue to retain an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist Bayer in assessing and evaluating its drug price reporting and compliance practices pursuant to the CIA. Pursuant to this Addendum, within 90 days after the Signing Date, Bayer shall retain an IRO to perform two additional reviews as specified below.

Bayer may select the same IRO for purposes of complying with this Addendum as it selected for the CIA provided two conditions are met. First, each IRO retained by Bayer shall have expertise in auditing and the requirements of the Federal health care programs as they relate to the reimbursement, marketing/sales, and reporting of pricing information for Government Reimbursed Products (including the requirements of the Medicaid Drug Rebate Program). Second, each IRO shall assess, along with Bayer, whether it can perform the IRO review(s) in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist, and must find that it can, in fact, perform the reviews in a professionally independent and/or objective fashion.

b. Types and Frequency of Engagements.

(i) Pursuant to the CIA, Bayer agreed to retain an IRO to conduct an engagement ("the Drug Price Reporting Engagement") with regard to Bayer's Average Sale Price reporting practices. That engagement is composed of two separate sets of procedures, "Reported Prices Procedures" and "Systems Procedures," both of which are described in detail

in Attachment B to the CIA. Bayer shall continue to retain an IRO to perform the Drug Price Reporting Engagement as set forth in the CIA for the original term of the CIA.

(ii) In addition to the Drug Price Reporting Engagement outlined above, the IRO shall conduct two other types of reviews. First, as set forth more fully in Attachment A to this Addendum, the IRO shall perform Medicaid Rebate Systems Reviews that shall address Bayer's systems, processes, policies and practices (including inquiries made to CMS) associated with tracking, gathering, and accounting for all relevant data for purposes of appropriately calculating the Best Prices reported under the Medicaid Drug Rebate Program. Second, as described in Attachment A hereto, the IRO shall conduct Managed Care Transactions Reviews that shall address and analyze Bayer's systems, policies and practices with regard to non-rebate payments made to managed care entities.

(iii) If there are no material changes in Bayer's Medicaid Drug Rebate Program-related systems, processes, policies and practices during the term of the Addendum, the IRO shall perform the Medicaid Rebate Systems Reviews for the first and fifth Reporting Periods under this Addendum. If Bayer materially changes its systems, processes, policies and practices relating to the Medicaid Drug Rebate Program, then the IRO shall perform a Medicaid Rebate Systems Review for the Reporting Period in which such changes were made in addition to conducting the Medicaid Rebate Systems Review for the first and fifth Reporting Periods under this Addendum. The Managed Care Transactions Reviews shall be performed annually and shall cover each of the Reporting Periods under this Addendum. Unless as otherwise specified in Attachment A, the IRO shall perform all components of each of the engagements described in this Section III.E.1.b.

c. Retention of Records. The IRO and Bayer shall retain and make available to OIG, upon request, all work papers, supporting

documentation, correspondence, and draft reports (those exchanged between the IRO and Bayer) related to the reviews.

2. *Review Report(s).* The IRO(s) shall prepare a report (or reports) based upon the Drug Price Reporting Engagements, the Medicaid Rebate Systems Reviews and the Managed Care Transactions Reviews performed (the "Review Reports"). Information to be included in the Review Reports is detailed in Appendix B to the CIA and in Attachment A to this Addendum.

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

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

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

F. Confidential Disclosure Program.

The terms of Section III.F of the CIA remain in effect and Bayer shall continue its obligations under Section III.F through the term of this Addendum.

G. Ineligible Persons.

The terms of Section III.G of the CIA remain in effect and Bayer shall continue its obligations under Section III.G through the term of this Addendum.

H. Notification of Government Investigation or Legal Proceedings.

The terms of Section III.H of the CIA remain in effect and Bayer shall continue its obligations under Section III.H through the term of this Addendum.

I. Certification Regarding Medicaid Rebate Policies and Procedures.

For the term of this Addendum, Bayer's Compliance Officer shall complete the certification set forth at Attachment B hereto. Bayer shall include the certification in each of its Annual Reports to the OIG.

IV. NEW BUSINESS UNITS OR LOCATIONS

The terms of Section IV of the CIA remain in effect and Bayer shall continue its obligations under Section IV through the term of this Addendum.

V. IMPLEMENTATION AND ANNUAL REPORTS

Section V of the CIA, as amended herein, shall remain in effect and Bayer shall continue its obligations under Section V through the term of this Addendum.

A. Implementation Information. Within 90 days after the Signing Date, Bayer shall notify and provide to the OIG, in writing, the following information:

1. the identity of the IRO(s) and a summary/description of all current engagements between Bayer and the IRO, including, but not limited to, any outside financial audits or reimbursement consulting; and

2. a certification from each IRO regarding its professional independence and/or objectivity with respect to Bayer as required by Section III.E.4.

B. Annual Reports. Bayer shall submit to OIG Annual Reports with respect to the status of, and findings regarding, Bayer's compliance activities for each of the six one-year periods beginning on the Effective Date of this Addendum. (The one-year period covered by each Annual Report shall be referred to as the "Reporting Period.")

Each Annual Report shall include the same items and information as specified in Section V.B. of the CIA, with the following amendments/additions.

Section V.B.5 is amended to read: a complete copy of the reports prepared pursuant to the IRO's Drug Price Reporting Engagement, Medicaid Rebate Systems Review, and Managed Care Transactions Review, including a copy of the methodology used and a copy of the IRO's engagement letter(s);

A new Section V.B.14 is added that reads: the certification set forth as Attachment B to this Addendum (relating to the Medicaid Drug Rebate Program).

Annual Reports submitted pursuant to Section V.B must be received by the OIG no later than 75 days after the end of each Reporting Period under the Addendum.

C. Certifications. The terms of Section V.C of the CIA remain in effect and Bayer shall continue its obligations under Section V.C through the term of this Addendum.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

The terms of Section VI of the CIA remain in effect and Bayer shall continue its obligations under Section VI through the term of this Addendum with the following changes. Notifications and reports to the OIG shall be submitted to the "Administrative and Civil Remedies Branch" rather than to the "Civil Recoveries Branch - Compliance Unit." The Bayer Compliance Officer is now Jeffrey M. Greenman. The Bayer phone number is: (203) 812-2647. The Bayer fax number is: (203) 812-3143.

VII. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

The terms of Section VII of the CIA remain in effect and Bayer shall continue its obligations under Section VII through the term of this Addendum.

VIII. DOCUMENT AND RECORD RETENTION

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

IX. DISCLOSURES AND PRIVILEGES

The terms of Section IX of the CIA remain in effect and Bayer shall continue its obligations under Section IX through the term of this Addendum.

X. BREACH AND DEFAULT PROVISIONS

Section X of the CIA, as amended herein, shall remain in effect through the term of this Addendum.

Section X.A.4 is amended to read as follows:

4. A Stipulated Penalty of $2,000 (which shall begin to accrue on the date the failure to comply began) for each day Bayer employs or engages an Ineligible Person as a Covered Person and that person: (a) has responsibility for, or involvement with, Bayer's business operations related to the Federal health care programs; or (b) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (the Stipulated Penalty described in this Subsection shall not be demanded for any time period during which Bayer 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).

The following new item is added as Section X.A.6.:

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

Section X.A.6. of the CIA shall be renumbered as X.A.7., and the reference to "any obligation of this CIA not already covered in sections X.A.1-5" shall refer to "any obligation of this CIA not already covered in sections X.A.1-6."

XI. EFFECTIVE AND BINDING AGREEMENT

Section XI of the CIA shall be amended to read as follows and shall remain in effect through the term of this Addendum.

Consistent with the provisions in the Settlement Agreements pursuant to which the CIA and this Addendum are entered, and into which the CIA and Addendum are incorporated, Bayer Corporation, Bayer Pharmaceuticals Corporation and Bayer HealthCare LLC, and OIG agree as follows:

A. The CIA and this Addendum shall be binding on the successors, assigns and transferees of Bayer Corporation, Bayer Pharmaceuticals Corporation and Bayer HealthCare LLC;

B. This Addendum shall become final and binding on the Signing Date;

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

D. The undersigned Bayer Corporation signatory represents and warrants that he is authorized by Bayer Corporation to execute this Addendum and that Bayer Corporation shall cause the Bayer Pharmaceuticals Corporation and the Biological Products Division of Bayer HealthCare LLC to fulfill its obligations under this Addendum. The undersigned OIG signatory represents that he is signing this Addendum in his official capacity and that he is authorized to execute this Addendum.

ON BEHALF OF BAYER CORPORATION

Jon R. Wyne
Senior Vice President and Treasurer
Bayer Corporation

DATE

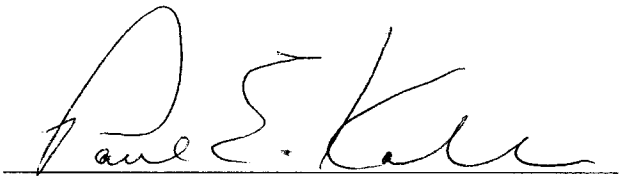
Paul E. Kalb, Esq.
I. Scott Bass, Esq.
Nathan C. Sheers, Esq.
James C. Stansel, Esq.
Sidley Austin Brown & Wood LLP
Counsel for Bayer Corporation

DATE

ON BEHALF OF BAYER CORPORATION

Jon R. Wyne
Senior Vice President and Treasurer
Bayer Corporation

DATE



4/15/03

Paul E. Kalb, Esq.
I. Scott Bass, Esq.
Nathan C. Sheers, Esq.
James C. Stansel, Esq.
Sidley Austin Brown & Wood LLP
Counsel for Bayer Corporation

DATE

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

Larry J. Goldberg

4/15/03
DATE

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

ADDENDUM TO CORPORATE INTEGRITY AGREEMENT BETWEEN OFFICE OF INSPECTOR GENERAL AND BAYER CORPORATION
Attachment A

A. Medicaid Rebate Systems Review

As specified more fully below, during the term of this Addendum to the CIA between the OIG and Bayer Corporation, Bayer shall retain an IRO to perform reviews that address Bayer's systems, processes, policies and practices (including inquiries made to CMS) associated with tracking, gathering, and accounting for all relevant data for purposes of appropriately calculating the Best Price reported under the Medicaid Drug Rebate Program.

If there are no material changes in Bayer's Medicaid Drug Rebate Program-related systems, processes, policies and practices during the term of this Addendum, the IRO shall perform these reviews for the first and fifth Reporting Periods under the Addendum. If Bayer materially changes its systems, processes, policies and practices relating to the Medicaid Drug Rebate Program, then the IRO shall perform a Medicaid Rebate Systems Review for the Reporting Period in which such changes were made in addition to conducting the Medicaid Rebate Systems Review for the first and fifth Reporting Periods.

In order to conduct this review, the IRO shall undertake the following steps:

1. The IRO shall interview the following Bayer personnel, as applicable, and any other appropriate personnel who are responsible for the quarterly calculation of Best Price for purposes of the Medicaid Drug Rebate Program:

   Director, Strategic Contracting and Contract Operations
   Manager, Strategic Contracting and Contract Operations
   IT Consultant
   Senior Contract Analyst, Rebate Operations
   Administrator, Rebate Operations
   Government Contract Analysts
   Administrator, Bids and Contracts
   Senior Financial Analyst
   Manager, Contract Analyst and Planning
   Manager, Internal Controls
   Contract Associate

2. The IRO shall review Bayer's policies and procedures and practices as they relate to the quarterly calculation of Best Price for Government Reimbursed Products as the term is defined in the CIA. Based upon the information obtained from the management interviews, the review of Bayer's policies

and procedures and other relevant document review, and the review of Bayer's practices, the IRO shall review and document the systems, policies, processes and controls associated with Bayer's calculation of Best Price for Government Reimbursed Products. In particular, the IRO shall review the following:

a. Bayer's determination of which sales and other transactions to exclude from the calculation of the Best Price because the transactions are exempt from the calculation;

b. Bayer's determination of which customers are considered for purposes of the calculation of Best Price;

c. Where applicable, Bayer's treatment of all types of discounts; chargebacks; free goods; rebates and all other price concessions provided to any relevant purchaser;

d. Any inquiries from Bayer to CMS in connection with calculation of the Best Price and any responses to those inquiries;

e. Bayer's computer or accounting systems used in the calculation of Best Price, including the data or information flow process by which data about relevant sales and other transactions are included in the calculation of Best Price;

f. Bayer's use of electronic and manual tools or other mechanisms to monitor or trend Best Price and identify any variations, exceptions or outliers in the calculated Best Price (including a review of the basis upon which variations, exceptions or outliers are identified and follow-up activities taken to identify the cause of the variations, exceptions or outliers); and

g. Bayer's systems and practices for reporting Best Price to CMS and for reporting any adjustments in previously reported Best Price or Unit Rebate Amount.

3. For each relevant Reporting Period, the IRO shall prepare a report based upon the Medicaid Rebate Systems Review. (This report may be combined with the report for the Managed Care Transactions Review and/or the report for the Drug Price Reporting Engagement.) Each report shall include the following items:

a. a description of the systems, processes, policies, and practices in place to track, gather, and appropriately include or exclude relevant transactions in the calculation of Best Price;

b. a description of the documentation, information, practices and systems reviewed and the personnel interviewed, including a description of Bayer's inquiries to CMS regarding Medicaid Best Price and any responses to those inquiries; and

c. observations, findings, and recommendations on possible improvements to Bayer's systems, processes, policies, and practices.

B. Managed Care Transactions Review

As specified more fully below, during the term of this Addendum to the CIA between the OIG and Bayer Corporation, the IRO shall annually perform reviews that shall address and analyze Bayer's systems, policies and practices with regard to non-rebate payments made to managed care entities.

1. Testing Period and Testing Objective

a. For the first Reporting Period under this Addendum, the IRO shall test sample units consisting of non-rebate expenditures made to managed care customers during the period from October 2002 through September 2003 ("Testing Period"). For subsequent Reporting Periods, unless otherwise agreed to by the OIG, the IRO shall test sample units from the next consecutive one-year periods.

b. For purposes of this review, a managed care customer is a for-profit or not-for-profit entity (a) whose principle business is managing or providing pharmacy and/or other health care benefits, including, but not limited to, health maintenance organizations, preferred provider organizations and pharmacy benefit management companies; and (b) that has entered into some form of discount agreement with Bayer that was in effect during the relevant Testing Period. The term "managed care customer" does not include government entities, hospitals or health care providers.

2. Review Scope – Sample Units and Sources of Documentation

a. For the Testing Period, the IRO will randomly identify 30 managed care customers based upon a listing of all managed care customers as provided by Bayer.

b. Definition of the Sample Unit - for the purposes of this discovery sample, the IRO will define the sample unit as one non-rebate payment to a managed care customer in the Testing Period.[1]

c. From the universe of all payments related to the first 20 managed care customers randomly identified, the IRO will randomly identify 50 sample units for testing.[2]

d. Definition of Control Documentation – for purposes of this discovery sample, Bayer will provide the IRO with all applicable documentation as required by Bayer's policies and procedures to support the sample units randomly identified ("Control Documentation"). Examples of the types of expenditures and Control Documentation to be tested include, but may not be limited to, the following:

(a) Speaker agreements;
(b) Honoraria requests;
(c) Consulting and other non-consulting arrangement agreements;
(d) Educational grants requests;
(e) CME agreements;
(f) Clinical or research grant requests; and
(g) Charitable contribution requests.

3. Testing Procedures

a. For the Testing Period, the IRO will test the randomly identified 50 sample units according to the following testing objectives:

(a) The appropriate and required Control Documentation exists for the sample unit as per Bayer's policies and procedures as communicated in Bayer's *"Compliance Policies and Procedures," Revised July 1, 2002 Updated December 1,* 2002;

(b) The Control Documentation was completed in accordance with the requirements set forth in Bayer's policies and procedures;

[1] The sample units will not contain rebates, chargebacks or administration fees.
[2] Should there be fewer than 50 sample units related to the first 20 managed care customers, the IRO will randomly select additional sample units from the remaining 10 managed care customers.

(c) The description of the expenditure in the Control Documentation provided is consistent with Bayer's policies and procedures; and

(d) The Control Documentation reflects that all required written or electronic approvals were obtained in accordance with Bayer's policies and procedures.

b. Any sample unit that does not satisfy the criteria set forth above in item B.3.a shall be considered an exception and shall be noted by the IRO. The IRO will consider a sample unit to have a Material Error if either of the following is identified:

(a) The appropriate and required Control Documentation does not exist and no corrective action has been taken prior to the IRO review; or

(b) Information or data is omitted from key fields in the Control Documentation that prevents the IRO's ability to understand the nature of the expenditure and/or assess compliance with Bayer's policies and procedures.

c. Additional Review if Material Errors are Discovered

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

4. Managed Care Transactions Review Report

The IRO shall annually prepare a report based upon each Managed Care Transaction Review performed. Each report shall include the following:

a. Elements to Be Included:

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

(b) Engagement Protocol: A detailed narrative description of the procedures performed and a description of each sampling unit utilized in performing the procedures; and

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

b. Results to Be Included:

The following results shall be included in each Managed Care Transactions Review Report:

(a) For each sample unit, the IRO shall describe, in general terms, the terms of any associated contract(s) and the types of expenditures made in connection with the managed care customer during the Testing Period;

(b) for each sample unit, the IRO shall describe the procedures performed and state its findings and supporting rationale as to whether: a) appropriate and requisite Control Documentation exists in connection with each expenditure under review; and b) the Control Documentation was completed in accordance with the requirements set forth in Bayer's Policies and Procedures;

(c) for each sample unit reviewed, the IRO shall identify all material errors and exceptions discovered. For the exceptions, the IRO shall describe in general terms what the errors were. The IRO shall describe those situations when corrective action was taken prior to IRO review, including a description of the circumstances requiring corrective action and the nature of the corrective action; and

(d) if any Material Errors were discovered, the IRO 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.

Addendum to Corporate Integrity Agreement
Between Office of Inspector General and Bayer Corporation

Attachment B - Medicaid Drug Rebate Certification

CERTIFICATION

In accordance with Section III.I of the Addendum to the Corporate Integrity Agreement ("CIA") entered between Bayer Corporation and the OIG, the undersigned hereby certifies the following to the best of my knowledge, information and belief:

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

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

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

_____
Jeffrey M. Greenman
Compliance Officer

_____
Date