

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

**I. PREAMBLE**

InterMune, Inc. (InterMune) 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 requirements). Contemporaneously with this CIA, InterMune is entering into a Settlement Agreement with the United States. InterMune will also enter into settlement agreements with various States, and InterMune's agreement to this CIA is a condition precedent to those agreements.

Prior to the investigation of InterMune by the United States, InterMune established a comprehensive voluntary 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 InterMune, to promote compliance with applicable laws and the promotion of high ethical standards.

InterMune shall continue the operation of the Compliance Program in accordance with the terms set forth below for the term of this CIA. InterMune may modify its Compliance Program as appropriate, but, at a minimum, InterMune shall ensure that during the term of this CIA, it shall comply with the integrity obligations enumerated in this CIA.

**II. TERM AND SCOPE OF THE CIA**

A. The period of the compliance obligations assumed by InterMune under this CIA shall be 5 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 the Effective Date, 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) InterMune's final Annual Report; or (2) any additional materials submitted by InterMune 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 InterMune; and
  - b. all contractors, subcontractors, agents, and other persons who perform sales, marketing, promotional, pricing, government contract, and research and development activities (except preclinical researchers and clinical investigators) on behalf of InterMune.

Notwithstanding the above, this term 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 InterMune whose job responsibilities relate to the provision of information about or services relating to InterMune's products; distribution of Actimmune or other InterMune products; research and development (except preclinical researchers and clinical investigators); or the sales, marketing, or promotion of InterMune's products (hereafter collectively referred to as "Product Services Related Functions.") This includes, but is not limited to, Medical Science Liaisons, and any individuals who work in the following areas: Clinical Affairs, Medical Affairs, Regulatory, Legal Affairs, Corporate Compliance, Corporate Administration, and Commercial Operations.<sup>1</sup>

3. "Third Party Personnel" shall mean personnel of the entities with whom InterMune has or may, in the future, enter agreements to distribute and purchase its products, joint venture agreements and/or other agreements to co-market its products. InterMune has represented that: 1) Third Party Personnel are employed by other independent entities; 2) InterMune does not control Third Party Personnel; and 3) it would be commercially impracticable to compel the compliance of Third Party Personnel with the requirements set forth in this CIA. However, InterMune agrees to use its best efforts to promote compliance by Third Party Personnel with Federal health care program and FDA requirements as set forth below in Sections III.B and V.

4. 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.

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<sup>1</sup> If there are future changes in the organizational structure of InterMune, individuals who undertake the functions of the specific groups enumerated in the preceding sentence shall be considered Relevant Covered Persons.

### III. CORPORATE INTEGRITY OBLIGATIONS

To the extent not already accomplished, InterMune shall maintain a Compliance Program throughout the term of this CIA that includes the following elements:

#### A. Compliance Officer and Committee.

1. *Compliance Officer.* InterMune presently has a Compliance Officer with responsibility for administering InterMune's Compliance Program. InterMune shall continue to employ an individual to serve as its Compliance Officer during 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 requirements and FDA requirements. The Compliance Officer shall be a member of senior management of InterMune, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of InterMune, and shall be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall also have the option of reporting any matter directly to the CEO. 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 InterMune as well as for any reporting obligations created under this CIA.

InterMune 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, InterMune established a Compliance Committee, and InterMune shall maintain the Compliance Committee during the term of this CIA. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as Clinical Affairs, Medical Affairs, Regulatory, Legal Affairs, Corporate Compliance, Corporate Administration, and Commercial Operations.) The Compliance Officer shall chair the Compliance Committee. The Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

InterMune 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.* Prior to the Effective Date, InterMune established a written Code of Conduct applicable to all Covered Persons. InterMune shall continue to 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. InterMune's commitment to full compliance with all Federal health care program and FDA requirements, including its commitment to market, sell, promote, research, develop, and advertise its products in accordance with such requirements;
- b. InterMune's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program and FDA requirements and with InterMune's own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this CIA);
- c. the requirement that all of InterMune's Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by InterMune, suspected violations of any Federal health care program or FDA requirements or of InterMune's own Policies and Procedures;
- d. the possible consequences to both InterMune and Covered Persons of failure to comply with Federal health care program and FDA requirements and with InterMune'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 InterMune's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

To the extent not already accomplished, 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 InterMune'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.

Within 90 days after the Effective Date, and annually thereafter by the anniversary of the Effective Date, InterMune shall send a letter to all entities which employ Third Party Personnel. The letter shall outline InterMune's obligations under the CIA and its commitment to full compliance with all Federal health care program and FDA requirements. The letter shall include a description of InterMune's Compliance Program. InterMune shall attach a copy of its Code of Conduct to the letter and shall ask that the other entity either: (a) make a copy of InterMune's Code of Conduct and the description of InterMune's Compliance Program available to all relevant personnel within its organization; or (b) represent to InterMune that it has and enforces a substantially comparable Code of Conduct and Compliance Program for relevant persons within its organization.

InterMune 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.

Distribution may include publishing the Code of Conduct on InterMune's intranet or other internal web site available to all employees. If InterMune uses such an electronic method of distribution, it must notify the individuals receiving the Code of Conduct that the Code of Conduct will be distributed in such a manner and InterMune must monitor the distribution to ensure that all appropriate individuals received the Code of Conduct.

2. *Policies and Procedures.* To the extent not already accomplished, within 90 days after the Effective Date, InterMune shall implement written Policies and Procedures regarding the operation of InterMune'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 InterMune 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);
- c. selling, marketing, promoting, advertising, and disseminating information about InterMune'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 InterMune's products;
- e. employee discipline for violations of InterMune's Policies and Procedures, including those policies relating to Federal health care program and FDA requirements;
- f. appropriate mechanisms by which Medical Affairs receives and responds to requests for information about off-label uses of InterMune's products, including but not limited to, the following: the form and content of information disseminated by Medical Affairs in response to such requests; and the internal review process for the information disseminated.

The Policies and Procedures shall include a requirement that InterMune develop a database (the Medical Affairs Inquiries Database) that includes the following items of information for each unique inquiry (Inquiry) received for information about InterMune'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 InterMune (including a record of the materials provided to the

HCP in response to the request); 7) the name of the InterMune representative who called on or interacted with the HCP; and 8) the status and findings of any follow-up review conducted by InterMune 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.4 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 InterMune'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 InterMune'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 InterMune'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 InterMune in a manner that is designed to ensure that InterMune'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.

To the extent not already accomplished, 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), InterMune 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.

Distribution may include publishing such Policies and Procedures on InterMune's intranet or other internal web site available to all employees. If InterMune uses such an electronic method of distribution, it must notify the individuals receiving the Policies and Procedures that the Policies and Procedures will be distributed in such a manner and InterMune must monitor the distribution to ensure that all appropriate individuals received the Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

### C. Training and Education.

1. *General Training.* Within 90 days after the Effective Date, InterMune shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain InterMune's:

- a. CIA requirements;
- b. InterMune'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 InterMune'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. InterMune may satisfy its remaining General Training obligation for those Covered Persons who received training as described above by notifying the Covered Persons of the fact that InterMune entered a CIA and notifying them of InterMune'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 90 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 90 days after the Effective Date, each Relevant Covered Person shall receive at least four hours of Specific Training in addition to the General Training required above. This Specific Training shall include a discussion of:

- a. all Federal health care program requirements relevant to the proper methods for selling, marketing, promoting, and providing information about

