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

The Office of Inspector General (OIG) of the Department of Health and Human Services and Novartis Pharmaceuticals Corporation (Novartis) entered into a Corporate Integrity Agreement effective September 29, 2010 (hereafter "Novartis CIA" or "CIA"). Pursuant to Section XI.C of the Novartis CIA, the Novartis CIA may be modified only with written consent of both Novartis and OIG.

The OIG and Novartis hereby agree that the Novartis CIA shall be extended and modified in accordance with the terms set forth below. This document shall hereafter be referred to as the "CIA Addendum." Contemporaneously with this CIA Addendum, Novartis is entering into a Stipulation and Order of Settlement and Dismissal with the United States. Novartis' agreement to this CIA Addendum is a condition precedent to that Stipulation.

I. TERM AND SCOPE OF THE CIA AND CIA ADDENDUM

All of the compliance obligations assumed by Novartis under the CIA shall be extended for a five-year period from the effective date of the CIA Addendum. In addition, the period of the new compliance obligations assumed by Novartis under this Addendum shall be 5 years from the effective date of the CIA Addendum. The Effective Date of the CIA Addendum shall be the date the final signatory signs this Addendum (Addendum Effective Date). The first Reporting Period shall be from the Addendum Effective Date through December 31, 2016. The second and subsequent Reporting Periods shall be from January 1 through December 31 of each of the subsequent four calendar years. Novartis shall comply with all obligations set forth in the CIA and in this CIA Addendum.

Unless otherwise specifically revised by this CIA Addendum, all of the provisions of the Novartis CIA shall remain in full force and effect during the five-year period covered by this Addendum. The scope of the CIA and CIA Addendum shall be governed by the definitions set forth in Section II of the CIA as further modified below.

A. Sections II.C.1.b and c of the CIA (the definition of "Covered Persons") shall be amended to read as follows:

1. *II.C.1.b*: all officers, directors, and employees of Novartis who are: (1) based in the United States or (2) based outside the United States and who

have responsibilities relating to Promotional Functions, Product Related Functions, and Specialty Pharmacy Related Functions, except as carved out below in this Section II.C.1;

2. *II.C.1.c*: all contractors, subcontractors, agents, and other persons who perform Promotional Functions, Product Related Functions, or Specialty Pharmacy Related Functions in the United States on behalf of Novartis.

   Notwithstanding the above, this term does not include (1) employees of Novartis who perform only manufacturing or building and facilities functions (i.e., facilities maintenance, grounds maintenance, and food services functions); (2) part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year; or (3) Novartis employees in the U.S. in Global Development, Global Oncology, Global Cell & Gene Therapeutics, or LatAm GenMeds so long as they do not: (i) market, distribute, sell, or promote Government Reimbursed Products; or (ii) have responsibilities relating to Promotional Functions, Product Related Functions, or Specialty Pharmacy Related Functions.

B. Section II.C.2 (the definition of "Relevant Covered Persons") shall be amended to read as follows:

1. "Relevant Covered Persons" includes all Covered Persons whose job responsibilities relate to Promotional Functions, Product Related Functions, and Specialty Pharmacy Related Functions.

C. Section II.C.5 (the definition of "Product Related Functions") shall be amended to read as follows:

1. The term "Product Related Functions" includes: (a) the preparation or external dissemination of non-promotional materials about Government Reimbursed Products, including those functions relating to any applicable review committees and to Novartis' Medical Affairs Department (Medical Affairs), and any materials about Government Reimbursed Products that are provided by Novartis to Specialty Pharmacies or created by Specialty Pharmacies at the direction of Novartis for use in connection with a Fee-For-Service Arrangement (as defined below); (b) contracting with healthcare professionals ("HCPs") in the United States to conduct post-marketing clinical trials and post-marketing studies relating to Government Reimbursed Products; (c)

authorship, publication, and disclosure of articles or study results relating to Government Reimbursed Products; and (d) activities related to the submission of information about Government Reimbursed Products in government-listed compendia (such as Drugdex or other compendia of information about Government Reimbursed Products).

D. The following new definitions shall be added as Sections II.C.8 through II.C.10 of the CIA and shall read as follows:

1. *II.C.8:* "Arrangements" shall mean every arrangement or transaction that: involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and is between Novartis and any Specialty Pharmacy and is related to the dispensing of a Government Reimbursed Product by the Specialty Pharmacy. Arrangements involving Novartis' payment to a Specialty Pharmacy for services provided shall be referred to as "Fee-for-Service (or FFS) Arrangements." Those Arrangements under which Novartis provides a pricing term (such as a discount) to the Specialty Pharmacy shall be referred to as "Discount Arrangements."

2. *II.C.9:* "Specialty Pharmacy Related Functions" includes the development, approval, review, management, implementation and operation of Arrangements; and

3. *II.C.10*: "Specialty Pharmacies" shall mean pharmacies located in the United States and licensed and regulated by one or more state pharmacy board(s) that dispense specialty prescription drugs (those pharmaceuticals that typically require special handling, administration, or inventory management), primarily by mail or third party delivery service; to patients with chronic conditions, acute events, or complex or high-cost therapies; and that provide services including patient education, support, and/or coordination with patients and prescribers.

II. CORPORATE INTEGRITY OBLIGATIONS

Novartis shall maintain a Compliance Program that includes all the elements specified in the CIA (as modified below, if applicable) and the additional elements established through this Addendum and specified below.

A. Section III.A.4 of the CIA (Management Accountability and Certification) shall be amended to read as follows:

1. In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Novartis officers or employees ("Certifying Employees") are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the

applicable Novartis business unit is compliant with applicable Federal health care program and FDA requirements, and with the obligations of this CIA. These Certifying Employees shall include the following: President NPC and Head Pharma, North America; Executive Vice President and North American Region Head, Oncology; Vice Presidents of commercial functions (including those vice presidents with sales, marketing, managed markets and his/her direct reports, new/mature products, Business Development & Licensing, commercial support, patient advocacy, patient services, and brand responsibilities); sales management (including general managers and direct reports, regional directors, directors of sales, and business directors); senior brand leaders and direct reports (commercial brand leaders and development brand leaders); Vice President Oncology Drug Regulatory Affairs; Drug Regulatory Affairs US Head; Director Government Price Reporting Compliance Managed Markets Finance; the Senior Vice President, Managed Markets Finance; the Senior Vice President, Managed Markets; Director, Government, Contracting, Planning & Analysis; Director, Strategic Sourcing; Executive Director, National Accounts and Specialty Channels; Director, Specialty Contract & Administration; Senior Director, Specialty Channels & Patient Services; the Vice President and Head Medical Affairs & Drug Regulatory Affairs; and the Senior Vice President or Head(s) Research and Development and/or Clinical Development and Medical Affairs and each of his/her respective direct reports with responsibilities for Clinical Development, Medical Affairs, Field Medical Relations, or Advertising & Promotion (as exists within respective departments); Vice President and Head Business & Administrative Services; US Oncology Head of Customer Innovation & Strategy; US Oncology Executive Director Therapeutic Area Marketing Analysis; US Oncology Executive Director Commercial Operations; and US Oncology Head Ethics & Compliance. This certification will not include individuals otherwise excluded as specified in the CIA "Covered Persons" definition.

The remainder of Section II.A.4 of the CIA shall remain unchanged.

B. The following changes shall be made to Section III.B.3 of the CIA (Policies and Procedures):

1. The last line of Section III.B.3.t shall be revised to read as follows: "research results made available to each author or contributor;"

2. The last line of Section III.B.3.u shall be revised to read as follows: "health care program and FDA requirements; and"

3. A new section III.B.3.v shall be added and shall read as follows:

"III.B.3.v. Specialty Pharmacy Related Functions as defined in Section II.C.9 and Arrangements as defined in Section II.C.8. These Policies and Procedures shall be designed to ensure that Novartis' Arrangements with Specialty Pharmacies are used for legitimate and lawful purposes in accordance with the federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b(b)) and other applicable Federal health care program and FDA requirements.

The Policies and Procedures shall include a requirement that all Arrangements be subject to a written review and approval process. With regard to FFS Arrangements, the Policies and Procedures shall include requirements about the business need for the Arrangements, the services provided under the Arrangements, and the amount of compensation provided under the Arrangements (including that the amount of compensation is fair market value for the service).

For FFS Arrangements, including those that include a medication therapy management program, the Policies and Procedures shall require that: 1) the services be provided in a manner that would not reasonably be expected to undermine or otherwise interfere with the clinical judgment of the patients' prescribing health care professionals; and 2) Novartis not direct or encourage a Specialty Pharmacy to cause or encourage health care professionals to prescribe, or patients to ask their health care professionals to prescribe, a Novartis Government Reimbursed Product over any other medically-appropriate product.

The Policies and Procedures shall also require that the terms of FFS Arrangements prohibit the offering of any financial inducement by a Specialty Pharmacy to any health care professional to prescribe or switch patients to a Novartis Government Reimbursed Product."

C. Section III.C.2 of the CIA (Training and Education) shall be amended to read as follows:

1. *Specific Training.* Within 120 days after the Effective Date, each Relevant Covered Person engaged in Promotional Functions, Product Related Functions, and/or Specialty Pharmacy Related Function shall receive at least three hours of Specific Training applicable to their specific job functions in addition to the General Training required above. This Specific Training shall include a discussion of:

    a. all applicable Federal health care program requirements relating to Promotional Functions, Product Related Functions, and/or Specialty Pharmacy Related Functions;

b. all applicable FDA requirements relating to Promotional Functions, Product Related Functions, and/or Specialty Pharmacy Related Functions;

c. all Novartis Policies and Procedures and other requirements applicable to Promotional Functions, Product Related Functions, and/or Specialty Pharmacy Related Functions;

d. the personal obligation of each individual involved in Promotional Functions, Product Related Functions, and/or Specialty Pharmacy Related Functions to comply with all applicable Federal health care program and FDA requirements and all other applicable legal requirements;

e. the legal sanctions for violations of the applicable Federal health care program and FDA requirements; and

f. examples of proper and improper practices related to Promotional Functions, Product Related Functions, and/or Specialty Pharmacy Related Functions.

D. The following new section shall be added as Section III.O (Specialty Pharmacy Related Provisions) to the CIA and shall read as follows:

Novartis shall develop and implement the following procedures and requirements specifically designed to ensure that its relationships with Specialty Pharmacies comply with the Anti-Kickback Statute.

1. Compliance with the Anti-Kickback Statute

   a. *Arrangements Procedures*. To the extent not already accomplished, within 120 days after the Addendum Effective Date, Novartis shall create procedures reasonably designed to ensure that each existing and new or renewed Arrangement does not violate the Anti-Kickback Statute or the regulations, directives, and guidance related to the statute (Arrangements Procedures). These procedures shall include the following:

      i. creating and/or maintaining a centralized tracking system for all existing and new or renewed Arrangements (Arrangements Tracking System);

      ii. tracking remuneration to and from all parties to Arrangements;

iii. tracking service and activity logs to ensure that parties to the Arrangement are performing the services required under the applicable Arrangement(s) (if applicable);

iv. establishing and implementing a written review and approval process for all Arrangements, the purpose of which is to ensure that all new and existing or renewed Arrangements do not violate the Anti-Kickback Statute and that includes at least the following: (i) a legal review of all Arrangements by counsel with expertise in the Anti-Kickback Statute, (ii) for FFS Arrangements, a process for specifying the business need or business rationale for each service provided under the FFS Arrangement and determining and documenting the fair market value of the remuneration specified in the FFS Arrangement;

v. requiring the Chief Compliance Officer (or designee) to review the Arrangements Tracking System, internal review and approval process, and other Arrangements Procedures on at least an annual basis and requiring the Chief Compliance Officer to provide a report on the results of such review to the Compliance Committee; and

vi. implementing effective responses when suspected violations of the Anti-Kickback Statute are discovered, including disclosing Reportable Events.

b. *New or Renewed Arrangements.* Prior to entering into new Arrangements or renewing existing Arrangements, in addition to complying with the Arrangements Procedures set forth above, Novartis shall comply with the following requirements (Arrangements Requirements):

i. ensure that each Arrangement is set forth in writing and signed by Novartis and the other parties to the Arrangement;

ii. Novartis shall provide each party to the Arrangement with a copy of its Code of Conduct and relevant Policies and Procedures relating to the Anti-Kickback Statute;

iii. include in the written agreement a certification by the parties to the Arrangement that the parties shall not violate

the Anti-Kickback Statute with respect to the performance of the Arrangement; and

iv. maintain on file a certification by the Vice President of Patient Access and Health Policy, the Vice President of Managed Markets and Market Access, the Vice President of Managed Markets Finance, and an appropriate manager with responsibility for the Arrangement, with respect to each Arrangement and provided at or about the time the Arrangement was first entered into and again upon or about each anniversary of the date such Arrangement was first entered into, that the written agreement for such Arrangement sets forth all material terms of the Arrangement.

c. *Arrangements Tracking System Verification and Certification.* For each Reporting Period, the Chief Compliance Officer shall review the entries in Novartis' Arrangements Tracking System and certify in writing to OIG that, to the best of his or her knowledge, the Arrangements Tracking System is complete and accurate, except for any discrepancies identified. The Chief Compliance Officer shall provide an explanation for: (1) any Arrangements found to have been missing from the Arrangements Tracking System; and (2) any entries in the Arrangements Tracking System found to have been incomplete or inaccurate.

d. *Records Retention and Access.* Novartis shall retain and make available to OIG, upon request, the Arrangements Tracking System and all supporting documentation of the Arrangements subject to this Section III.O and, to the extent available, all non-privileged communications related to the Arrangements and the actual performance of the duties under the Arrangements.

2. Review Procedures

a. General Description

i. *Engagement of Independent Review Organization.* Within 120 days after the Amendment Effective Date, Novartis shall engage an entity (or entities), such as an accounting, auditing, law, or consulting firm (hereinafter "Independent Review Organization" or "IRO") to perform the reviews listed in this Section III.O. The applicable requirements

relating to the IRO(s) are outlined in Appendix C to this CIA, which is incorporated by reference.

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

iii. *Responsibilities and Liabilities*. Nothing in this Section III.O affects Novartis' responsibilities or liabilities under any criminal, civil, or administrative laws or regulations applicable to any Federal health care program including, but not limited to, the Anti-Kickback Statute.

b. *Arrangements Review*. The IRO shall perform an Arrangements Review and prepare an Arrangements Review Report as outlined in Appendix D to this Addendum, which is incorporated by reference.

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

Prior to initiating a Validation Review, OIG shall notify Novartis in writing of its intent to do so and provide an explanation of the reasons OIG has determined a Validation Review is necessary. Novartis shall have 30 days following the date of the OIG's written notice to submit a written response to OIG that includes any additional or relevant information to clarify the results of the Arrangements Review or to correct the inaccuracy of the Arrangements Review and/or propose alternatives to the proposed Validation Review. The final determination as to

whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

d. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Novartis a certification that the IRO: (1) has evaluated its professional independence and objectivity with respect to the reviews required under this Section II.D.2; and (2) concluded that it is, in fact, independent and objective, in accordance with the requirements specified in Appendix C to this Addendum.

3. Risk Assessment and Internal Review Process

Within 120 days after the Addendum Effective Date, Novartis shall develop and implement a centralized annual risk assessment and internal review process, such as Novartis' Healthcare Compliance Risk Management (HCRM) process, to identify and address risks associated with Arrangements (as defined in Section II.C.8 above). The risk assessment and internal review process should require compliance, legal and department leaders, at least annually, to: (1) identify and prioritize risks, (2) develop monitoring and/or audit work plans, or other appropriate remediation, related to the identified risk areas, (3) implement the monitoring and/or audit work plans or other appropriate remediation, (4) develop corrective action plans in response to the results of any monitoring or audit work performed, and (5) track the implementation of the corrective action plans in order to assess the effectiveness of such plans. Novartis shall maintain the risk assessment and internal review process as described above in this paragraph for the term of the CIA.

4. Interim Report.

a. Within 150 days of the Addendum Effective Date, Novartis shall submit an Interim Report to the OIG. The Interim Report shall contain the following information:

i. a summary of all Policies and Procedures required by Section III.B.3.v (copies of the Policies and Procedures shall be made available to OIG upon request);

ii. a description of: (a) the Arrangements Tracking System required by Section III.O.1.a.i; (b) the internal review and approval process required by Section III.O.1.a.v; and (c) the tracking and monitoring procedures and other Arrangements Procedures required by Section III.O.1.a; and

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

III. Changes to Business Units or Locations

As used in Sections IV.A and IV.B of the CIA, the phrase "related to Promotional Functions or Product Related Functions" shall be amended to read as follows: "related to Promotional Functions, Product Related Functions, or Specialty Pharmacy Related Functions."

IV. Implementation and Annual Reports

A. Annual Reports

1. The last line of Section V.B.22 shall be amended to read as follows: "Section III.B.3.r;"

2. The Section V.B.23 shall be amended to read as follows: "the certifications required by Section V.C; and"

3. The following new items are added to Section V.B of the CIA as sections V.B.24-30

    a. *V.B.24.* a description of: (a) any changes to the Arrangements Tracking System required by Section III.O.1.a.i; (b) any changes to the internal review and approval process required by Section III.O.1.a.iv.; and (c) any changes to the tracking and monitoring procedures and other Arrangements Procedures required by Section III.O.1.a;

    b. *V.B.25.* the certification regarding the completeness and accuracy of the Arrangements Tracking System required by Section III.O.1.c, as well as an explanation of: (1) any Arrangements found to have been missing from the Arrangements Tracking System; and (2) any entries in the Arrangements Tracking System found to have been incomplete or inaccurate;

c. *V.B.26.* a complete copy of all reports prepared pursuant to Section III.O.2, along with a copy of the IRO's engagement letter;

d. *V.B.27.* Novartis' response to the reports prepared pursuant to Section III.O.2, along with corrective action plan(s) related to any issues raised by the reports;

e. *V.B.28.* a summary and description of any and all current and prior engagements and agreements between Novartis and the IRO (if different from what was submitted as part of the Interim Report) and a certification from the IRO regarding its professional independence and objectivity with respect to Novartis;

f. *V.B.29.* a description of the risk assessment and internal review process required by Section III.O.3, a summary of any changes to the process and a description of the reasons for such changes; and

g. *V.B.30.* a summary of all internal reviews performed pursuant to Section III.O.3 during the Reporting Period and any corrective action plans developed in response to those internal reviews. Copies of the internal review reports and corrective actions plans shall be made available to OIG upon request.

4. The following new sections are added to Section V.C.2 of the CIA (Compliance Officer Certifications).

   a. V.C.5. to the best of his or her knowledge, Novartis has implemented procedures reasonably designed to ensure that all Arrangements do not violate the Anti-Kickback Statute, including the Arrangements Procedures required in Section III.O.I.a of the CIA; and

   b. V.C.6. to the best of his or her knowledge, Novartis has fulfilled the requirements for New and Renewed Arrangements under Section III.O.1.b of the CIA.

V. Breach and Default Provisions

A. The following section is added to section X.A.1 of the CIA (Stipulated Penalties) as section X.A.1.o.

1. *X.A.1.o.* the Specialty Pharmacy requirements, including the Arrangements Tracking System and review and risk assessment and internal review processes set forth in Section III.O.

B. Section X.A.3 of the CIA is amended to read as follows:

1. *X.A.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 Novartis fails to submit to the OIG by the deadlines for submission the Interim Report required by Section III.O.4 or any Annual Report in accordance with the requirements of Section V.

C. Section X.A.4 of the CIA is amended to read as follows:

1. *X.A.4.* A stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Novartis fails to submit any IRO Review Report in accordance with the requirements of Section III.D and Appendix B and/or the Arrangements Review Report in accordance with the requirements of Section III.O and Appendix D.

D. Section X.A.6 of the CIA is amended to read as follows:

1. *X.A.6.* A Stipulated Penalty of $50,000 for each false certification submitted by or on behalf of Novartis as part of its Interim Report, any Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

E. Section X.D.c. of the CIA (Exclusion for Material Breach) is amended to read as follows:

1. *X.D.c.* a failure to engage and use an IRO in accordance with Sections III.D and III.O and Appendices B and D of the CIA.

VI. EFFECTIVE AND BINDING AGREEMENT

A. All terms and conditions of the CIA not modified in this Addendum shall remain in effect.

B. The undersigned signatories represent and warrant that they are authorized to execute this Addendum. The undersigned OIG signatories represent that they are signing this Addendum in their official capacities and that they are authorized to execute this Addendum.

C. This Addendum may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Addendum. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Addendum.

ON BEHALF OF NOVARTIS PHARMACEUTICALS CORPORATION

/Bryant Aaron/

Nov 18 2015

BRYANT AARON
VICE-PRESIDENT, ETHICS & COMPLIANCE
CHIEF COMPLIANCE OFFICER
NOVARTIS PHARMACEUTICALS CORPORATION

DATE

/Matthew J. O'Connor/

11/18/15

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DATE

ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
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11-18-2015
DATE

APPENDIX C

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

1. Novartis shall engage a IRO that possesses the qualifications set forth in Section B, below, to perform the responsibilities in Section C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Section D, below. Within 30 days after OIG receives the information identified in Section III.O.4.a.iii or any additional information submitted by Novartis in response to a request by OIG, whichever is later, OIG will notify Novartis if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Novartis may continue to engage the IRO.

2. If Novartis engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Novartis shall submit the information identified in Section III.O.4.a.iii of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by Novartis at the request of OIG, whichever is later, OIG will notify Novartis if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Novartis may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Arrangements Review who are knowledgeable in the requirements of the Anti-Kickback Statute and the regulations, directives, and other guidance documents related to this statute;

2. possess expertise in fair market valuation issues or have the ability to associate with a valuation firm to assist in conducting the transactions review component of the Arrangements Review;

3. assign or retain individuals to conduct the Arrangements Review who are knowledgeable in the requirements of the Anti-Kickback Statute and the regulations and other guidance documents related to this statute. These individuals shall have the expertise and qualifications necessary to perform legal analyses as required in

connection with the Arrangements Review including specifically as it relates to items C.7 and C.11 of the Arrangements Transactions Review described in Appendix D and the legal analysis described in Section D.2 of Appendix D (Arrangements Transactions Review Report); and

4. have sufficient staff and resources to conduct the Arrangements Review required by the CIA on a timely basis.

C. IRO Responsibilities

The IRO shall:

1. perform each Arrangements Review in accordance with the specific requirements of the CIA;

2. respond to all OIG inquires in a prompt, objective, and factual manner; and

3. prepare timely, clear, well-written reports that include all the information required by Section III.O of the CIA and Appendix D to the CIA.

D. IRO Independence and Objectivity

The IRO must perform the Arrangements Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the U.S. Government Accountability Office.

E. Assertions of Privilege

Novartis shall not assert claims of attorney-client privilege in order to avoid disclosing to OIG information related to or resulting from the IRO's engagement. Novartis's engagement letter with the IRO shall include a provision stating that the IRO agrees not to assert claims of work product privilege in order to avoid disclosing to OIG information related to or resulting from its engagement.

F. IRO Removal/Termination

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

2. *OIG Removal of IRO.* In the event OIG has reason to believe that the IRO does not possess the qualifications described in Section B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Section C, OIG shall notify Novartis in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. OIG may, at its sole discretion, require Novartis to engage a new IRO in accordance with Section A of this Appendix. Novartis must engage a new IRO within 60 days of its receipt of OIG's written notice.

Prior to requiring Novartis to engage a new IRO, OIG shall notify Novartis of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Novartis may present additional information regarding the IRO's qualifications, independence, or performance of its responsibilities. OIG will attempt in good faith to resolve any differences regarding the IRO with Novartis prior to requiring Novartis to terminate the IRO. However, the final determination as to whether or not to require Novartis to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX D

ARRANGEMENTS REVIEW

The Arrangements Review shall consist of two components: a systems review and a transactions review. The IRO shall perform all components of each Arrangements Review. If there are no material changes to Novartis' systems, processes, policies, and procedures relating to Arrangements, the Arrangements Systems Review shall be performed for the first and fourth Reporting Periods after the Addendum Effective Date. If Novartis materially changes the Arrangements systems, processes, policies, and procedures, the IRO shall perform an Arrangements Systems Review of the material changes for the Reporting Period in which such changes were made in addition to conducting the systems review for the first and fourth Reporting Periods. The Arrangements Transactions Review shall be performed annually and shall cover each of the five Reporting Periods after the Addendum Effective Date.

A. Arrangements Systems Review. The Arrangements Systems Review shall be a review of Novartis' systems, policies, processes, and procedures relating to the initiation, review, approval, and tracking of Arrangements. Specifically, the IRO shall review the following:

1. Novartis' systems, policies, processes, and procedures with respect to creating and maintaining a centralized tracking system for all existing and new and renewed Arrangements (Arrangements Tracking System), including a detailed description of the information captured in the Arrangements Tracking System;

2. Novartis' systems, policies, processes, and procedures for tracking remuneration to and from all parties to Arrangements;

3. Novartis' systems, policies, processes, and procedures for tracking service and activity logs to ensure that parties to the Arrangement(s) are performing the services required under the applicable Arrangement(s) (if applicable);

4. Novartis' systems, policies, processes, and procedures for the review and approval of materials provided by Novartis to Specialty Pharmacies or created by Specialty Pharmacies at the direction of Novartis for use in connection with a Fee-for-Service (FFS) Arrangement;

5. Novartis' systems, policies, processes, and procedures for initiating, reviewing, and approving Arrangements, including those policies that identify the individuals with authority to initiate an Arrangement and those policies that specify the business need or business rationale required to initiate an FFS Arrangement;

6. Novartis' systems, policies, processes, and procedures relating to Novartis' evaluation of services and activities in potential Arrangements and the classification of contract approach (*e.g.*, discount or fee-based contracts);

7. Novartis' systems, policies, processes, and procedures designed to ensure that, to the extent that a Specialty Pharmacy provides services under a FFS Arrangement, including any FFS Arrangement with a medication therapy management program, the services be provided in a manner that would not reasonably be expected to undermine or otherwise interfere with the clinical judgment of patients' prescribing health care professionals;

8. Novartis' systems, policies, processes, and procedures designed to ensure that, to the extent that a Specialty Pharmacy provides services under the terms of a FFS Arrangement, (a) Novartis shall not direct or encourage a Specialty Pharmacy to cause or encourage a health care professional to prescribe, or patients to ask their health care professionals to prescribe, a Novartis Government Reimbursed Product over any other medically-appropriate product; and (b) the terms of such Arrangements shall prohibit the offering of any financial inducement by the Specialty Pharmacy to any health care professional to prescribe or switch patients to a Novartis Government Reimbursed Product;

9. Novartis' systems, policies, processes, and procedures relating to any allocation of patients to specified Specialty Pharmacies in connection with an Arrangement (if applicable);

10. Novartis' systems, policies, processes, and procedures for the internal review and approval of all Arrangements, including those policies that identify the individuals required to approve each type or category of Arrangement entered into by Novartis, the internal controls designed to ensure that all required approvals are obtained, and the processes for ensuring that all Arrangements are subject to a legal review by counsel with expertise in the Anti-Kickback Statute;

11. the Compliance Officer's (or designee's) annual review of and the Compliance Officer's reporting to the Compliance Committee on the Arrangements Tracking System; Novartis' internal review and approval process; and other Arrangements systems, policies, processes, and procedures;

12. Novartis' systems, policies, processes, and procedures for implementing effective responses when suspected violations of the Anti-Kickback Statute are discovered, including disclosing Reportable Events;

13. Novartis' systems, policies, processes, and procedures for ensuring that all new and renewed Arrangements comply with the Arrangements Requirements set forth in Section III.O.1.b of the CIA;

14. Novartis' systems, policies, processes, and procedures for auditing the performance of Specialty Pharmacies under the FFS Arrangements to ensure and assess compliance with the contractual terms of the Arrangements; and

15. Novartis' systems, policies, processes, and procedures for ensuring that applicable Novartis policies and guidelines are followed during the analysis, initiation, and implementation of Arrangements and that the policies and guidelines are compliant with applicable legal requirements (including the Anti-Kickback Statute).

B. Arrangements Systems Review Report. The IRO shall prepare a report based upon each Arrangements Systems Review performed. The Arrangements Systems Review Report shall include the following information:

1. a description of the documentation (including policies) reviewed and personnel interviewed;

2. a detailed description of Novartis' systems, policies, processes, and procedures relating to the items identified in Section A.1–15, above;

3. findings and supporting rationale regarding weaknesses in Novartis' systems, policies, processes, and procedures relating to Arrangements described in Section A.1–15, above; and

4. recommendations to improve Novartis' systems, policies, processes, or procedures relating to Arrangements described in Section A.1–15, above.

C. Arrangements Transactions Review. For the first Reporting Period, the Arrangements Transactions Review shall consist of a review by the IRO of 3 selected Discount Arrangements and 15 selected FFS Arrangements (as reflected in 15 Task Orders) that were in existence, entered into, or renewed by Novartis during the first Reporting Period.

For the second and subsequent Reporting Periods, the IRO shall review a total of 18 Arrangements which shall be divided between Discount Arrangements and FFS Arrangements as specified by the OIG. Prior to the determination of the number of each type of Arrangement to be reviewed during the second and subsequent Reporting Periods, Novartis shall provide to the OIG the information specified below in the next paragraph within 60 days prior to the end of the applicable preceding Reporting Period.

The IRO shall select its sample of Arrangements for review in consultation with OIG after the provision of information about the Arrangements to the OIG. Novartis shall provide information to the OIG about: 1) the number of Arrangements in place during the Reporting Period; 2) the identity of the parties to each Arrangement; 3) the type of each Arrangement (*e.g.*, discount or service fee Arrangement); 4) a description of the services to be provided under each Arrangement; 5) the duration and value of each Arrangement; and 6) the Novartis Government Reimbursed Product to which each Arrangement relates.

The IRO's assessment with respect to each Arrangement that is subject to review (Reviewed Arrangement) shall include:

1. verifying that the Reviewed Arrangement is maintained in Novartis' centralized tracking system in a manner that permits the IRO to identify the parties to the Arrangement and the relevant terms of the Arrangement (*i.e.*, the services/data to be provided, the amount of compensation, the products at issue, the effective date, the expiration date, etc.);

2. verifying that the Reviewed Arrangement was subject to the applicable internal review and approval process and obtained the necessary approvals and whether such review and approval was appropriately documented;

3. verifying that the services and activities in the Reviewed Arrangement were evaluated and the contract approach (*i.e.,* discount or fee-based contracts) classified according to Novartis policies and procedures;

4. verifying that the remuneration (*e.g.,* discount or service fee) related to the Reviewed Arrangement is properly documented and that the amount of the compensation for services under a FFS Arrangement is supported by a sound fair market valuation methodology;

5. verifying that any Reviewed Arrangement which is a FFS Arrangement is supported by a valid and properly documented business need or business rationale;

6. verifying that: (a) the service and activity logs or other documents to be provided by a Specialty Pharmacy under a FFS Reviewed Arrangement reflecting activities and/or services provided by the Specialty Pharmacies are properly completed and are reviewed by Novartis, and (b) based on a review of the documents and related information, it appears that the parties to the Reviewed Arrangement are performing the activities and/or services required under the applicable Arrangement (if applicable);

7. to the extent that a Reviewed Arrangement involves any allocation of patients to specified Specialty Pharmacies, an identification of the quantities (*e.g.*, percentage of patients) involved in any allocation, and a legal analysis of the basis for the allocation;

8. verifying that any materials provided by Novartis to the Specialty Pharmacy or created by the Specialty Pharmacy at the direction of Novartis for use in connection with a Reviewed FFS Arrangement were approved through Novartis' material approval process (if applicable);

9. verifying that the Reviewed Arrangement satisfies the Arrangements Requirements of Section III.O.1.b of the CIA;

10. to the extent that a Specialty Pharmacy provides services under the terms of a Reviewed FFS Arrangement, including an FFS Arrangement with a medication therapy management program, assessing (based on the information set forth in the Arrangements Tracking System, supporting documentation about the Arrangement, and the IRO's review of Items 1-9 above) whether the services were provided in a manner that would not reasonably be expected to undermine or otherwise interfere with the clinical judgment of the patients' prescribing health care professionals;

11. to the extent that a Specialty Pharmacy provides services under the terms of a Reviewed FFS Arrangement, a legal analysis of whether (based on the information set forth in the Arrangements Tracking System, supporting documentation about the Arrangement, and the IRO's review of Items 1-10 above): (a) the provision of services could reasonably be expected to encourage patients to use, or health care professionals to prescribe, a Novartis Government Reimbursed product over any other medically-appropriate product or (b) the Arrangement appeared to involve the offering of a financial inducement by the Specialty Pharmacy to any health care professional to prescribe or switch patients to a Novartis Government Reimbursed Product; and

12. to the extent a Reviewed Arrangement was subject to an internal audit or review by Novartis, assessing the findings of Novartis' review as to whether the performance of the Specialty Pharmacy complied with the contractual terms of the Arrangements. If the internal Novartis review determined any instances of non-compliance, the IRO shall conduct an assessment of whether Novartis took any action in response to the findings of non-compliance and, if so, whether such action addressed the non-compliance.

D. Arrangements Transactions Review Report. The IRO shall prepare a report based on each Arrangements Transactions Review performed. The Arrangements Transactions Review Report shall include the following information:

1. *Review Methodology*

   a. Review Protocol: A narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for the sample reviewed.

   b. Sources of Data: A full description of the documentation and other information, if applicable, relied upon by the IRO in performing the Arrangements Transactions Review.

   c. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Arrangements selected as part of the Arrangements Transactions Review and Novartis shall furnish such documentation and materials to the IRO, prior to the IRO initiating its review of the Arrangements. If the IRO accepts any supplemental documentation or materials from Novartis after the IRO has completed its initial review of the Arrangements (Supplemental Materials), the IRO shall identify in the Arrangements Transactions Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Arrangements Transactions Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

2. *Review Findings*. The Arrangements Transactions Review Report shall include the IRO's findings with respect to each of the items set forth in Section C.1–12, above. In addition, the IRO shall identify in the Arrangements Transactions Review Report any Reviewed Arrangement(s) that a reasonable person would consider a probable violation of the Anti-Kickback Statute, along with the IRO's basis for reaching that conclusion. If the IRO concludes that none of the Reviewed Arrangements are probable violations, the IRO shall include a statement in the report reflecting this conclusion.