

ANNUAL DESCRIPTION OF KRYSTAL BIOTECH, INC.'S COMPREHENSIVE COMPLIANCE PROGRAM

Pursuant to California Health and Safety Codes §§ 119400-119402

Krystal Biotech, Inc. ("Krystal") is committed to the principles of good corporate citizenship, integrity and compliance with applicable laws and regulations. A key component of this commitment—which is relevant to Krystal's relationships with the government, employees, and customers—is establishing and maintaining an effective compliance program.

The "Compliance Program Guidance for Pharmaceutical Manufacturers," published by the Office of Inspector General, U.S. Department of Health and Human Services (the "OIG Guidance") outlines seven key elements of an effective compliance program. Based on these elements, Krystal has implemented a comprehensive compliance program (the "Compliance Program"), which puts Krystal's ethical principles into practice on a daily basis. In addition, Krystal's compliance program adopts the "Code on Interactions with Health Care Professionals" as may be amended from time to time by the Pharmaceutical Research and Manufacturers of America (PhRMA).

The fundamental elements of the current Compliance Program are described below.

1. Leadership and Structure

Krystal maintains a Healthcare Compliance Officer ("Compliance Officer") and Healthcare Compliance Committee ("Compliance Committee"). Together, the Compliance Officer and Compliance Committee are responsible for overseeing Krystal's program for complying with the applicable federal and state healthcare laws and regulations, and for adhering to the highest ethical standards in its activities including research and development, education, marketing and promotional, activities. Krystal is committed to ensuring that the Compliance Officer and Compliance Committee have the resources and authority to exercise independent judgment and to effectuate change within the organization as necessary to establish and maintain the Compliance Program.

2. Written Standards

Krystal's Compliance Program includes a Code of Business Conduct and Ethics (available at www.krystalbio.com) and set of written compliance policies, procedures and practices that guide Krystal and the conduct of its employees in day-to-day operations. These policies and procedures have been developed under the direction and supervision of Krystal's Compliance Officer, Compliance Committee, and management from various functional areas.

3. Education and Training

The education and training of Krystal personnel regarding their legal and ethical obligations under applicable laws, including federal healthcare programs, is a critical element of Krystal's Compliance Program.

Relevant personnel receive annual training that covers pertinent areas of Krystal's Compliance Program, including healthcare compliance policies and procedures and the relevant legal requirements. Training takes a variety of forms, including live training and written materials. Employees must certify completion of training and/or complete a testing

regimen. Krystal also regularly reviews and revises its education and training programs, as well as identifies any new areas of education and training that may have become necessary.

4. <u>Internal Lines of Communication</u>

Krystal is committed to fostering dialogue between management and employees. Employees may seek guidance when uncertain as to the appropriate course of conduct in adhering to Krystal's ethics and compliance standards. In most instances, employees with questions or concerns regarding appropriate conduct should address the issue to their supervisor. Alternatively, any employee may request assistance and advice from various departments within Krystal and may contact the Compliance Officer directly. Finally, Krystal maintains an email address for the reporting of compliance concerns including on an anonymous basis. Krystal's goal is that all employees, when addressing concerns or reporting potential violations, should know who to turn to for a meaningful response and should be able to do so without fear of retribution.

5. Auditing and Monitoring

Krystal's Compliance Officer, supported by the Compliance Committee, is responsible for monitoring, auditing and evaluating the Compliance Program. Such auditing and monitoring may include internal reviews as well as use of third parties. In accordance with OIG Guidance, the nature, extent and frequency of compliance monitoring and auditing varies according to a number of factors, including new regulatory requirements, changes in business practices and other considerations.

6. Responding to Potential Violations

Violation of applicable laws, any of the provisions of the Compliance Program, or other Krystal policies may result in disciplinary action pursuant to Krystal policies. Upon identification of possible violations or other noncompliance, the Compliance Officer is responsible for commencing an investigation to determine whether there has been a violation and the materiality of any such violation. Although each situation is considered on a case-by-case basis, Krystal will consistently undertake appropriate disciplinary action to address inappropriate conduct and deter future violations.

7. Corrective Action Procedures

An effective Compliance Program increases the likelihood of identifying and preventing non-compliant, unlawful and/or unethical behavior. However, OIG recognizes that even an effective Compliance Program may not prevent all violations. As such, it is Krystal's policy to respond promptly to potential violations of law, regulation or Krystal policies, take appropriate disciplinary action, assess whether the violation is in part due to gaps in policies, practices or internal controls and, if so, revise its policies, practices and internal controls to help prevent future violations.

Further to Krystal's Compliance Program, Krystal has developed and implemented a variety of policies and procedures that, together, form a Marketing Code of Conduct that adopts the principles of the Pharmaceutical Research and Manufacturers of America (PhRMA) "Code on Interactions with Health Care Professionals," as updated from time to time. All Krystal employees are trained on, and expected to follow these policies and procedures, which address the following principles:

- A. Basis of Interactions Our interactions with Healthcare Professionals ("HCPs") are professional exchanges designed to benefit patients and to enhance the practice of medicine. Krystal always communicates about its products, and relevant disease states, in a manner that is truthful, accurate and not misleading, and in compliance with all applicable laws, regulations and guidelines regarding promotional and non-promotional communications including the Food Drug and Cosmetics Act.
- **B.** Informational Presentations Accompanied by Modest Meals Krystal Commercial Personnel may communicate with HCPs to educate and inform them about the benefits, risks and appropriate uses of Krystal products and related disease areas. When presenting information to HCPs during mealtimes, Krystal employees may provide a meal for the attendees of the presentation so long as it is conducive to the presentation and not the focus of the meeting. All meals must be modest as judged by local standards.
- **C. Prohibition on Entertainment and Recreation -** The provision of, or payment for, entertainment or recreational items of any kind to HCPs (e.g., tickets to concerts, sporting, golfing, or other recreational events) is entirely prohibited.
- D. Company Support for Continuing Medical Education and 3rd Party Educational or Professional Meetings - Krystal may not provide funding for Continuing Medical Education (CME), sponsorships, medical education grants, or charitable donations to induce an HCP to prescribe or recommend a Krystal product, or as a reward for having previously done so. Krystal sales personnel may not be involved in funding CME, medical education grants, or charitable donations.
- **E.** Consultants Where a legitimate business need exists, Krystal may retain the services of HCPs. Such engagements may never be entered with the intent of inducing the HCP to prescribe or recommend a Krystal product, or as a reward for having previously done so. Krystal policies require a legitimate documented business need for the services, appropriate selection of the HCP based on their qualifications and expertise, payment of Fair Market Value compensation, and execution of an approved contract.
- F. Educational Speaker Programs and Speaker Training Meetings Educational Speaker Programs are Krystal-sponsored meetings lead by HCPs who have been retained as speakers to educate other HCPs about Krystal's approved products and disease areas. Speakers must be trained by Krystal prior to conducting a speaker program. Speakers are selected based only on objective criteria founded in the HCP's medical expertise, reputation, therapeutic experience, and communication skills. Krystal may only provide speakers with Fair Market Value (FMV) compensation for their bona fide services in

connection with completing their training and conducting speaker programs. Speakers may also receive reimbursement for reasonable travel, lodging, and meals, consistent with Krystal policies.

- G. HCPs Who are Members of Formulary or Clinical Practice Guideline Committees HCP who serve as consultants for Krystal and who are also members of a formulary or clinical guideline committee must disclose their relationship with Krystal to the committee.
- H. **Scholarships and Educational Funds -** Krystal may provide grants to hospitals and universities to support the attendance of HCPs at major medical conferences. This funding must always be provided to the institution and not an individual. Krystal may not be involved in identifying HCPs to benefit from this funding.
- **I. Prohibition of Non-Education and Practice Related Items -** Krystal personnel may not provide gifts or other non-educational items or services to HCPs even if they are of nominal value or are accompanied by patient or physician educational materials.
- **J. Educational Items -** Krystal personnel may occasionally provide HCPs with items designed to educate patients or HCPs, or for use by patients to assist in the administration of their treatment or management of their conditions, if the items are not of substantial value (\$100 or less) and do not have value to the HCP outside of his/her professional responsibilities.
- K. **Prescriber Data -** Krystal respects the confidential nature of prescriber data and will abide by the wishes of any HCP who asks that their prescriber data not be made available to company sales representatives.
- L. **Independence of Decision Making -** No grants, scholarships, subsidies, support, consulting contracts, or educational- or practice-related items should be provided or offered to an HCP in exchange for prescribing products or for a commitment to continue prescribing products. Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a HCP's prescribing practices.
- M. **Training and Conduct of Company Representatives -** Relevant Krystal personnel receive annual training that covers pertinent areas of Krystal's Compliance Program, including healthcare compliance policies and procedures and the relevant legal requirements.

Dated July 1, 2023