

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
UNITED THERAPEUTICS CORPORATION**

I. PREAMBLE

United Therapeutics Corporation (United Therapeutics) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, United Therapeutics is entering into a Settlement Agreement with the United States.

United Therapeutics represents that, prior to the Effective Date of the CIA (as defined below), United Therapeutics established a compliance program that includes, among other things, the appointment of a Compliance Officer, the development and dissemination of United Therapeutics' Code of Conduct and Business Ethics, the establishment of written policies and procedures, a Disclosure Program, screening measures for Ineligible Persons, review and disciplinary proceedings, auditing and monitoring, and regular training concerning United Therapeutics' Code of Conduct and Business Ethics and policies and procedures.

United Therapeutics shall continue the operation of its compliance program in accordance with the terms set forth below for the term of this CIA. United Therapeutics may modify its compliance program as it deems appropriate, but at a minimum, during the term of this CIA, it shall comply with the obligations set forth herein.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by United Therapeutics under this CIA shall be five years from the effective date of this CIA. The “Effective Date” shall be the date on which the final signatory of this CIA executes this CIA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a “Reporting Period.”

B. Sections VII, X, and XI shall expire no later than 120 days after OIG’s receipt of: (1) United Therapeutics’ final Annual Report; or (2) any additional materials submitted by United Therapeutics pursuant to OIG’s request, whichever is later.

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

1. “Covered Persons” includes:

- a. all owners of United Therapeutics who are natural persons (other than shareholders who: (i) have an ownership interest of less than 5% and (ii) acquired the ownership interest through public trading) and all officers and directors of United Therapeutics;
- b. all employees of United Therapeutics; and
- c. all contractors, subcontractors, agents, and other persons who perform any of the Contribution and Assistance Related Functions or Promotional Functions (as defined below) on behalf of United Therapeutics.

2. “Government Reimbursed Products” refers to all United Therapeutics products that are: (a) marketed or sold by United Therapeutics in the United States (or pursuant to contracts with the United States) and (b) reimbursed by Federal health care programs.

3. The term “Promotional Functions” includes: (a) the selling, detailing, marketing, advertising, promoting, or branding of Government Reimbursed Products; and (b) the preparation or external dissemination of promotional materials or

information about, or the provision of promotional services relating to, Government Reimbursed Products, including those functions relating to United Therapeutics' review and approval processes for promotional materials and any applicable review committee(s).

4. The term "Contribution and Assistance Related Functions" includes: all activities, systems, processes, and procedures relating to the following: (a) grants provided by United Therapeutics or any entity acting on behalf of United Therapeutics to any independent third-party patient assistance program (Independent Charity PAP); (b) charitable contributions provided by United Therapeutics or any entity acting on behalf of United Therapeutics to any Independent Charity PAP; (c) donations (in cash or in kind) to any Independent Charity PAP by United Therapeutics or any entity acting on behalf of United Therapeutics; (d) the operation of, or participation in, any patient assistance program by United Therapeutics or any entity acting on behalf of United Therapeutics.

5. The term "United Therapeutics Affiliate" shall mean any entity, other than United Therapeutics Corporation, that is owned or controlled directly or indirectly, by United Therapeutics Corporation and whose employees or contractors perform Contribution and Assistance Related Functions. All obligations set forth in Section III below shall apply to the Contribution and Assistance Related Functions performed by United Therapeutic Affiliates and all references to "United Therapeutics" in the defined terms set forth in this Section II shall mean United Therapeutics and United Therapeutics Affiliates. In addition, the notice requirements in Section IV and the certification obligations set forth in Section V.C. below shall apply to both United Therapeutics and any United Therapeutics Affiliate(s).

III. CORPORATE INTEGRITY OBLIGATIONS

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

A. Compliance Officer and Committee, Board of Directors, and Management Compliance Obligations.

1. *Compliance Officer.* Within 90 days after the Effective Date, United Therapeutics shall appoint a Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be an employee and a member of senior management of United Therapeutics; shall report directly to the

President of United Therapeutics; and shall not be, or be subordinate to, the General Counsel or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for United Therapeutics. The Compliance Officer shall be responsible for, without limitation:

- a. developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements;
- b. making periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of United Therapeutics and shall be authorized to report on such matters to the Board of Directors at any time. Written documentation of the Compliance Officer's reports to the Board of Directors shall be made available to OIG upon request; and
- c. monitoring the day-to-day compliance activities engaged in by United Therapeutics as well as for any reporting obligations created under this CIA.

Any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

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

2. *Compliance Committee.* Within 90 days after the Effective Date, United Therapeutics shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments). The Compliance Officer shall chair the Compliance Committee and the Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of United Therapeutics' risk areas and shall oversee monitoring of internal and external audits and investigations).

The Compliance Committee shall meet at least quarterly. The minutes of the Compliance Committee meetings shall be made available to OIG upon request.

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

3. *Board of Directors Compliance Obligations.* The Board of Directors (or a committee of the Board) of United Therapeutics (the Board) shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements and the obligations of this CIA. The Board must include independent (i.e., non-executive) members.

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

- a. meeting at least quarterly to review and oversee United Therapeutics' Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Committee;
- b. submitting to OIG a description of the documents and other materials it reviewed, as well as any additional steps taken, such as the engagement of an independent advisor or other third party resources, in its oversight of the compliance program and in support of making the resolution below during each Reporting Period; and
- c. for each Reporting Period of the CIA, adopting a resolution, signed by each individual member of the Board, summarizing its review and oversight of United Therapeutics' compliance with Federal health care program requirements and the obligations of this CIA.
- d. for the first Reporting Period of the CIA, the Board shall retain an individual or entity with expertise in compliance with Federal health care program requirements (Compliance Expert) to perform a review of the effectiveness of United Therapeutics' Compliance Program (Compliance Program

Review). The Compliance Expert shall create a work plan for the Compliance Program Review and prepare a written report about the Compliance Program Review. The written report (Compliance Program Review Report) shall include a description of the Compliance Program Review and any recommendations with respect to United Therapeutics' compliance program. The Board shall review the Compliance Program Review Report as part of its review and oversight of United Therapeutics' compliance program. A copy of the Compliance Program Review report shall be provided to OIG in each Annual Report submitted by United Therapeutics. In addition, copies of any materials provided to the Board by the Compliance Expert, along with minutes of any meetings between the Compliance Expert and the Board, shall be made available to OIG upon request.

At minimum, the resolution shall include the following language:

“The Board of Directors has made a reasonable inquiry into the operations of United Therapeutics' Compliance Program during the preceding twelve-month period including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, United Therapeutics has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the CIA.”

If the Board is unable to provide such a conclusion in the resolution, the Board shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program at United Therapeutics.

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

4. *Management Certifications:* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain United Therapeutics employees

(Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable United Therapeutics business unit is compliant with applicable Federal health care program requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: the Senior Vice President of Global Medical Affairs; the Vice President of Marketing; the Vice President of Sales; the Senior Vice President of Strategic Operations; and the Senior Vice President and Chief Compliance Officer. For each Reporting Period, each Certifying Employee shall sign a certification that states:

“I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department or functional area], an area under my supervision. My job responsibilities include ensuring compliance with regard to the _____ [insert name of the department or functional area] with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, and United Therapeutics policies, and I have taken steps to promote such compliance. To the best of my knowledge, the _____ [insert name of department or functional area] of United Therapeutics is in compliance with all applicable Federal health care program requirements and the obligations of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States.”

If any Certifying Employee is unable to provide such a certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above.

Within 90 days after the Effective Date, United Therapeutics shall develop and implement a written process for Certifying Employees to follow for the purpose of completing the certification required by this section (e.g., reports that must be reviewed, assessments that must be completed, sub-certifications that must be obtained, etc. prior to the Certifying Employee making the required certification).

B. Written Standards.

Within 90 days after the Effective Date, United Therapeutics shall implement written policies and procedures regarding the operation of its compliance program, including the compliance program requirements outlined in this CIA and United Therapeutics' compliance with Federal health care program requirements (Policies and

Procedures). Throughout the term of this CIA, United Therapeutics shall enforce its Policies and Procedures and shall make such compliance an element in evaluating the performance of all employees. The Policies and Procedures shall be made available to all Covered Persons. At a minimum, the Policies and Procedures shall address the following:

- a. appropriate ways to conduct Contribution and Assistance Related Functions in compliance with: (i) all applicable Federal healthcare program requirements, including but not limited to, the Federal Anti-Kickback Statute (codified at 42 U.S.C. § 1320a-7b(b)) and the False Claims Act;
- b. arrangements and interactions with (including donations to and sponsorship of) independent third-party patient assistance programs (Independent Charity PAPs). These Policies and Procedures shall be designed to ensure that United Therapeutics' arrangements and interactions comply with all applicable Federal health care program requirements. The Policies and Procedures shall also be designed to ensure that United Therapeutics' arrangements and interactions (including donations and sponsorship) comply with all guidance issued by OIG relating to the support and funding of patient assistance programs, including but not limited to, the OIG's Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623 (Nov. 22, 2005) and OIG's Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31120 (May 30, 2014);
- c. the operation of, or participation in, any patient assistance program by United Therapeutics or any entity acting on behalf of United Therapeutics. These Policies and Procedures shall be designed to ensure that United Therapeutics' operation of or in participation in such programs complies with all applicable Federal health care program requirements. The Policies and Procedures shall also be designed to ensure that United Therapeutics' operation of or participation in any such patient assistance program complies with all guidance

issued by OIG relating to assistance provided to patients by pharmaceutical manufacturers to reduce or eliminate the cost of copayments for drugs, including but not limited to, the OIG's Special Advisory Bulletin on Pharmaceutical Manufacturer Copayment Coupons (Sept. 2014);

- d. the materials and information that may be distributed by appropriate United Therapeutics personnel about Independent Charity PAPs or Contribution and Assistance Related Functions and the manner in, and circumstances under, which appropriate United Therapeutics personnel may respond to requests for information about Independent Charity PAPs or Contribution and Assistance Related Functions; and
- e. appropriate ways to conduct Promotional Functions in compliance with all: (i) applicable Federal healthcare program requirements, including but not limited to, the Federal Anti-Kickback Statute (codified at 42 U.S.C. § 1320a-7b(b)) and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733) and (ii) applicable Food and Drug Administration (FDA) requirements.

At least annually (and more frequently, if appropriate), United Therapeutics shall assess and update, as necessary, the Policies and Procedures. Any new or revised Policies and Procedures shall be made available to all Covered Persons.

All Policies and Procedures shall be made available to OIG upon request.

C. Training and Education.

1. *Training Plan.* Within 90 days after the Effective Date, United Therapeutics shall develop a written plan (Training Plan) that outlines the steps United Therapeutics will take to ensure that: (a) all Covered Persons receive at least annual training regarding United Therapeutics' CIA requirements and compliance program; (b) all Covered Persons who engage in or supervise Covered Persons who engage in Contribution and Assistance Related Functions receive at least annual training regarding: (i) all applicable Federal health care program requirements relating to Contribution and Assistance Related Functions and (ii) all United Therapeutics Policies and Procedures

and other requirements applicable to Contribution and Assistance Related Functions; and (c) all Covered Persons who engage in or supervise Covered Persons who engage in Promotional Functions receive at least annual training regarding (i) all applicable Federal health care program and FDA requirements relating to Promotional Functions and (ii) all United Therapeutics Policies and Procedures and other requirements applicable to Promotional Functions.

The Training Plan shall include information regarding the following: training topics, categories of Covered Persons required to attend each training session, length of the training session(s), schedule for training, and format of the training. United Therapeutics shall furnish training to its Covered Persons pursuant to the Training Plan during each Reporting Period.

2. *Board Member Training.* Within 120 days after the Effective Date, United Therapeutics shall provide at least two hours of training to each member of the Board of Directors. This training shall address the corporate governance responsibilities of board members, and the responsibilities of board members with respect to review and oversight of the compliance program. Specifically, the training shall address the unique responsibilities of health care Board members, including the risks, oversight areas, and strategic approaches to conducting oversight of a health care entity. This training may be conducted by an outside compliance expert hired by the Board and should include a discussion of OIG's guidance on Board member responsibilities.

New members of the Board of Directors shall receive the Board Member Training described above within 30 days after becoming a Board member or within 90 days after the Effective Date, whichever is later.

3. *Training Records.* United Therapeutics shall make available to OIG, upon request, training materials and records verifying that Covered Persons and Board members have timely received the training required under this section.

D. Risk Assessment and Mitigation Process.

Within 120 days after the Effective Date, United Therapeutics shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with each of United Therapeutics' Government Reimbursed Products and with applicable Federal health care program requirements. The risk assessment and internal review process shall require compliance, legal, and department

leaders, at least annually, to: (1) identify and prioritize risks associated with each Government Reimbursed Product, including risks associated with the sales, marketing, and promotion of such products and risks associated with United Therapeutics' operation of any patient assistance program and the company's arrangements and interactions with any Independent Charity PAPs, (2) develop internal audit work plans related to the identified risk areas, (3) implement the internal audit work plans, (4) develop corrective action plans in response to the results of any internal audits performed, and (5) track the implementation of the corrective action plans in order to assess the effectiveness of such plans. United Therapeutics shall maintain the risk assessment and internal review process for the term of the CIA.

E. Review Procedures.

1. *General Description.*

- a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, United Therapeutics shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform the reviews listed in this Section III.E. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.
- b. *Retention of Records.* The IRO and United Therapeutics shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and United Therapeutics) related to the reviews.

2. *System, Transaction, and Additional Items Reviews.* As set forth more fully in Appendix B, the IRO Reviews shall consist of two components: Systems Reviews and Transactions Reviews. The Systems Reviews shall assess United Therapeutics' systems, processes, policies, and procedures relating to the Contribution and Assistance Related Functions. If there are no material changes in United Therapeutics' relevant systems, processes, policies, and procedures, the Systems Reviews shall be performed for the first and fourth Reporting Periods. If United Therapeutics materially changes its relevant systems, processes, policies, and procedures, the IRO shall

perform a Systems Review for the Reporting Period in which such changes were made in addition to conducting the Systems Review for the first and fourth Reporting Periods, as set forth more fully in Appendix B.

The Transactions Reviews shall be performed annually and shall cover each of the five Reporting Periods. The Transactions Reviews shall assess Contribution and Assistance Related Functions and may assess Promotional Functions. The IRO(s) shall perform all components of each annual Transaction Review. As set forth more fully in Appendix B, the Transactions Review shall include several components.

In addition, as set forth in Appendix B, as part of the Transactions Reviews, OIG may at its discretion require a review of up to three additional areas or practices of United Therapeutics identified by OIG in its discretion (hereafter "Additional Items"). For purposes of identifying the Additional Items to be included in the Transactions Review for a particular Reporting Period, OIG will consult with United Therapeutics and may consider internal audit and monitoring work conducted by United Therapeutics, the Government Reimbursed Product portfolio, the nature and scope of United Therapeutics' promotional practices and arrangements with HCPs and HCIs, and other information known to it.

As set forth more fully in Appendix B, United Therapeutics may propose to OIG that its internal audit(s) be partially substituted for one or more of the Additional Items that would otherwise be reviewed by the IRO as part of the Transactions Review. OIG retains sole discretion over whether, and in what manner, to allow United Therapeutics' internal audit and monitoring work to be substituted for any portion of the Additional Items review conducted by the IRO.

OIG shall notify United Therapeutics of the nature and scope of the IRO review for each of the Additional Items not later than 120 days prior to the end of each Reporting Period. Prior to undertaking the review of the Additional Items, the IRO and/or United Therapeutics shall submit an audit work plan to OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by OIG.

3. *IRO Review Reports.* The IRO shall prepare a report based upon each IRO Review performed (IRO Review Report). Information to be included in the IRO Review Report is described in Appendix A and Appendix B.

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to United Therapeutics a certification that the IRO has: (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.E; and (b) concluded that it is, in fact, independent and objective in accordance with the requirements specified in Appendix A. The IRO's certification shall include a summary of current and prior engagements between United Therapeutics and IRO.

F. Disclosure Program.

Within 90 days after the Effective Date, United Therapeutics shall establish a Disclosure Program that includes 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 United Therapeutics' policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. United Therapeutics shall appropriately publicize the existence of the Disclosure Program and the disclosure mechanism (e.g., via periodic e-mails to employees, or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. The Disclosure Program also shall include a requirement that all of United Therapeutics' Covered Persons shall be expected to report suspected violations of any Federal health care program requirements to the Compliance Officer or other appropriate individual designated by United Therapeutics. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that it obtains all necessary information to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, United Therapeutics shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a disclosure log and shall record each disclosure in the disclosure log within two business days of receipt of the disclosure. The disclosure log shall include a summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews.

G. Ineligible Persons.

1. *Definitions.* For purposes of this CIA:

- a. an “Ineligible Person” shall include an individual or entity who:
 - i. is currently excluded from participation in the Federal health care programs; or
 - ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded.
- b. “Exclusion List” means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at <http://www.oig.hhs.gov>).

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

- a. United Therapeutics shall screen all prospective Covered Persons against the Exclusion List prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.
- b. United Therapeutics shall screen all current Covered Persons against the Exclusion List within 90 days after the Effective Date and on an annual basis thereafter.

- c. United Therapeutics shall maintain a policy requiring all Covered Persons to disclose immediately if they become an Ineligible Person.

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

3. *Removal Requirement.* If United Therapeutics has actual notice that a Covered Person has become an Ineligible Person, United Therapeutics shall remove such Covered Person from responsibility for, or involvement with, United Therapeutics' business operations related to the Federal health care program(s) from which such Covered Person has been excluded and shall remove such Covered Person from any position for which the Covered Person's compensation is paid in whole or part, directly or indirectly, by any Federal health care program(s) from which the Covered Person has been excluded at least until such time as the Covered Person is reinstated into participation in such Federal health care program(s).

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

H. Notification of Government Investigation or Legal Proceeding.

Within 30 days after discovery, United Therapeutics shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to United Therapeutics conducted or brought by a governmental entity or its agents involving an allegation that United Therapeutics has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating

or prosecuting agency, and the status of such investigation or legal proceeding. United Therapeutics shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceeding, if any.

I. Reportable Events.

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

- a. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;
- b. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or
- c. the filing of a bankruptcy petition by United Therapeutics.

A Reportable Event may be the result of an isolated event or a series of occurrences.

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

3. *Reportable Events under Section III.I.1.a.* For Reportable Events under Section III.I.1.a, the report to OIG shall include:

- a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event, the period during which the conduct occurred, and the names of entities and individuals believed to be implicated, including an explanation of their roles in the Reportable Event;

- b. a statement of the Federal criminal, civil or administrative laws probably violated by the Reportable Event;
- c. the Federal health care programs affected by the Reportable Event; and
- d. a description of United Therapeutics' actions taken to correct the Reportable Event and prevent it from recurring.

4. *Reportable Events under Section III.I.1.b.* For Reportable Events under Section III.I.1.b, the report to OIG shall include:

- a. the identity of the Ineligible Person and the job duties performed by that individual;
- b. the dates of the Ineligible Persons employment or contractual relationship;
- c. a description of the Exclusion List screening that United Therapeutics completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the Ineligible Persons screening process that led to the hiring or contracting with the Ineligible Person;
- d. a description of how the Ineligible Person was identified; and
- e. a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

5. *Reportable Events under Section III.I.1.c.* For Reportable Events under Section III.I.1.d, the report to OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program requirements implicated.

J. Independent Charity Patient Assistance Program Activities

To the extent that United Therapeutics makes monetary donations to Independent Charity PAPs, it shall comply with the provisions of this Section III.J.

1. *Role and Responsibilities of the Independent Charity Interaction Team.* Within 90 days after the Effective Date, United Therapeutics shall vest sole responsibility and authority for budgeting and other donation related activities relating to Independent Charity PAPs in its existing Grants Review Committee and Compliance Officer (referred to herein as the “Independent Charity Interaction Team”).

The Independent Charity Interaction Team shall operate separately and independently from United Therapeutics’ commercial organization. For purposes of this CIA, the “commercial organization” shall be defined to include the sales, marketing, and similar commercial business units of United Therapeutics. United Therapeutics’ commercial organization shall have no involvement in, or influence over, the review, approval, or implementation of any budget or other decisions or activities relating to donations to Independent Charity PAPs.

Sole responsibility and authority for communicating with Independent Charity PAPs regarding United Therapeutics’ donations to such PAPs shall be vested in the Independent Charity Interaction Team. United Therapeutics’ commercial organization shall not communicate with, influence, or be involved in communications with, or receive information from Independent Charity PAPs.

2. *Budgeting Process.* Within 90 days after the Effective Date, United Therapeutics’ Independent Interaction Team shall establish a budget process to be followed for United Therapeutics’ donations to Independent Charity PAPs. The Independent Charity Interaction Team shall propose an annual budget for donations to Independent Charity PAPs based on objective criteria in accordance with general guidelines approved by the legal department with input from the compliance department. The commercial organization shall have no involvement in the budget process, and the budget to be used for donations to Independent Charity PAPs shall not be based on monies allocated to the Independent Charity Interaction Team from the commercial organization.

United Therapeutics shall approve the annual budget for donations to Independent Charity PAPs at a level within the organization above the commercial organization (e.g.,

at the executive level). After the annual budget is approved, the Independent Charity Interaction Team shall have sole responsibility for allocating the approved budget across donations to Independent Charity PAPs and to any disease state fund established by the Independent Charity PAP.

The Independent Charity Interaction Team shall have sole responsibility for assessing requests for additional or supplemental funding from Independent Charity PAPs outside of the annual budget. Such requests shall be assessed against standardized, objective criteria established by the Independent Charity Interaction Team. United Therapeutics legal and compliance personnel shall also be involved in the review and approval of requests for additional/supplemental funding. The purpose of this review shall be to ensure that any supplemental funding to the Independent Charity PAP is provided in accordance with applicable Federal health care program requirements, OIG guidance, and United Therapeutics Policies and Procedures.

3. *Criteria Relating to Donations to Independent Charity PAPs.* Within 90 days after the Effective Date, the Independent Charity Interaction Team (with input from the legal department and compliance departments) shall establish standardized, objective written criteria that govern donations to Independent Charity PAPs and any specific disease state funds of such PAPs. The criteria shall be designed to ensure that the Independent Charity PAP does not function as a conduit for payments or other benefits from United Therapeutics to patients and does not impermissibly influence patients' drug choices.

United Therapeutics' Independent Charity Interaction Team shall gather information about Independent Charity PAPs and their disease funds in a manner that does not exert or attempt to exert any direct or indirect control over the entity operating the PAP or over its assistance program. United Therapeutics shall not influence or attempt to influence, directly or indirectly, the identification, delineation, establishment, or modification of, or the parameters relating to, any disease fund by the Independent Charity PAP.

Personnel from United Therapeutics' legal and compliance departments shall review all proposed donations and arrangements between United Therapeutics and any Independent Charity PAP. United Therapeutics shall not make donations to any Independent Charity Group or to any disease state fund of an Independent Charity PAP until after the legal and compliance review has occurred.

United Therapeutics agrees that it will donate to an Independent Charity PAP only if the following criteria are satisfied:

- a. United Therapeutics does not and shall not exert (directly or through any affiliate) any influence or control over the identification, delineation, establishment, or modification of any specific disease funds operated by the Independent Charity PAP. Among other things, United Therapeutics has not made and shall not make (directly or through any affiliate) suggestions or requests to the Independent Charity PAP about the identification, delineation, establishment, or modification of disease state funds;
- b. United Therapeutics does not and shall not exert (directly or through any affiliate) any direct or indirect influence or control over the Independent Charity PAP's process or criteria for determining eligibility of patients who qualify for its assistance program;
- c. United Therapeutics does not and shall not solicit or receive (directly or indirectly through third parties) any data or information from the Independent Charity PAP that would enable it to correlate the amount or frequency of its donations with support for United Therapeutics' products or services; and
- d. United Therapeutics does not and shall not provide donations for a disease state fund that covers only a single product or that covers only United Therapeutics' products.

United Therapeutics shall continue the Independent Charity PAP processes described above (or equivalent processes) throughout the term of the CIA, and shall notify OIG in writing at least 60 days prior to the implementation of any modifications to the process described above.

United Therapeutics shall include a summary of the Independent Charity PAP processes, policies, and procedures outlined in this section III.J as part of each Annual Report.

IV. SUCCESSOR LIABILITY

In the event that, after the Effective Date, United Therapeutics proposes to (a) sell any or all of its United States-based business, business units or departments (whether through a sale of assets, sale of stock or other type of transaction) that are subject to this CIA; or (b) purchases or establishes a new United States-based business, business unit or department with activities related to Government Reimbursed Products, the CIA shall be binding on the purchaser of any business, business unit or department and any new business, business unit or department (and all Covered Persons at each new business, business unit or department) shall be subject to the applicable requirements of this CIA, unless otherwise determined and agreed to in writing by OIG.

If, in advance of a proposed sale or a proposed purchase, United Therapeutics wishes to obtain a determination by OIG that the proposed purchaser or the proposed acquisition will not be subject to the requirements of the CIA, United Therapeutics must notify OIG in writing of the proposed sale or purchase at least 30 days in advance. This notification shall include a description of the business, business unit, or department to be sold or purchased, a brief description of the terms of the transaction and, in the case of a proposed sale, the name and contact information of the prospective purchaser.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report.

Within 120 days after the Effective Date, United Therapeutics shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A.1, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
2. the names and positions of the members of the Compliance Committee required by Section III.A.2;
3. the names of the members of the Board of Directors who are responsible for satisfying the compliance obligations described in Section III.A.3;

4. the identity and credentials of the Compliance Expert required by Section III.A.3;
5. the names and positions of the Certifying Employees required by Section III.A.4;
6. a list of the Policies and Procedures required by Section III.B.3;
7. the Training Plan required by Section III.C.1 and a description of the Board of Directors training required by Section III.C.2 (including a summary of the topics covered, the length of the training and when the training was provided);
8. a description of the risk assessment and internal review process required by Section III.D;
9. 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 A; and (d) a certification from the IRO regarding its professional independence and objectivity with respect to United Therapeutics;
10. a description of the Disclosure Program required by Section III.F;
11. a description of the Ineligible Persons screening and removal process required by Section III.G.;
12. a list of all of United Therapeutics' locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers;
13. a description of United Therapeutics' corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and
14. the certifications required by Section V.C.

B. Annual Reports.

United Therapeutics shall submit to OIG a report on its compliance with the CIA requirements for each of the five Reporting Periods (Annual Report). Except as otherwise specified, each Annual Report shall include, at a minimum, the following information:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer; a current list of the Compliance Committee members; a current list of the Board members who are responsible for satisfying the Board of Directors compliance obligations; and a current list of the Certifying Employees, along with any changes made during the Reporting Period to the Compliance Committee, Board of Directors, and Certifying Employees;
2. the dates of each report made by the Compliance Officer to the Board (written documentation of such reports shall be made available upon request);
3. the Board resolution required by Section III.A.3 and a description of the documents and other materials required by the Board, as well as any additional steps taken, in its oversight of the compliance program and in support of making the resolution;
4. for the first Reporting Period, a copy of the Compliance Expert Review Report generated by the Compliance Expert required by Section III.A.3;
5. a list of any new or revised Policies and Procedures required by Section III.B developed during the Reporting Period;
6. a description of any changes to United Therapeutics' Training Plan developed pursuant to Section III.C and a summary of any Board of Directors training provided during the Reporting Period;
7. a summary of changes to the risk assessment and internal review process required by Section III.D, including the reasons for such changes;
8. a summary of the following components of the risk assessment and internal review process during the Reporting Period: (a) work plans developed; (b) internal audits performed; (c) corrective action plans developed in response to internal audits; and (d) steps taken to track the implementation of the corrective action plans.

Copies of any work plans, internal audit reports, and corrective action plans shall be made available to OIG upon request;

9. a complete copy of all reports prepared pursuant to Section III.E and Appendix B and United Therapeutics' response to the reports, along with corrective action plan(s) related to any issues raised by the reports;

10. a certification from the IRO regarding its professional independence and objectivity with respect to United Therapeutics;

11. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs or Government Reimbursed Products, including at least the following information: a description of the disclosure, the date the disclosure was received, the resolution of the disclosure, and the date the disclosure was resolved (if applicable). The complete disclosure log shall be made available to OIG upon request;

12. a description of any changes to the Ineligible Persons screening and removal process required by Section III.G, including the reasons for such changes;

13. 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;

14. a summary of Reportable Events (as defined in Section III.I) identified during the Reporting Period;

15. a summary of the Independent Charity PAP processes, policies, and procedures outlined in section III.J;

16. a description of all changes to the most recently provided list of United Therapeutics' locations (including addresses) as required by Section V.A.12; and

17. the certifications required by Section V.C.

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

no later than the anniversary date of the due date of the first Annual Report.

C. Certifications.

1. *Certifying Employees.* In each Annual Report, United Therapeutics shall include the certifications of Certifying Employees as required by Section III.A.4;

2. *Compliance Officer and President.* The Implementation Report and each Annual Report shall include a certification by the Compliance Officer and President that:

- a. to the best of his or her knowledge, except as otherwise described in the report, United Therapeutics is in compliance with the requirements of this CIA;
- b. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful;
- c. for each disease fund of an Independent Charity PAP to which United Therapeutics made a donation during the Reporting Period, the facts and circumstances relating to the donation were reviewed by competent legal counsel and were found to be in compliance with all applicable Federal health care program requirements, OIG guidance, and United Therapeutics' policies and procedures (including those outlined in Section III.J); and
- d. for each patient assistance program that United Therapeutics or any entity acting on behalf of United Therapeutics operates or participates in (e.g., through cash or in-kind donations), the facts and circumstances relating to the program were reviewed by competent legal counsel and were found to be in compliance with all applicable Federal health care program requirements, OIG guidance, and United Therapeutics' policies and procedures.

D. Designation of Information.

United Therapeutics shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. United Therapeutics shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: 202.619.2078
Facsimile: 202.205.0604

United Therapeutics:

Rebecca McCarty
Senior Vice President
Chief Compliance Officer
1735 Connecticut Ave, N.W.
Washington, DC 20009
Telephone: 202.483.7000
Facsimile: 202.518.8477

Unless otherwise specified, all notifications and reports required by this CIA may be made by electronic mail, overnight mail, hand delivery, or other means, provided that

there is proof that such notification was received. Upon request by OIG, United Therapeutics may be required to provide OIG with an electronic copy of each notification or report required by this CIA in addition to a paper copy.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine and/or request copies of or copy United Therapeutics' books, records, and other documents and supporting materials and/or conduct on-site reviews of any of United Therapeutics' locations for the purpose of verifying and evaluating: (a) United Therapeutics' compliance with the terms of this CIA and (b) United Therapeutics' compliance with Federal health care program requirements. The documentation described above shall be made available by United Therapeutics to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of United Therapeutics' owners, employees, contractors and directors 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. United Therapeutics shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. United Therapeutics' owners, employees, contractors and directors may elect to be interviewed with or without a representative of United Therapeutics present.

VIII. DOCUMENT AND RECORD RETENTION

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

IX. DISCLOSURES

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

C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

United Therapeutics is expected to fully and timely comply with all of its CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, United Therapeutics and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as “Stipulated Penalties”) in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day United Therapeutics fails to establish, implement or comply with any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. the Board of Directors compliance obligations and the engagement of a Compliance Expert, the performance of a Compliance Program Review and the preparation of a Compliance Program Review Report;
- d. the management certification obligations;
- e. written Policies and Procedures;
- f. training and education of Covered Persons and Board Members;
- g. a risk assessment and internal review process;
- h. a Disclosure Program;

- i. Ineligible Persons screening and removal requirements;
- j. notification of Government investigations or legal proceedings;
- k. reporting of Reportable Events; and
- l. the Independent Charity PAP processes, policies, and procedures required by Section III.J.

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 United Therapeutics fails to engage and use an IRO as required by Section III.E, Appendix A, or Appendix B.

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 United Therapeutics fails to submit a complete Implementation Report, Annual Report or any certification to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day United Therapeutics fails to submit any IRO Review report in accordance with the requirements of Section III.E and Appendix B.

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

6. A Stipulated Penalty of \$50,000 for each false certification submitted by or on behalf of United Therapeutics as part of its Implementation Report, any Annual Report, additional documentation to a report (as requested by OIG), or otherwise required by this CIA.

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

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

B. Timely Written Requests for Extensions. United Therapeutics 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 United Therapeutics fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three days after United Therapeutics 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 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 United Therapeutics has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify United Therapeutics of: (a) United Therapeutics' failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, United Therapeutics shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event United Therapeutics elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until United Therapeutics cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

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

D. Exclusion for Material Breach of this CIA.

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

- a. repeated violations or a flagrant violation of any of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- b. a failure by United Therapeutics to report a Reportable Event and take corrective action as required in Section III.I;
- c. a failure to engage and use an IRO in accordance with Section III.E, Appendix A, or Appendix B; or
- d. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by United Therapeutics constitutes an independent basis for United Therapeutics' exclusion from participation in the Federal health care programs. The length of the exclusion shall be in OIG's discretion, but not more than five years per material breach. Upon a determination by OIG that United Therapeutics has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify United Therapeutics of: (a) United Therapeutics' material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* United Therapeutics shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

- a. the alleged material breach has been cured; or
- b. the alleged material breach cannot be cured within the 30 day period, but that: (i) United Therapeutics has begun to take action to cure the material breach; (ii) United Therapeutics is pursuing such action with due diligence; and (iii) United Therapeutics has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, United Therapeutics fails to satisfy the requirements of Section X.D.3, OIG may exclude United Therapeutics from participation in the Federal health care programs. OIG shall notify United Therapeutics in writing of its determination to exclude United Therapeutics (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of United Therapeutics' receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, United Therapeutics may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to United Therapeutics of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, United Therapeutics shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving

exclusion shall be made within 25 days after receipt of the Exclusion Letter. The procedures relating to the filing of a request for a hearing can be found at <http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.html>.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether United Therapeutics was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. United Therapeutics shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders United Therapeutics to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless United Therapeutics requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be whether United Therapeutics was in material breach of this CIA and, if so, whether:

- a. United Therapeutics cured such breach within 30 days of its receipt of the Notice of Material Breach; or
- b. the alleged material breach could not have been cured within the 30 day period, but that, during the 30 day period following United Therapeutics' receipt of the Notice of Material Breach: (i) United Therapeutics had begun to take action to cure the material breach within that period; (ii) United Therapeutics pursued such action with due diligence; and (iii) United Therapeutics provided to OIG within that period a reasonable timetable for curing the material breach.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for United Therapeutics, only after a DAB

decision in favor of OIG. United Therapeutics' election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude United Therapeutics upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that United Therapeutics may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. United Therapeutics shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of United Therapeutics, United Therapeutics shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

XI. EFFECTIVE AND BINDING AGREEMENT

United Therapeutics and OIG agree as follows:

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

B. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA.

C. All requirements and remedies set forth in this CIA are in addition to and do not affect (1) United Therapeutics' responsibility to follow all applicable Federal health care program requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable Federal health care program requirements.

D. The undersigned United Therapeutics signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacity and that they are authorized to execute this CIA.

E. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Electronically-transmitted signatures shall constitute acceptable, binding signatures for purposes of this CIA.

ON BEHALF OF UNITED THERAPEUTICS CORPORATION

/Rebecca McCarty/

REBECCA MCCARTY *U* —
Chief Compliance Officer
United Therapeutics Corporation

12/14/2017
DATE

/William Sarraille/

—
AMY DELINE
ROBERT KEELING
WILLIAM SARRAILLE
Sidley Austin LLP
Counsel for United Therapeutics Corporation

12/14/17
DATE

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

/Lisa M. Re/

LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

12/18/17

DATE

/Mary E. Riordan/

MARY E. RIORDAN
Senior Counsel
Office of Counsel to the Inspector General

12/18/17

DATE

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

1. United Therapeutics shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information identified in Section V.A.9 of the CIA or any additional information submitted by United Therapeutics in response to a request by OIG, whichever is later, OIG will notify United Therapeutics if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, United Therapeutics may continue to engage the IRO.

2. If United Therapeutics engages a new IRO during the term of the CIA, that IRO must also meet the requirements of this Appendix. If a new IRO is engaged, United Therapeutics shall submit the information identified in Section V.A.9 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 United Therapeutics at the request of OIG, whichever is later, OIG will notify United Therapeutics if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, United Therapeutics may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the IRO Reviews who have expertise in the pharmaceutical industry and in Federal health care program requirements (including but not limited to, the Federal Anti-Kickback Statute and the False Claims Act) applicable to the reviews being conducted;

2. assign individuals to design and select samples for the Transactions Reviews who are knowledgeable about the appropriate statistical sampling techniques; and

3. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities

The IRO shall:

1. perform each component of the IRO Review in accordance with the specific requirements of the CIA;
2. follow all applicable Federal health care program requirements in making assessments in the IRO Review;
3. request clarification from the appropriate authority (e.g., CMS), if in doubt of the application of a particular Federal health care program requirement;
4. respond to all OIG inquiries in a prompt, objective, and factual manner; and
5. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. IRO Independence and Objectivity

The IRO must perform the IRO 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. IRO Removal/Termination

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

2. *OIG Removal of IRO.* In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify United Therapeutics in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. United Therapeutics shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's qualifications, independence or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by United Therapeutics regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify

United Therapeutics in writing that United Therapeutics shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. United Therapeutics must engage a new IRO within 60 days of its receipt of OIG's written notice. The final determination as to whether or not to require United Therapeutics to engage a new IRO shall be made at the sole discretion of OIG.

CIA with United Therapeutics Corporation
Appendix B

I. IRO Engagement, General Description

As specified more fully below, United Therapeutics shall retain an Independent Review Organization (IRO) to perform engagements to assist United Therapeutics in assessing and evaluating its systems, processes, policies, and procedures related to Contribution and Assistance Related Functions and, potentially, Promotional Functions, as defined in the CIA (IRO Reviews). The IRO Reviews shall consist of two components - a systems review (Systems Review) and a transactions review (Transactions Review) as described more fully below. United Therapeutics may engage, at its discretion, a single entity to perform both components of the IRO Reviews provided that the entity has the necessary expertise and capabilities to perform both.

If there are no material changes in United Therapeutics' systems, processes, policies, and procedures relating to Contribution and Assistance Related Functions, the IRO shall perform the Systems Review for the first and fourth Reporting Periods. If United Therapeutics materially changes its systems, processes, policies, and procedures relating to Contribution and Assistance Related Functions, the IRO shall perform a Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Review as set forth above. The additional Systems Review(s) shall consist of: 1) an identification of the material changes; 2) an assessment of whether other systems, processes, policies, and procedures previously reported did not materially change; and 3) a review of the systems, processes, policies, and procedures that materially changed. The IRO shall conduct the Transactions Review for each Reporting Period of the CIA.

II. IRO Systems Review

The Systems Review shall be a review of United Therapeutics' systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to select Contribution and Assistance Related Functions. Where practical, United Therapeutics personnel may compile documentation, schedule and organize interviews, and undertake other efforts to assist the IRO in performing the Systems Review. The IRO is not required to undertake a de novo review of the information gathered or activities undertaken by United Therapeutics pursuant to the preceding sentence.

More specifically, the IRO shall review United Therapeutics' systems, processes, policies, and procedures associated with the following (hereafter "Reviewed Policies and Procedures"):

- 1) United Therapeutics' systems, policies, processes, and procedures relating to arrangements and interactions with (including donations to and sponsorship of) independent third-party patient assistance programs (Independent Charity PAPs).

This review shall include an assessment of the following:

- a. United Therapeutics' organizational structure as it relates to arrangements and interactions with Independent Charity PAPS, including:
 - i. the identification of those individuals, departments, or groups within United Therapeutics (e.g., the Compliance Officer, the Grants Committee, legal, compliance, medical affairs, executive level officers) that have responsibility for, or involvement with, such arrangements and interactions;
 - ii. the respective scope and nature of the responsibilities of each individual, department, or group with responsibility for, or involvement with, arrangements and interactions with Independent Charity PAPs;
 - iii. the identification of those individuals, departments, or groups within United Therapeutics (e.g., the commercial organization) that are precluded from involvement with arrangements and interactions with Independent Charity PAPs; and
 - iv. the manner by which the separation of Independent Charity PAP-related responsibilities from the commercial organization is enforced.
- b. United Therapeutics' written policies and procedures as they relate to arrangements and interactions with Independent Charity PAPs, including:
 - i. the criteria governing whether and under what circumstances United Therapeutics would donate to an Independent Charity PAP or any specific disease state fund of such a PAP;
 - ii. communications (including any limitations on such communications) between any representatives of United Therapeutics and any Independent Charity PAP (including the identity of individuals authorized to engage in such communications, the circumstances of such communications, and the subject matter of such communications including the exchange of any data);
 - iii. communications (including any limitations on such communications) between those individuals, departments, or groups

- within United Therapeutics with responsibility for Independent Charity PAPs and the commercial organization of United Therapeutics (including the identity of individuals authorized to engage in such communications, the circumstances of such communications, and the subject matter of such communications); and
- iv. communications (including any limitations on such communications) between representatives of United Therapeutics and health care providers or patients regarding assistance available through any Independent Charity PAP.
 - c. United Therapeutics' policies and practices as they relate to the budgeting process applicable to donations to Independent Charity PAPs as outlined in Section III.J.2, including as it relates to initial or annual donation amounts and any supplemental amounts;
 - d. United Therapeutics' policies and practices as they relate to the process by which decisions about the following are made and approved: i) whether to donate (or continue to donate) to a particular Independent Charity PAP; and ii) the amount of the donation (including any initial or annual amount and any supplemental amount);
 - e. United Therapeutics' policies and practices as they relate to donations made by United Therapeutics to any Independent Charity PAPs as referenced in Section III.J.3, including the internal review process followed in connection with any donations to Independent Charity PAPs; and
 - f. United Therapeutics' policies and practices as they relate to information provided, directly or indirectly, to the public about the availability of patient assistance for United Therapeutics' products.
- 2) United Therapeutics' systems, policies, processes, and procedures relating to any patient assistance program that was formed or is funded, controlled, or operated (directly or indirectly) by United Therapeutics or any person or entity acting on behalf of (or affiliated with) United Therapeutics (including, but not limited to, its employees, agents, officers, shareholders, or contractors). This shall include any programs designed to provide free product or to provide other assistance (e.g., coupons) to patients to reduce or eliminate the cost of copayments for drugs. These programs shall be collectively referred to as "Pharmaceutical Manufacturer PAPs".

This review shall include an assessment of the following:

- a. United Therapeutics' organizational structure as it relates to Pharmaceutical Manufacturer PAPs, including:
 - i. the identification of those individuals, departments, or groups within United Therapeutics that have responsibility for, or involvement with Pharmaceutical Manufacturer PAPs; and
 - ii. the respective scope and nature of the responsibilities of each individual, department, or group with responsibility for, or involvement with, Pharmaceutical Manufacturer PAPs.

- b. United Therapeutics' written policies and procedures as they relate to Pharmaceutical Manufacturer PAPs, including:
 - i. the nature and amounts (or value) of the assistance provided to patients under each of the Pharmaceutical Manufacturer PAPs;
 - ii. the eligibility criteria governing whether and under what circumstances United Therapeutics provides assistance to patients under each of the Pharmaceutical Manufacturer PAPs;
 - iii. United Therapeutics' external communications about the Pharmaceutical Manufacturer PAPs;
 - iv. the maintenance of records regarding free product and other assistance provided to or through Pharmaceutical Manufacturer PAPs;
 - v. ensuring effective communication between United Therapeutics, Pharmaceutical Manufacturer PAPs, or both, and Medicare Part D plans; and
 - vi. billing for free product provided to or through Pharmaceutical Manufacturer PAPs.

- c. United Therapeutics' policies and practices as they relate to the budgeting process for financial or in-kind assistance provided under any Pharmaceutical Manufacturer PAPs, including as they relate to initial or annual donation amounts and any supplemental amounts;

- d. United Therapeutics' policies and practices as they relate to the process by which decisions about the following are made and approved: i) whether to provide (or continue to provide) assistance through any Pharmaceutical Manufacturer PAP; and ii) the amount (or value) of the assistance to be provided through each program (including any initial or annual amount and any supplemental amount);

- e. United Therapeutics' policies and practices as they relate to any contracts or arrangements entered between United Therapeutics and outside entities relating to any Pharmaceutical Manufacturer PAPs or the distribution of free product, including the individuals, groups, or departments involved in the negotiation process, the requirements and terms of the contracts or arrangements, and the review and approval of such contracts or arrangements.

III. IRO Systems Review Report

The IRO shall prepare a report based upon each Systems Review. For each of the Reviewed Policies and Procedures identified in Section II above, the report shall include the following items:

- 1) a description of the documentation (including policies) reviewed and any personnel interviewed;
- 2) a detailed description of United Therapeutics' systems, policies, processes, and procedures relating to the items identified in Sections II.1-2 above, including a general description of United Therapeutics' control and accountability systems (e.g., documentation and approval requirements, and tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;
- 3) a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Sections II.1-2 above are made known or disseminated within United Therapeutics;
- 4) a detailed description of any system(s) used to track requests for donations or other assistance from any Independent Charity PAP;
- 5) a detailed description of any system(s) used to track donations or other assistance provided in response to requests from Independent Charity PAPs;
- 6) a detailed description of any system(s) used to track requests for donations or other assistance from or through any Pharmaceutical Manufacturer PAP;
- 7) a detailed description of any system(s) used to track donations or other assistance provided in response to requests from or through any Pharmaceutical Manufacturer PAP;

- 8) findings and supporting rationale regarding any weaknesses in United Therapeutics' systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and
- 9) recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

IV. IRO Transactions Review

As described more fully below in Sections IV.A-C, the Transactions Review shall include: (1) a review of United Therapeutics' arrangements with selected Independent Charity PAPs; and (2) a review of up to three additional items identified by OIG in accordance with Section III.E.2 of the CIA (hereafter "Additional Items".) The IRO shall report on all aspects of its reviews in the Transactions Review Reports.

A. IRO Review of Arrangements with Independent Charity PAPs

The IRO shall conduct a review and assessment of United Therapeutics' compliance with the Independent Charity PAP processes, policies, and procedures outlined in Section III.J of the CIA. More specifically, the IRO shall review the arrangements and interactions with all Independent Charity PAPs or disease state funds with which United Therapeutics entered charitable donation arrangements during the Reporting Period.

For purposes of this IRO review, the term "Reviewed Materials" shall include the following for each Independent Charity PAP reviewed: 1) all budget-related documents; 2) all documents relating to any decision to provide donations to the Independent Charity PAP; 3) any agreements between United Therapeutics and the Independent Charity PAP; 4) all email, correspondence and other documents reflecting communications and interactions between United Therapeutics and the Independent Charity PAP; 5) all email, correspondence and other documents reflecting communications and interactions within United Therapeutics (or between United Therapeutics and any entity acting on its behalf) relating to the arrangement with the Independent Charity PAP; and 6) other available information relating to the arrangements and interactions between United Therapeutics and the selected Independent Charity PAP. In addition to reviewing documents and written materials, the IRO shall also interview individuals at United Therapeutics who have responsibility for arrangements and interactions with Independent Charity PAPs.

For each Independent Charity PAP selected as part of the IRO review, the IRO shall assess the Reviewed Materials and conduct interviews to evaluate whether the Independent Charity PAP-related activities were conducted in a manner consistent with United Therapeutics' policies and procedures including those described in Section III.J of

the CIA and with OIG guidance. More specifically, the IRO Review shall evaluate and identify:

- 1) Whether activities relating to arrangements and interactions with the Independent Charity PAP were undertaken by the appropriate individuals, departments, or groups within United Therapeutics in accordance with the company's policies and procedures including those outlined in Section III.J of the CIA;
- 2) Whether United Therapeutics' commercial organization (as defined in Section III.J) played a role in any arrangement or interaction with the Independent Charity PAP in violation of United Therapeutics' policies and procedures or OIG guidance;
- 3) Whether United Therapeutics followed the budgeting policies and practices outlined in Section III.J.2 of the CIA with regard to any initial or annual donation amounts to the Independent Charity PAP and any supplemental amounts;
- 4) Whether United Therapeutics followed the decision-making and approval process outlined in Section III.J of the CIA with regard to any decisions: i) whether to donate (or continue to donate) to the Independent Charity PAP; ii) the amount of the donation (including any initial or annual amount and any supplemental amount); and iii) the criteria governing whether United Therapeutics would donate to the Independent Charity PAP or any specific disease state fund of such a PAP;
- 5) Whether United Therapeutics followed the policies and practices outlined in Section III.J.3 of the CIA in connection with all donations made by United Therapeutics to any Independent Charity PAP, including as they pertain to the internal review of potential donations and the adherence to the criteria specified in Section III.J.3;
- 6) Any communications that occurred between any representatives of United Therapeutics and the Independent Charity PAP (including the identity of individuals authorized to engage in such communications, the circumstances of such communications, and the subject matter of such communications (including the exchange of any data)) and whether any such communications complied with United Therapeutics' policies and procedures and OIG guidance;

- 7) Any communications that occurred between the groups or departments within United Therapeutics responsible for Independent Charity PAP functions and the commercial organization and whether any such communications complied with United Therapeutics' policies and procedures;
- 8) Any communications that occurred between any representatives of United Therapeutics and health care providers or patients relating to assistance available through the Independent Charity PAP and whether any such communications complied with United Therapeutics' policies and procedures;
- 9) Whether, for each donation from United Therapeutics to any Independent Charity PAP, United Therapeutics complied with the requirements outlined in Sections III.J.3; and
- 10) Whether, based on its review, the IRO found that United Therapeutics exerted influence or control over the Independent Charity PAP in violation of United Therapeutics' policies and procedures, including those outlined in Section III.J.3.

B. IRO Review of Additional Items

As set forth in Section III.E.2 of the CIA, for each Reporting Period, OIG at its discretion may identify up to three additional items for the IRO to review (hereafter "Additional Items"). The Additional Items may include activities undertaken by United Therapeutics in connection with Promotional Functions, as defined in Section II.C.3 of the CIA. For the second through fifth Reporting Periods, the Additional Items Review may include activities undertaken by United Therapeutics in connection with any Pharmaceutical Manufacturer PAP, including the provision of free product to patients.

No later than 150 days prior to the end of the applicable Reporting Period, OIG shall notify United Therapeutics of the nature and scope of the IRO review to be conducted for each of the Additional Items. Prior to undertaking the review of the Additional Items, the IRO and/or United Therapeutics shall submit an audit work plan to OIG for approval.

The IRO shall conduct the review of the Additional Items based on a work plan approved by OIG. The IRO shall include information about its review of each Additional Item in the Transactions Review Report (including a description of the review conducted for each Additional Item; the IRO's findings based on its review for each Additional Item; and the IRO's recommendations for any changes in United Therapeutics' systems, processes, policies, and procedures based on its review of each Additional Item).

United Therapeutics may propose to OIG that relevant internal audit(s) and/or other

reviews conducted by outside entities at United Therapeutics' request be substituted for one or more of the Additional Item reviews that would otherwise be conducted by the IRO for the applicable Reporting Period. OIG retains sole discretion over whether, and in what manner, to allow United Therapeutics' internal audit work to be substituted for a portion of the Additional Items review conducted by the IRO.

In making its decision, OIG agrees to consider, among other factors, the nature and scope of United Therapeutics' planned monitoring activities and internal audit work, the results of the Transactions Review(s) during prior Reporting Period(s), and United Therapeutics' demonstrated audit capabilities to perform the proposed audit work internally. If OIG denies United Therapeutics' request to permit its internal audit work to be substituted for a portion of the IRO's review of Additional Items in a given Reporting Period, United Therapeutics shall engage the IRO to perform the Review as outlined in this Section IV.

If OIG agrees to permit certain of United Therapeutics' internal audit work for a given Reporting Period to be substituted for a portion of an Additional Items review, such internal work may be subject to verification by the IRO (Verification Review). In such an instance, OIG would provide additional details about the scope of the Verification Review to be conducted by the IRO.

C. Transactions Review Report

For each Reporting Period, the IRO shall prepare a report based on its Transactions Reviews. The report shall include the following:

1. General Elements to Be Included in Report

- a) Review Objectives: A clear statement of the objectives intended to be achieved by each part of the review;
- b) Review Protocol: A detailed narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for each sample reviewed; and
- c) Sources of Data: A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Transactions Review.

2. Results to be Included in Report

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

(for the review of Independent Charity PAP arrangements)

- a) a list of the Independent Charity PAPs with which United Therapeutics entered arrangements or had interactions during the Reporting Period;
- b) for each Independent Charity PAP for which the IRO reviewed arrangements or interactions during the Reporting Period: i) a description of the review conducted by IRO; and ii) a summary of all instances in which it appears that United Therapeutics failed to follow its policies and procedures and/or OIG guidance regarding its arrangements or interactions with the Independent Charity PAP;
- c) for each Independent Charity PAP reviewed by the IRO, findings regarding each element specified above in Sections IV.A.1-10;
- d) the findings and supporting rationale regarding any overall weaknesses in United Therapeutics' systems, processes, policies, procedures, and practices relating to its arrangements and interactions with Independent Charity PAPs; and
- e) recommendations, if any, for changes in United Therapeutics' systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to its arrangements and interactions with Independent Charity PAPs.

(Relating to the Review of Additional Items)

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