CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
JAZZ PHARMACEUTICALS, INC.

I. PREAMBLE

Jazz Pharmaceuticals, Inc. (Jazz) 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) and the statutes, regulations, and written directives of the Food and Drug Administration (FDA) (FDA requirements). Contemporaneously with this CIA, Jazz is entering into a Settlement Agreement with the United States. Jazz will also enter into settlement agreements with various states and Jazz's agreement to this CIA is a condition precedent to those settlement agreements.

Prior to the Effective Date, Jazz established a comprehensive compliance program (Compliance Program), which includes a corporate Compliance Officer and compliance committee, a code of conduct for all employees, written policies and procedures, educational and training initiatives, review and disciplinary procedures, a confidential disclosure program, and internal review procedures designed, as represented by Jazz, to promote compliance with applicable laws and the promotion of high ethical standards.

Jazz shall continue its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. Jazz may modify its compliance measures as appropriate, but, at a minimum, Jazz shall ensure that during the term of this CIA, it shall comply with the integrity obligations set forth herein.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Jazz under this CIA shall be five years from the effective date of this CIA, unless otherwise specified. The effective date shall be the date on which the final signatory of this CIA executes this CIA (Effective Date). Each one-year period, beginning with the one-year period following July 1, 2007 shall be referred to as a "Reporting Period."

B. Sections VII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Jazz's final Annual Report; or (2) any additional materials submitted by Jazz 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 who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5%; and (2) acquired the ownership interest through public trading), officers, directors, and employees of Jazz; and

b. all contractors, subcontractors, agents, and other persons who perform Product Services Related Functions (as defined below in Section II.C.2) on behalf of Jazz.

Notwithstanding the above, the term "Covered Persons" does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year.

2. "Relevant Covered Persons" includes all Covered Persons of Jazz whose job responsibilities relate to: i) the sales, marketing, or promotion of Jazz's products; ii) research and development (except preclinical researchers and clinical investigators); iii) the distribution of Jazz's products (except those Covered Persons with no sales, marketing, or promotional related responsibilities); or iv) the provision of information about or services

relating to Jazz products (collectively "Product Services Related Functions.").

3. An "Educational or Informational Activity" shall mean any continuing medical education (CME), disease awareness, or other scientific, educational or professional program, meeting, or event, including, but not limited to, sponsorship of booths or activities at medical conferences or symposia.

III. CORPORATE INTEGRITY OBLIGATIONS

Jazz shall maintain a Compliance Program that includes the following elements:

A. Compliance Officer and Committee.

1. *Compliance Officer.* Within 120 days after the Effective Date, Jazz shall appoint an individual to serve as its compliance officer (Compliance Officer), and Jazz shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program and FDA requirements. The Compliance Officer is and shall continue to be a member of the management of Jazz, shall report to the Chief Executive Officer, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Jazz, and shall be authorized to report on such matters to the Board of Directors (or a designated committee or subcommittee of the Board) at any time. The Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Jazz as well as for any reporting obligations created under this CIA.

Jazz shall report to OIG, in writing, any changes in the identity or position description of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

2. *Compliance Committee.* Prior to the Effective Date, Jazz established a Compliance Committee, and Jazz shall maintain the Compliance Committee during the term of this CIA. The Compliance Committee shall, at a minimum, consist of the General

Counsel; the Compliance Officer; the Senior Vice President, Development; the Chief Financial Officer; the Vice President, Sales; and the Vice President, Marketing and New Product Planning. As represented by Jazz, the aforementioned individuals are the members of management necessary to meet the requirements of this CIA. The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of Jazz's risk areas and shall oversee monitoring of internal and external audits and investigations).

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

B. Written Standards.

1. *Code of Conduct.* To the extent not already accomplished, within 90 days after the Effective Date, Jazz shall develop, implement, and distribute a written Code of Conduct to all Covered Persons. Jazz shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

a. Jazz's commitment to full compliance with all Federal health care program and FDA requirements, including its commitment to comply with all requirements relating to Product Services Related Functions;

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

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

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

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

Within 90 days after the Effective Date, each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by Jazz's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

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

2. *Policies and Procedures*. To the extent not already accomplished, within 90 days after the Effective Date, Jazz shall implement written Policies and Procedures regarding the operation of Jazz's compliance program and its compliance with Federal health care program and FDA requirements. At a minimum, the Policies and Procedures shall address:

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

b. selling, marketing, and promoting of Jazz products in compliance with all applicable Federal health care 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;

c. selling, marketing, promoting, advertising, and disseminating information about Jazz's products in compliance with all applicable FDA requirements, including procedures governing the response to requests for information about off-label uses;

d. compensation (including salaries and bonuses) for Covered Persons that are designed to ensure that financial incentives do not inappropriately motivate sales and marketing personnel to engage in the improper promotion, sales, and marketing of Jazz's products;

e. disciplinary policies and procedures for violations of Jazz's Policies and Procedures, including those policies relating to Federal health care program and FDA requirements;

f. the manner in which Jazz receives and response to requests for information about off-label uses of Jazz's products; the form and content of information disseminated by Jazz in response to such requests; and the internal review process for the information disseminated.

The Policies and Procedures shall include a requirement that Jazz develop one or more databases to track requests for information about Jazz' products that are made to Jazz' Medical Information department. Collectively these databases shall be referred to as the "Inquiries Database." The Inquiries Database shall includes the following items of information for each unique inquiry (Inquiry) received for information about Jazz's products: 1) date of Inquiry; 2) form of Inquiry (*e.g.,* fax, phone, etc.); 3) name of the requesting health care professional (HCP); 4) nature and topic of request (including exact language of the Inquiry if made in writing); 5) an evaluation of whether the Inquiry relates to information about an off-label indication for the product; 6) nature/form of the response from Jazz (including a record of the materials provided to the HCP in response to the request); 7) the name of the Jazz representative who called on or interacted with the HCP; and 8) the status and findings of any follow-up review conducted by Jazz in situations in which it

appears that the Inquiry may have related to improper off-label promotion;

g. speaker programs, advisory board programs, focus group programs, and all other consultant arrangements. These policies shall be designed to ensure that the consultant arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements. The policies shall include requirements about the uses, content, and circumstances of such arrangements and events;

h. funding of, or participation in, any Educational or Informational Activity as defined in Section II.C.3 above (*e.g.*, third party educational grants or sponsorship for CME or other third-party educational programs or events). These Policies and Procedures shall be designed to ensure that Jazz's funding and/or sponsorship of such programs satisfies all applicable Federal health care program and FDA requirements related to the sponsorship of any Educational or Informational Activity.

The Policies and Procedures shall require: 1) the disclosure of Jazz's financial support of the Educational or Informational Activity and any financial relationships with faculty, speakers, or organizers at such Educational or Informational Activity; 2) that the Educational or Informational Activity have an educational focus; 3) that the Educational or Informational Activity be independent; 4) that the Educational or Informational Activity be non-promotional in tone/nature; and 5) that the information provided at the Educational or Informational Activity be fair, balanced, accurate and not misleading;

i. funding of charitable grants or sponsorships in a manner that is designed to ensure that Jazz's funding complies with all applicable Federal health care program requirements and FDA requirements; and

j. sponsorship or funding of research activities (including clinical

trials, market research, or authorship of articles or other publications) by Jazz in a manner that is designed to ensure that Jazz's funding or sponsorship of such activities complies with all applicable Federal health care program and FDA requirements. In addition, such Policies and Procedures shall ensure that sales and marketing activities are separate from clinical trial enrollment.

Within 90 days after the Effective Date, the relevant portions of the Policies and Procedures shall be distributed to all individuals whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

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

C. Training and Education.

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

a. CIA requirements;

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

c. in general, the proper methods of promoting, marketing, selling, conducting research (including clinical trials), and disseminating information about Jazz's products in accordance with Federal health care program and FDA requirements.

To the extent that General Training provided to Covered Persons during the 90 days immediately prior to the execution of this CIA satisfies the requirements of Sections III.C.1.b-c, above, the OIG shall credit the training toward the training requirements set

forth in this Section III.C.1 for the first Reporting Period. Jazz may satisfy its remaining General Training obligation for those Covered Persons who received training as described above by notifying the Covered Persons in writing of the fact that Jazz entered a CIA and notifying them of Jazz's requirements and obligations under the CIA.

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. *Specific Training.* Within 120 days after the Effective Date, each Relevant Covered Person shall receive at least two hours of Specific Training in addition to the General Training required above. Each Relevant Covered Person shall also receive at least one additional hour of Specific Training during the first Reporting Period. This Specific Training shall include a discussion of:

a. all Federal health care program requirements relevant to Product Services Related Functions, including, but not limited to, the requirements of the Federal anti-kickback statute; the Civil Monetary Penalties Law; the civil False Claims Act; and the Medicaid Drug Rebate statute;

b. all applicable FDA requirements relevant to Product Services Related Functions, including but not limited to, the requirements of the Federal Food, Drug, and Cosmetic Act and FDA regulations;

c. the personal obligation of each Relevant Covered Person involved in Product Services Related Functions to comply with all applicable legal requirements;

d. the legal sanctions for violations of the Federal health care program requirements or FDA requirements relating to Product Services Related Functions; and

e. examples of proper and improper practices relating to Product Services Related Functions.

To the extent that Specific Training provided to Relevant Covered Persons during the 90 days immediately prior to the execution of this CIA satisfies the requirements of this Section III.C.2, the OIG shall credit the training toward the Specific Training requirements for the first Reporting Period.

New Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 120 days after the Effective Date, whichever is later. A Jazz employee who has completed the Specific Training shall review a new Relevant Covered Person's work, to the extent that the work relates to Product Services Related Functions, until such time as the new Relevant Covered Person completes his or her Specific Training.

After receiving the initial Specific Training described in this Section, each Relevant Covered Person shall receive at least two hours of Specific Training in each subsequent Reporting Period.

In addition to the Specific Training obligations set forth in this Section III.2.C, as part of its Compliance Program, Jazz provides additional regular periodic training to Relevant Covered Persons on the topics outlined above in this Section III.C.2. This training shall be known as the "Periodic Compliance Training". Jazz shall continue to provide Periodic Compliance Training to Relevant Covered Persons during the term of the CIA. Jazz shall include a description of the Periodic Compliance Training as part of its Annual Reports, but Jazz shall not be required to formally track the Periodic Compliance Training for each individual Relevant Covered Person.

3. *Certification.* Each individual who is required to attend training shall certify, in writing, or in electronic form, if applicable, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

4. *Qualifications of Trainer.* Persons providing the training shall be knowledgeable about the subject area, including the applicable Federal health care program and FDA requirements.

5. *Update of Training.* Jazz shall review the training annually, and, where appropriate, update the training to reflect changes in applicable Federal health care

program or FDA requirements, any issues discovered during internal audits or any of the IRO Reviews, and any other relevant information.

6. *Computer-based Training.* Jazz may provide the training required under this CIA through appropriate computer-based training approaches. If Jazz chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

D. Review Procedures.

1. *General Description.*

a. Engagement *of Independent Review Organization.* Within 90 days after the Effective Date, Jazz shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform a Promotional and Product Services Engagement.

Each IRO engaged by Jazz shall have expertise in the requirements of the requirements of the Federal health care program and FDA requirements applicable to the Promotional and Product Services Engagement. Each IRO shall assess, along with Jazz, whether it can perform the IRO review in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or other engagements that may exist. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

b. *Description and Frequency of Reviews.* The Promotional and Product Services Engagement shall consist of two components – a systems review (the Promotional and Product Services Systems Review) and a transactions review (Promotional and Product Services Transactions Review), as described more fully in Appendix B to this CIA, which is incorporated by reference.

The Promotional and Product Services Transactions Review shall be performed annually and shall cover each of the Reporting Periods.

The IRO(s) shall perform all components of each of these annual Reviews.

The IRO shall perform the Promotional and Product Services Systems Review for the first Reporting Period as outlined in Appendix B.

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

2. *Review Reports*. The IRO shall prepare a report (Report) based upon each Promotional and Product Services Transaction Review and Promotional and Product Services Systems Review performed. Information to be included in each Report is described in Appendix B.

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

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

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

E. Disclosure Program.

Prior to the Effective Date, Jazz established a Disclosure Program that includes mechanisms (a toll-free compliance telephone line and an e-mail mechanism) 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 Jazz's policies, conduct, practices, or procedures with respect to any Federal health care program or FDA requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. Jazz shall continue the Disclosure Program during the term of this CIA. Jazz shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

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. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Jazz 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, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be made available to OIG upon request.

F. Ineligible Persons.

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

a. an "Ineligible Person" shall include an individual or entity who:

i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or

ii. has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. "Exclusion Lists" include:

i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.oig.hhs.gov); and

ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://www.epls.gov).

c. "Screened Persons" include prospective and current owners (other than shareholders who: (1) have an ownership interest of less than 5%; and (2) acquired the ownership interest through public trading), officers, directors, employees, contractors, and agents of Jazz.

2. *Screening Requirements.* Jazz shall ensure that all Screened Persons are not Ineligible Persons, by implementing the following screening requirements.

a. Jazz shall screen all Screened Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Screened Persons to disclose whether they are Ineligible Persons.

b. Jazz shall screen all Screened Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.

c. Jazz shall implement a policy requiring all Screened Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

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

3. *Removal Requirement.* If Jazz has actual notice that a Screened Person has become an Ineligible Person, Jazz shall remove such Screened Person from responsibility for, or involvement with, Jazz's business operations related to the Federal health care programs and shall remove such Screened Person from any position for which the Screened Person's compensation or the items or services furnished, ordered, or prescribed by the Screened Person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the Screened Person is reinstated into participation in the Federal health care programs.

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

G. Notification of Government Investigation or Legal Proceedings.

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

H. Reporting.

1. *Reportable Events.*

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

i. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program and/or applicable to any FDA requirements relating to the promotion of prescription drugs for which penalties or exclusion may be authorized; or

iii. the filing of a bankruptcy petition by Jazz.

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

b. Reporting *of Reportable Events.* If Jazz determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Jazz shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:

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

iii. a description of Jazz's actions taken to correct the Reportable Event; and

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

v. If the Reportable Event involves the filing of a bankruptcy petition, the report to the OIG shall include documentation of the filing and a description of any Federal health care program and/or FDA authorities implicated.

I. Notification of Communications with FDA.

Within 30 days after the date of any written report, correspondence, or communication from Jazz to the FDA that materially discusses Jazz's or a Covered Person's unlawful or improper promotion of Jazz's products (including any improper dissemination of information about off-label indications), Jazz shall provide a copy of the report, correspondence, or communication to the OIG. Jazz shall also provide written notice to the OIG within 30 days after the resolution of any such disclosed off-label matter, and shall provide the OIG with a description of the findings and/or results of the matter, if any.

J. Review of Records Reflecting the Content of Detailing Sessions.

Each Reporting Period beginning with the second Reporting Period, Jazz shall obtain non-Jazz records (*e.g.*, Verbatims or similar records) generated by an independent entity (Survey Entity) reflecting the purported content and subject matter of detailing interactions between sales representatives and HCPs for up to three Jazz products (Covered Products) to be selected by OIG as described below. In order to satisfy its obligations under this Section III.J, Jazz may propose that it obtain an alternative type of survey record (*e.g.*, message recall studies) rather than the records of the detailing sessions. The OIG will consider Jazz's proposal, and, after considering Jazz's proposal, shall, in its discretion, identify the type of survey records to be obtained. Prior to the beginning of the second Reporting Period, the OIG will determine (after input from Jazz) whether the Field Sales Force Monitoring Program outlined below in Section III.L and the accompanying documentation required under that Section are sufficient to justify waiving the requirement to obtain and review records reflecting the content of detailing sessions as set forth in this Section III.J.

For each Covered Product, Jazz shall contract with the Survey Entity to conduct inquiries into the content and subject matter of the detailing interactions. The OIG shall

select and notify the Survey Entity of a one-week period within every other quarter of the Reporting Period for which the surveys shall be conducted, beginning in the second full quarter after the Effective Date. For each Covered Product, Jazz shall obtain records reflecting the purported content and subject matter of detailing sessions during the identified week in all regions across the United States.

Jazz shall review the records obtained and shall identify any instances in which the records appear to indicate that Covered Persons may have discussed and/or disseminated information about off-label uses of the Covered Products. Jazz shall make findings based on its review (Off-Label Findings) and shall take any responsive action it deems necessary. If necessary for purposes of its review, Jazz shall endeavor to gather additional factual information about the circumstances relating to any Off-Label Findings. As part of each Annual Report, Jazz shall provide the OIG with copies of the underlying records of the detailing interactions, a copy of Jazz's Off-Label Findings, and a description of the action(s), if any, Jazz took in response to the Off-Label Findings.

Prior to the start of the second Reporting Period and every Reporting Period thereafter, based on the information provided by Jazz and other information known to it, and after consultation with Jazz, the OIG shall select up to three Jazz products to be reviewed under this Section III.J. These products shall be known as the "Covered Products", and the OIG shall notify Jazz of the Covered Products for each applicable Reporting Period. The parties have already identified the Covered Products for the first Reporting Period.

K. Monitoring and Review of Medical Information Requests.

Jazz's Policies and Procedures address the selling, marketing, promoting, and dissemination of information about Jazz's products in compliance with all applicable Federal health care program and FDA requirements and the procedures governing the manner in which sales personnel are to respond to requests for information about non-FDA approved uses (*e.g.*, off-label uses). Among other things, Jazz's Policies and Procedures provide that its sales personnel may not directly or indirectly solicit, encourage, or promote any Jazz product for off-label uses. In addition, the Policies and Procedures provide that inquiries about off-label uses are to be directed to Jazz's Medical Information department. Jazz's Medical Information department responds to requests for medical and scientific information from physicians, patients, and others (Inquiries).

Jazz records and documents all Inquiries in the Inquiries Database. The Inquiries Database contains the information identified in Section III.B.2.f above for each Inquiry. On at least a monthly basis, Jazz generates and shall continue to generate reports of the Inquiries received and the responses to the Inquiries. These reports shall continue to be forwarded to the Compliance Officer or other compliance personnel. The Compliance Officer (or designee) shall continue to review these reports to assess whether the information contained in the report suggests that improper promotion may have occurred in connection with any Inquiry(ies).

If the Compliance Officer, in consultation with other appropriate Jazz personnel, suspects that improper promotion may have occurred in connection with one or more Inquiries, the Compliance Officer shall undertake a follow-up review of the Inquiry (Off-Label Review). The Compliance Officer shall make specific findings based on the Off-Label Review, and take any responsive action (including disciplinary action and reporting of the conduct (including disclosing Reportable Events pursuant to Section III.H above, if applicable) deemed necessary and appropriate. On at least a semi-annual basis, the Compliance Officer shall review the Medical Information department's policies and procedures relating to the handling of Inquiries concerning off-label uses of Jazz's products and shall provide a report on the results of such review to the Compliance Committee.

Jazz shall maintain a record of the steps undertaken during each Off-Label Review, including a general description of the process by which the Compliance Officer conducted the Off-Label Review, the types of records reviewed and the identities of individuals interviewed. Any findings made during the Off-Label Review and any corrective action taken shall be recorded in the files of the Compliance Department and summarized in the Annual Reports. Jazz shall make its records relating to its reviews of Inquiries and any Off-Label Reviews available to the OIG upon request

L. Jazz's Field Sales Force Monitoring Program.

Jazz compliance and legal personnel conduct at least two types of reviews of the activities of Jazz's field sales force. First, Jazz conducts periodic and regular reviews of the call notes recorded by its field sales force (Call Note Reviews). Second, Jazz conducts compliance-focused ride-alongs with its field sales force personnel (Ride-Along Reviews). These activities shall collectively be referred to as the "Field Sales Force Monitoring Program", and Jazz shall continue the Field Sales Force Monitoring Program as set forth below during the term of the CIA.

In connection with the Call Note Review, in the first quarter of each Reporting Period, Jazz shall conduct an audit of a sample of call notes prepared by field sales representatives. The sample will consist of all call notes prepared by at least 20 percent of Jazz's field sales representatives during two different months of the preceding Reporting Period. If the number of field sales representatives for the applicable Reporting Period exceeds 100 employees, Jazz shall notify the OIG of this fact and the OIG will determine, after input from Jazz, whether to reduce the percentage of field sales representatives whose call notes are included as part of the sample. The field sales representatives and the months to be sampled will be selected randomly by Jazz's compliance department. After the sample of call notes has been selected, the Compliance Officer (or designee) shall review the call notes to assess whether the information contained in the call notes suggests that any improper promotion may have occurred.

In connection with the Ride Along Reviews, the Compliance Officer or other trained personnel from the Compliance, legal, or regulatory affairs departments shall directly observe all meetings between Jazz field sales representatives and HCPs during a full work day for at least 10 of Jazz's field sales representatives during each Reporting Period. The field sales representatives observed shall be located throughout the country and shall be supervised by different sales managers. If the number of field sales representatives for the applicable Reporting Period exceeds 100 employees, Jazz shall notify the OIG of this fact and the OIG will determine, after input from Jazz, whether to increase the number of field sales representatives who are observed during Ride Along Reviews and, if so, the number of field sales representatives to be observed. Jazz shall continue these Ride Along Reviews during the term of this CIA as outlined below.

After the completion of each observation day conducted as part of the Ride Along Reviews, compliance personnel shall complete an Observation Report which, for each interaction observed between a sales representatives and an HCP or his/her office staff, shall include the following information: 1) the identity of the sales representative and the compliance or other personnel conducting the observation; 2) the date and duration of the observation; 3) the Jazz product(s) promoted during the observation; 4) assessments about the interaction between the sales representative and each HCP visited; and 5) an identification and description of any potential improper promotion of any Jazz product(s). The Observation Reports shall be forwarded to the Compliance Officer for review.

If the Compliance Officer, in consultation with other appropriate Jazz personnel, suspects that improper promotion may have occurred in connection with either the Call Note Review or any Ride Along Review, the Compliance Officer shall undertake

a follow-up review (Compliance Review). The Compliance Officer shall make specific findings based on the Compliance Review, and take any responsive action (including disciplinary action and reporting of the conduct (including disclosing Reportable Events pursuant to Section III.H above, if applicable) deemed necessary and appropriate. Jazz shall retain records relating to the Call Note Reviews, the Ride Along Reviews, and any Compliance Reviews, and shall make such records available to the OIG upon request. A description of the Call Note Reviews, the Ride Along Reviews, any Compliance Reviews, and any findings made during the Compliance Reviews shall be summarized in the Annual Reports.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, Jazz changes locations or sells, closes, purchases, or establishes a new business unit or location related to Product Services Related Functions, Jazz shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change of location, sale, closure, purchase, or establishment. This notification shall include the address of the new business unit or location, phone number, fax number, any Federal health care program provider identification number and/or supplier number, and any corresponding contractor's name and address that has issued each Federal health care program provider number. Each new business unit or location shall be subject to all the requirements of this CIA.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the Effective Date, Jazz 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, and a summary of other noncompliance job responsibilities the Compliance Officer may have;

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

3. a copy of Jazz's Code of Conduct required by Section III.B.1;

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

5. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

6. the following information regarding each type of training required by Section III.C:

a. a description of such training, including a summary of the topics covered, the length of sessions and a schedule of training sessions;

b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

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

8. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; and (c) a summary and description of any and all current and prior engagements and agreements between Jazz and the IRO; and the proposed start and completion dates of each Review;

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

10. a description of the process by which Jazz fulfills the requirements of Section III.F regarding Ineligible Persons;

11. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; and the actions taken in response to the screening and removal obligations set forth in Section III.F;

12. a list of all of Jazz's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the

corresponding phone numbers and fax numbers; each location's Federal health care program provider and/or supplier number(s) (if applicable); and the name and address of each Federal health care program contractor to which Jazz currently submits claims (if applicable);

13. a description of Jazz's 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. Jazz shall submit to OIG annually a report with respect to the status of, and findings regarding, Jazz's compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee described in Section III.A;

2. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in contractor policy);

3. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

4. the following information regarding each type of training required by Section III.C:

a. a description of such training, including a summary of the topics covered, the length of sessions and a schedule of training sessions;

b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

5. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter (if applicable);

6. Jazz's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.D;

7. a summary and description of any and all current and prior engagements and agreements between Jazz and the IRO, if different from what was submitted as part of the Implementation Report;

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

9. a summary of all internal reviews, audits, or analyses related to Speaker Programs/Teleconferences or any other Product Services Related Functions (including, at a minimum, the objective of the review, audit, or analysis; the protocol or methodology for the review, audit, or analysis; and the results of the review, audit, or analysis) and any corrective action plans developed in response to such reviews, audits, or analyses;

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

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

12. any changes to the process by which Jazz fulfills the requirements of Section III.F regarding Ineligible Persons;

13. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; and the actions taken by Jazz in response to the screening and removal obligations set forth in Section III.F;

14. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a

description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

15. a summary describing any ongoing communication with the FDA required to have been reported pursuant to Section III.I. The summary shall include a description of the matter, and the status of such matter;

16. a copy of all information required by Section III.J;

17. a list and description of all actively promoted Jazz products; and information about the estimated relative usage (*e.g.*, the percentage) of those products for off-label purposes;

18. a summary describing the findings resulting from any Off-Label Reviews, as required by Section III.K;

19. a copy of all information required by Section III.L;

20. a description of all changes to the most recently provided list of Jazz's locations (including addresses) as required by Section V.A.12; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal health care program provider or supplier number(s) (if applicable), and the name and address of each Federal health care program contractor to which Jazz currently submits claims (if applicable); and

21. 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. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that:

1. to the best of his or her knowledge, except as otherwise described in the applicable Report, Jazz is in compliance with all of the requirements of this CIA;

2. 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;

3. if applicable, Jazz has complied with its obligations under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs; and

4. Jazz': 1) Policies and Procedures as referenced in Section III.B.2 above; 2) templates for the standardized contracts and other similar documents; 3) training materials used for purposes of Section III.C, above; and 4) promotional or educational materials containing claims or information about Jazz's products have been reviewed by competent legal counsel and have been found to be in compliance with the requirements of the Federal anti-kickback statute, the Prescription Drug Marketing Act, and other applicable laws. If the applicable legal requirements have not changed, after the initial review of the documents listed above, only material changes to the documents must be reviewed by competent legal counsel. The certification shall include a description of the document(s) reviewed and approximately when the review was completed. The documentation supporting this certification shall be available to OIG, upon request.

D. Designation of Information. Jazz 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. Jazz 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

Jazz: Compliance Officer
Jazz Pharmaceuticals, Inc.
3180 Porter Drive
Palo Alto, CA 94304
Telephone: 650.496.2777
Facsimile: 650.396.3781

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

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Jazz's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Jazz's locations for the purpose of verifying and evaluating: (a) Jazz's compliance with the terms of this CIA; and (b) Jazz's compliance with the requirements of the Federal health care programs in which it participates and with applicable FDA requirements. The documentation described above shall be made available by Jazz to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Jazz's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Jazz shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Jazz's employees may elect to be interviewed with or without a representative of Jazz present.

VIII. DOCUMENT AND RECORD RETENTION

Jazz shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA, for six years (or longer if otherwise required by law) 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 Jazz prior to any release by OIG of information submitted by Jazz pursuant to its obligations under this CIA and identified upon submission by Jazz as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Jazz shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

Jazz 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, Jazz 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 Jazz fails to establish and implement any of the following obligations as described in Section III:

a. a Compliance Officer;

b. a Compliance Committee;

c. a written Code of Conduct;

d. written Policies and Procedures;

e. the training of Covered Persons;

f. a Disclosure Program;

g. Ineligible Persons screening and removal requirements;

h. notification of Government investigations or legal proceedings;

i. notification of communications regarding off-label related matters;

j. a review of records reflecting the content of detailing sessions;

k. monitoring and review of Medical Information Requests; and

l. the Field Sales Force Monitoring Program as described in Section III.L.

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 Jazz fails to engage an IRO, as required in Section III.D and Appendices A and 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 Jazz fails to submit the Implementation Report or any Annual Reports 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 Jazz fails to submit the annual Report associated with any of the Reviews in accordance with the requirements of Section III.D and Appendix B.

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

6. A Stipulated Penalty of $5,000 for each false certification submitted by or on behalf of Jazz as part of its Implementation Report, Annual Report, additional

documentation to a report (as requested by the OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of $1,000 for each day Jazz fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Jazz stating the specific grounds for its determination that Jazz has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Jazz shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Jazz 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. Jazz 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 Jazz fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Jazz receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that Jazz 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 Jazz of: (a) Jazz's 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, Jazz 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 Jazz elects to request an ALJ

hearing, the Stipulated Penalties shall continue to accrue until Jazz cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in Section VI.

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

D. Exclusion for Material Breach of this CIA.

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

a. a failure by Jazz to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section III.H;

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

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

d. a failure to engage and use an IRO in accordance with Section III.D and Appendices A-B.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Jazz constitutes an independent basis for Jazz's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Jazz has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Jazz of: (a) Jazz's material breach; and (b) OIG's intent to

exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* Jazz 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. Jazz is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;

b. the alleged material breach has been cured; or

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

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Jazz fails to satisfy the requirements of Section X.D.3, OIG may exclude Jazz from participation in the Federal health care programs. OIG shall notify Jazz in writing of its determination to exclude Jazz (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 Jazz's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Jazz 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 Jazz 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, Jazz shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall

be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Jazz was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Jazz 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 Jazz to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Jazz 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:

a. whether Jazz was in material breach of this CIA;

b. whether such breach was continuing on the date of the Exclusion Letter; and

c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Jazz had begun to take action to cure the material breach within that period; (ii) Jazz has pursued and is pursuing such action with due diligence; and (iii) Jazz provided to OIG within that period a reasonable timetable for curing the material breach and Jazz has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after

an ALJ decision favorable to OIG, or, if the ALJ rules for Jazz, only after a DAB decision in favor of OIG. Jazz's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Jazz 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 Jazz 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. Jazz 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 Jazz, Jazz 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

Jazz and OIG agree as follows:

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

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

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

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

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

ON BEHALF OF JAZZ PHARMACEUTICALS, INC.

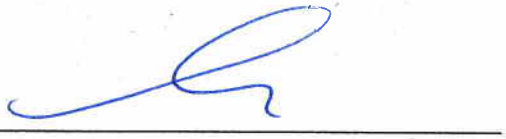
Samuel R. Saks, M.D.
Chief Executive Officer
Jazz Pharmaceuticals, Inc.

7/13/07
DATE

John T. Bentivoglio
Mark A. Jensen
Counsel for Jazz Pharmaceuticals, Inc.

7/13/07
DATE

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



7/13/07

Gregory E. Demske
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

DATE

APPENDIX A
INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement.

Jazz 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 written notice of the identity of the selected IRO, OIG will notify Jazz if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Jazz may continue to engage the IRO.

If Jazz engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Jazz shall submit the information identified in Section V.A.8 to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Jazz if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Jazz may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the Promotional and Product Services Engagement who have expertise in the Federal health care program and FDA requirements applicable to Product Services Related Functions. The assigned individuals shall also be knowledgeable about the general requirements general requirements of the Federal health care program(s) under which Jazz products are reimbursed;

2. assign individuals to design and select the Promotional and Product Services Engagement samples 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 Promotional and Product Services Engagement in accordance with the specific requirements of the CIA, including Appendix B to the CIA;

2. follow all applicable Federal health care program and FDA requirements in making assessments in the Promotional and Product Services Engagement;

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

4. prepare timely, clear, well-written reports that include all the information required by Appendix B.

D. IRO Independence and Objectivity.

The IRO must perform the Promotional and Product Services Engagement in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and Jazz.

E. IRO Removal/Termination.

1. *Provider.* If Jazz terminates its IRO during the course of the engagement, Jazz must submit a notice explaining its reasons to OIG no later than 30 days after termination. Jazz must engage a new IRO in accordance with Paragraph A of this Appendix.

2. *OIG Removal of IRO.* In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and/or objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Jazz to engage a new IRO in accordance with Paragraph A of this Appendix.

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

Appendix B
Promotional and Product Services Engagement

I. IRO Engagement, General Description

As specified more fully below, Jazz shall retain an Independent Review Organization (IRO) to perform engagements to assist Jazz in assessing and evaluating its systems, processes, policies, and procedures related to Product Services Related Functions (Promotional and Product Services Engagement). The Promotional and Product Services Engagement shall consist of two components - a systems review (the Promotional and Product Services Systems Review) and a transactions review (Promotional and Product Services Transactions Review), as described more fully below. Jazz may engage, at its discretion, a single IRO to perform both components of the Promotional and Product Services Engagement, provided that the entity has the necessary expertise and capabilities to perform both. As set forth below and in the CIA, Jazz shall engage an IRO to conduct the Promotional and Product Services Transactions Review for each year of the CIA. The IRO shall perform the Promotional and Product Services Systems Review for the first Reporting Period.

II. Promotional and Product Services Systems Review

A. Description of Reviewed Policies and Procedures

The Promotional and Product Services Systems Review shall be a review of Jazz's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to Product Services Related Functions. Where practical, Jazz 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 Jazz pursuant to the preceding sentence.

For the first Reporting Period, the IRO shall review Jazz' systems, processes, policies, and procedures associated with the following (hereinafter, "Reviewed Policies and Practices"):

1. Jazz's systems, policies, processes, and procedures applicable to the manner in which the Jazz field sales force and Jazz headquarters personnel handle requests or inquiries relating to information about off-label uses of Jazz products, and the manner in which Jazz disseminates materials relating to off-label uses of products. This

review includes:

(i) the instructions to field sales personnel and/or headquarters personnel who receive and respond to requests for information about off-label uses and the manner in which such personnel implement the instructions;

(ii) the procedures for reviewing the form and content of information disseminated by headquarters personnel (*e.g.* the Medical Information department);

(iii) Jazz's internal review process for the information disseminated by headquarters personnel;

(iv) Jazz's systems, processes, and procedures (including its Inquiries Database described in Section III.B.2.f of the CIA) to track requests for information about off-label uses of products and responses to those requests;

(v) the manner in which Jazz collects and supports information reported in its Inquiries Database;

(vi) the processes and procedures by which the Compliance Officer (and other appropriate individuals within Jazz) identify situations in which it appears that improper off-label promotion may have occurred; and

(vii) Jazz's processes and procedures for investigating, documenting, resolving, and taking appropriate disciplinary action for potential situations involving off-label promotion;

2. Jazz's policies and procedures applicable to the manner and circumstances under which Medical Information personnel participate in meetings or events with physicians, pharmacists, or other health care professionals (HCPs) (either alone or with members of the sales force) and the role of the Medical Information personnel at such meeting or events;

3. Jazz's systems, policies, processes, and procedures relating to the retention of HCPs as consultants (*e.g.,* including as members of

advisory boards, focus groups, or clinical research project teams) or speakers. This shall include a review of:

(i) the criteria used to determine whether, how many, and under what circumstances (including venue for the performance of any services) Jazz will enter contracts for such consulting or speaking arrangements;

(ii) the processes and criteria used to identify and select HCPs with whom Jazz enters consultant, speaker, or other contractual arrangements, including the role played by field sales personnel in the process. This includes a review of Jazz's internal review and approval process for such contracts, and the circumstances under which there may be exception to the process;

(iii) Jazz's tracking or monitoring of services provided or the work performed by the consultants or speakers (including the receipt of the consultant's work product, if any);

(iv) Jazz's policies and procedures related to circumstances, if any, under which the recipient or the recipient's agent is required to disclose the existence of the consulting or speaking arrangement in place between Jazz and the HCP;

(v) the uses made of work product received from consultants or speakers, if any;

(vi) Jazz's processes for establishing the amounts paid to HCPs and the reasons or justifications for any differentials in the amounts paid to different HCPs;

(vii) the criteria used to determine under what circumstances entertainment, recreation, travel, lodging, meals and/or other items or reimbursements are provided to consultants or speakers, and Jazz's processes for establishing the amounts reimbursed or the type of entertainment or recreation provided;

(viii) whether and in what manner Jazz tracks or monitors the

prescribing habits or product use of individuals or entities with whom it enters consulting, speakers, or other contractual arrangements, if any; and

(ix) the budget funding source within Jazz (*e.g.*, department or division) for the consulting or contractual arrangement;

4. Jazz's systems, policies, processes, and procedures relating to funding or sponsorship of any Educational or Informational Activity. This review shall include a review of the following items:

(i) the processes and procedures used to approve the funding or sponsorship of an Educational or Informational Activity;

(ii) the criteria used to determine whether and under what circumstances the funding or sponsorship will be provided;

(iii) the processes and criteria used to select recipients of the funding or sponsorships, including the role played by field sales personnel in the processes (if any), and the circumstances under which there may be exceptions to the processes;

(iv) Jazz's policies and procedures related to circumstances, if any, under which the recipient or the recipient's agent is required to disclose Jazz's funding or sponsorship and any financial relationship Jazz may have with the recipients;

(v) Jazz's policies or procedures for determining and memorializing the amounts paid to recipients of the funding or sponsorship and the purpose or justifications for the amounts paid;

(vi) Jazz's policies and procedures relating to the independence of any programs funded through the funding or the sponsorship;

(vii) Jazz's policies and procedures relating to the content and promotional nature of any programs sponsored through the funding or sponsorship;

(viii) whether and in what manner Jazz tracks or monitors the prescribing habits or product use of individuals or entities receiving the funding or sponsorship, if any; and

(ix) the budget funding source within Jazz (*e.g.*, department or division) from which the funding or sponsorships are provided;

5. Jazz's systems, policies, processes, and procedures for compensating (including with salaries and bonuses) non-Overtime Eligible employees, with regard to whether the systems, policies, processes, and procedures are designed to ensure that financial incentives do no inappropriately motivate sales and marketing personnel to engage in the improper promotion, sales, and marketing of Jazz's products. This shall include a review of the bases upon which compensation is determined and the extent to which compensation is based on product performance; and

6. Jazz's systems, policies, processes, and procedures relating to the development of call plans for Jazz's sales staff. This shall include a review of the basis upon which physician specialties are included or excluded from the call plan based upon their potential on-label and off-label utilization of Jazz products.

B. Promotional and Product Services Systems Review Report

The IRO shall prepare a report which, for each of the Reviewed Policies and Practices identified in Section II.A above, shall include the following items:

1) a description of the documentation (including policies) reviewed and any personnel interviewed, and a list and description of the activities and efforts undertaken by Jazz to assist the IRO in connection with the Systems Review;

2) a detailed description of Jazz's systems, policies, processes, and practices with regard to the items identified in Sections II.A.1-6 above, including a general description of Jazz's control and accountability systems (*e.g.*, documentation and approval requirements, tracking mechanisms) and written policies regarding the Reviewed Policies and Practices;

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.A.1-6 above are made known or disseminated within Jazz;

4) a detailed description of any system used to track and respond to requests for information about Jazz's products (*e.g.*, through the Inquiries Database);

5) a detailed description of Jazz's compensation system (including salaries and bonuses) for non-Overtime Eligible employees, included a description of the bases upon which compensation is determined and the extent to which compensation is based on product performance. To the extent that Jazz may establish compensation differently for individual products, the IRO shall report separately on each such type of compensation arrangements;

6) findings and supporting rationale regarding any weaknesses in Jazz's systems, policies, processes, and practices relating to Reviewed Policies and Practices, if any; and

7) recommendations to improve any of the systems, policies, processes, or practices relating to the Reviewed Policies and Practices, if any.

Prior to the IRO's submission of the report to the OIG, Jazz shall be provided with a copy of the report and an opportunity to respond to each comment made by the IRO. Provided it does not delay the timely filing of the Annual Reports, any responses by Jazz may be included in the IRO report submitted to the OIG. Otherwise, any responses by Jazz to the IRO's findings may be submitted separately to the OIG following the Annual Report submission.

III. Promotional and Product Services Transactions Review

The IRO shall conduct a Promotional and Product Services Transactions Review for each Reporting Period. As described below, each Transactions Review shall include a review of a sample of Inquiries reflected in the Inquiries Database.

A. Promotional and Product Services Transactions Review

As described in Section III.K of the CIA, Jazz has implemented a policy

addressing the appropriate handling of requests for information about non-FDA approved uses of products (off-label information). Jazz documents and records all Inquires (as defined in Section III.B.2.f) and the responses thereto in an Inquiries Database. The Inquiries Database shall include the items set forth in Section III.B.2.f for each Inquiry. On a monthly basis, reports of the Inquiries are provided to the Compliance Officer and reviewed to determine whether improper promotion may have occurred in connection with one or more Inquires. If the Compliance Officer suspects that improper promotion may have occurred, the Compliance Officer undertakes an Off-Label Review as described in Section III.K.

As part of the Promotional and Product Services Transactions Review, the IRO shall evaluate Jazz's processes relating to its Inquiries Database. Specifically, the IRO shall select a random sample of 25 Inquiries from among the Inquiries reflected in the Inquiries Database for each Reporting Period.

For each Inquiry reviewed, the IRO shall determine:

i) whether each item of information listed in Section III.B.2.f of the CIA is reflected in the Inquiries Database for each reviewed Inquiry; and

ii) for each Inquiry for which the Compliance Officer conducted an Off-Label Review, the basis for suspecting that improper off-label promotion may have occurred; the steps undertaken as part of the Off-Label Review; the findings of the Compliance Officer as a result of the Off-Label Review; and any follow-up actions taken by Jazz based on the Compliance Officer's findings.

B. Promotional and Product Services Transactions Review Report

The IRO shall prepare a report which shall include the following:

1. Elements to be Included:

a. Promotional and Product Services Transactions Review Objectives: A clear statement of the objectives intended to be achieved by the Review;

b. Engagement Protocol: A detailed narrative description of the procedures performed and a description of the universe of Inquiries from which the samples were selected; and

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

2. Results to Be Included:

The following results shall be included in each Promotional and Product Services Transactions Review Report:

a. a description of each type of sample unit reviewed, including the number of each type of sample reviewed (*i.e.,* the number of Inquiries) and an identification of the types of documents and information reviewed for the Inquiries;

b. for each Inquiry sample unit, the IRO shall summarize the information contained in the Inquiries Database about the Inquiry;

c. for each Inquiry sample unit, the IRO shall state its findings and supporting rational as to whether: (i) each element listed in Section III.B.2.f of the CIA is reflected in the Inquiries Database for each reviewed Inquiry; (ii) for each Inquiry for which the Compliance Officer conducted an Off-Label Review, the basis for suspecting that improper off-label promotion may have occurred; the steps undertaken as part of the Off-Label Review; the findings of the Compliance Officer as a result of the Off-Label Review; and any follow-up actions taken by Jazz as a result of the Compliance Officer's findings;

d. the findings and supporting rationale regarding any weaknesses in Jazz's systems, processes, policies, and practices relating to the Inquiries, if any; and

e. recommendations for improvement in Jazz's systems, processes, policies, and practices relating to the Inquires, if any.

Prior to the IRO's submission of the report to the OIG, Jazz shall be provided with a copy of the report and an opportunity to respond to each comment made by the IRO. Provided it does not delay the timely filing of the Annual Reports, any responses by Jazz may be included in the IRO report submitted to the OIG. Otherwise,

any responses by Jazz to the IRO's findings may be submitted separately to the OIG following the Annual Report submission.