

## **Policy**

Policy No.: 00007406 Version Number: 6

**Policy Title:** Jazz Pharmaceuticals Comprehensive Compliance Program

**Effective** Owning

Date: Jun 1, 2019 4:46:20 PM Department: Corporate: Legal & Compliance

## **Jazz Pharmaceuticals Comprehensive Compliance Program**

Jazz Pharmaceuticals has declared its commitment to support a comprehensive compliance program as required by California Health and Safety Code §§ 119400 to 119402. As a part of this effort, we have adopted a Comprehensive Compliance Program ("CCP") that addresses the matters covered by the May 2003 publication "Compliance Program Guidance for Pharmaceutical Manufacturers" ("OIG Guidance"), which was developed by the United States Department of Health and Human Services Office of Inspector General ("OIG"). The OIG Guidance gives broad discretion to manufacturers in the development, design and definition of scope of a compliance program. In particular, the CCP establishes a specific annual dollar amount on those gifts, promotional materials, or items or activities that Jazz Pharmaceuticals may provide to an individual medical or healthcare professional ("HCP"), as required by California law.

The CCP's purpose is to assist Jazz Pharmaceuticals in maintaining compliance with the laws, regulations and company directives and guidance that apply to the development and commercialization of our products, to train our employees on these matters and to prevent, detect, and correct instances of non-compliance. Jazz Pharmaceuticals expects that our employees and agents will comply with all applicable Jazz Pharmaceuticals directives and guidance relating to the development and commercialization of our products, as well as the related laws, regulations, and health plan program requirements that apply to our development and commercialization activities. In the event that Jazz Pharmaceuticals becomes aware of non-compliance relating to the development and commercialization of our products, we will investigate the matter and, where appropriate, take disciplinary action, up to and including employee termination, and implement corrective measures to prevent future non-compliance.

The CCP is summarized below. The CCP is dynamic; Jazz Pharmaceuticals intends to regularly review and modify the CCP to meet its evolving compliance needs. Accordingly, the CCP may be amended or revised by Jazz Pharmaceuticals from time to time.



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# Summary of Jazz Pharmaceuticals' Comprehensive Compliance Program

- As a condition of new or continued employment at Jazz Pharmaceuticals, all employees receive training on Jazz Pharmaceuticals' Code of Conduct. New personnel will receive such training as part of their initial training and existing personnel are expected to receive compliance training on at least an annual basis. Moreover, Jazz Pharmaceuticals will review and update its training programs periodically, as well as identify additional areas of training on an ongoing basis.
- Jazz Pharmaceuticals also has established guidance regarding appropriate interactions with health care professionals. It is Jazz Pharmaceuticals' policy to comply with the Pharmaceutical Research and Manufacturers of America ("PhRMA") "Code on Interactions with Health Care Professionals," updated January 2009, which includes limits on gifts, meals and other activities with health care professionals. Accordingly, Jazz Pharmaceuticals has implemented policies and procedures to ensure that the annual dollar amount on gifts, promotional materials, or items or activities provided to an individual medical or healthcare professional practicing in the state of California does not exceed \$1,500. This limit excludes financial support for continuing medical education forums, financial support for health educational scholarships, and payments made at fair market value for legitimate professional services provided by healthcare professionals as permitted by the applicable rules.
- Jazz Pharmaceuticals' Chief Compliance Officer has overall responsibility for oversight of the CCP. This includes oversight of the development and operation of the CCP. The Chief Compliance Officer has been vested with the authority relating to compliance within the organization and shall exercise independent judgment concerning these matters. In this role, the Chief Compliance Officer reports directly to the Chief Executive Officer and makes reports to the Chief Executive Officer and Board of Directors concerning operation of the CCP.
- Jazz Pharmaceuticals has various methods for employees, directors and third parties to report suspected violations of laws, rules, regulations or company policies. Employees are encouraged to report possible violations to a manager or a member of the Human Resources department or a member of the Legal or Compliance departments. Employees may also contact directly the Chief Compliance Officer, the General Counsel, Chief Financial Officer or the Chair of the Audit Committee, or their respective designees, depending on the nature of the possible violation. Suspected violations may also be reported anonymously to EthicsPoint, a compliance reporting service, using any of the following methods:



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• **Telephone**: Local country numbers and other information about the Compliance Hotline are available on the corporate website.

• Web: http://www.jazzpharma.ethicspoint.com or http://www.ethicspoint.com

Information provided is kept strictly confidential to the extent reasonably possible. It is the company's policy to comply with the legal protections provided to employees who report suspected violations or participate in investigation of such reports.

- Acts of retaliation or retribution against an employee who in good faith reports a potential, suspected, planned or actual violation or application of Jazz Pharmaceuticals directives and guidelines and/or laws which govern Jazz Pharmaceuticals' activities are not permitted and will be dealt with appropriately.
- The Chief Compliance Officer, or a designee, is to oversee the review of non-compliance reports and determine whether further investigation is necessary. When deemed necessary, the Chief Compliance Officer, or a designee, will conduct an investigation into potentially non-compliant activity to determine whether a violation of the Compliance Program has occurred. As necessary to evaluate a report or to undertake further investigation, the Chief Compliance Officer may request the assistance of outside experts or legal counsel.
- It is a role of the Chief Compliance Officer to develop a plan for auditing and monitoring compliance with the CCP and the implementation of related directives and guidelines. These audits are intended to identify potential or existing problem areas and to take corrective measures in an effort to prevent the recurrence of non-compliance. The nature of our reviews as well as the extent and frequency of our compliance monitoring and auditing varies according to a variety of factors, including new regulatory requirements, changes in business practices and other considerations.
- The Chief Compliance Officer is also responsible for overseeing the implementation of corrective measures in response to non-compliance with the CCP. Corrective measures take into account the findings of reviews of non-compliance, and may include appropriate and consistent disciplinary action regardless of the individual's position within the organization (up to and including termination), assessing whether enhancements should be made to our policies, practices, training, or internal controls, and taking action to prevent future non-compliance.

This version of the Jazz Comprehensive Compliance Program is effective on 1 June 2019.