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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. INTERMUNE, INC., Defendant.	No. CR 06-0707 JSW VIOLATION: 21 U.S.C. §§ 331(k), 333(a)(2) - Misbranding SAN FRANCISCO VENUE **DEFERRED PROSECUTION AGREEMENT**

DEFERRED PROSECUTION AGREEMENT

InterMune, Inc. ("InterMune"), by its undersigned officer, and the Department of Justice, by the United States Attorney's Office for the Northern District of California (the "Department"), enter into this Agreement in resolution of the Department's ongoing criminal investigation into matters relating to the promotion of the pharmaceutical product Actimmune® (interferon gamma-1b) by InterMune from a time period spanning 2000 to 2003.

For purposes of this Agreement, the relevant time period is from August 2002 through

January 2003 (the "Investigative Period"). The effective date of this Agreement will be the date that it is accepted by the Court for the Northern District of California.

This Agreement is binding upon InterMune, Inc. and the Attorney General for the United States, the United States Department of Justice, and all United States Attorneys. This Agreement does not bind the Tax Division of the U.S. Department of Justice or the Internal Revenue Service of the U.S. Department of the Treasury. InterMune, Inc. understands that this Agreement does not bind any state or local prosecutive authorities.

INFORMATION

1. The United States will file an Information in the United States District Court for the Northern District of California charging InterMune with One Count of doing an act, with intent to defraud or mislead, with respect to a drug while the drug was held for sale after shipment in interstate commerce that resulted in the drug being misbranded, in violation of Title 21, United States Code, Sections 331(k) and 333(a)(2) (the "Information").

THE DEPARTMENT'S INVESTIGATION

2. During the course of the investigation, the Department notified InterMune that certain former InterMune personnel violated federal criminal law, specifically that certain former InterMune employees promoted Actimmune® for unapproved indications and made misleading statements regarding Actimmune in violation of: (a) the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 331; and (b) Health Care Fraud, 18 U.S.C. § 1347. As described more fully below, InterMune has provided extensive cooperation to the Department in this investigation.

3. InterMune does not contest that the Department has developed evidence during its investigation that one or more former InterMune employees violated federal criminal law during the Investigative Period. One or more former InterMune employees instructed certain members of the Actimmune sales force and a specialty pharmacy to promote Actimmune for idiopathic pulmonary fibrosis, an indication other than those for which the drug had received FDA approval. InterMune acknowledges that part of the Department's investigation is set forth in

Attachment A and does not contest the facts set forth in Attachment A. InterMune accepts responsibility for the conduct of its former employees and conduct its former employees directed. InterMune does not endorse, ratify or condone criminal conduct, and, as set forth below, has taken steps to prevent such conduct from occurring in the future.

COOPERATION AND REMEDIAL MEASURES

4. InterMune provided substantial cooperation and assistance to the Department's investigation.

A. First, InterMune disclosed the results of internal investigations that had occurred prior to the Department's investigation and related to the conduct set forth in Attachment A.

B. Second, InterMune fully complied with the subpoena served by the Department and provided significant information regarding the conduct of certain former employees and officers.

C. Third, InterMune made numerous presentations that were helpful to the Department's investigation.

D. Fourth, InterMune made certain current employees and officers who were employed by the Company during the period of investigation available to the Department in connection with its investigation.

InterMune has agreed to, and will, continue to fully cooperate with the Department as may be reasonably required during the term of this agreement, which is two (2) years from the effective date of this Agreement.

5. InterMune's management team -- the great majority of whom were hired after the Investigative Period -- also instituted numerous and comprehensive compliance changes, including new compliance policies, audits and internal reviews, and revised sales representative compensation programs. These compliance changes were instituted by the Company prior to the commencement of the Department's investigation.

AGREEMENT

6. Based upon InterMune's significant cooperation and the corrective measures it has implemented, and InterMune's commitment to implement and audit such measures and its willingness to continue to cooperate with the Department in its investigation of these matters, the Department, on the understandings specified below, agrees that the Department shall recommend to the Court that prosecution of InterMune on the Information be deferred for a period of two (2) years from the effective date of this Agreement (the "Effective Period"). InterMune shall expressly waive all rights to a speedy trial pursuant to the Sixth Amendment of the United States Constitution, Title 18, United States Code, Section 3161, Federal Rule of Criminal Procedure 48(b), and any applicable Local Rules of the United States District Court for the Northern District of California for the period during which this Agreement is in effect.

7. The Department agrees that if InterMune is in compliance with all of its obligations under this Agreement, the Department will, within 30 days of the expiration of two (2) years from the effective date of this Agreement, seek dismissal with prejudice of the Information filed against InterMune pursuant to paragraph 1 of this Agreement, and this Agreement shall expire. Except in the event of a breach of this Agreement, the Department will bring no additional criminal charges against InterMune relating to or arising out of matters set forth in the Information or in Attachment A or the promotion of Actimmune during the period 2000 through 2003; the Department acknowledges that this Agreement protects InterMune from indictment and/or trial as to such matters. InterMune and the Department understand that the Agreement to defer prosecution of InterMune must be approved by the Court, in accordance with 18 U.S.C. § 3161(h)(2). Should the Court decline to approve the Agreement to defer prosecution for any reason, both the Department and InterMune are released from any obligation imposed upon them by this Agreement, and this Agreement shall be null and void.

8. This Agreement does not provide any protection to any former employee of InterMune or any other entity, except successor entities as described in Paragraph 19, below. InterMune understands and agrees that if it violates this Agreement, the Department can prosecute

InterMune for any crimes committed by its employees, officers or directors relating to the promotion of Actimmune®.

The understandings on which this Agreement are premised are:

9. For the Effective Period, InterMune shall continue to fully cooperate with the Department regarding any matter relating to the Department's investigation of the promotion of Actimmune about which InterMune has information or knowledge, including, but not limited to, the following: (a) InterMune shall truthfully disclose all information of which it may be aware with respect to the activities of InterMune, its directors, officers and employees, about which the Department shall inquire; (b) InterMune shall provide to the Department, on written request, any document, record or other tangible evidence, including but not limited to information and documents concerning presentations, publications, and patient registries, about which the Department shall inquire; (c) InterMune shall provide to the Department reasonable access to InterMune's facilities, documents and employees. In addition,

A. InterMune will use its best efforts to continue to make records and witnesses available during the Effective Period regarding activities of the Company during the Investigative Period, provided, however, this agreement to cooperate does not apply to any information provided by InterMune to legal counsel after May 1, 2004 in connection with the provision of legal advice and the legal advice itself, and nothing in this Agreement shall be construed to require InterMune to provide any such information or advice to the Department.

B. This agreement by InterMune to cooperate shall not be construed as a waiver with respect to third parties of the attorney-client privilege, work-product protection, or any other privilege applicable to information or documents provided to the Department pursuant to this Agreement; InterMune neither expressly nor implicitly waives its right to assert any privilege that may be available against entities other than the Department of Justice.

C. This agreement to cooperate shall not apply in the event that the Department pursues a criminal prosecution against InterMune.

10. Upon request of the Department, with respect to any issue relevant to its investigation of the promotion of Actimmune at any time (not limited to the Investigative Period), InterMune shall designate knowledgeable employees, agents or attorneys to provide non-privileged information and/or materials on InterMune's behalf to the Department. It is further understood that InterMune must at all times give complete, truthful and accurate information to the Department.

11. With respect to any information, testimony, document, record or other tangible evidence relating to the promotion of Actimmune provided by InterMune to the Department or a grand jury, InterMune consents to any and all disclosures to governmental law enforcement entities of such materials as the Department, in its reasonable discretion and in good faith, deems appropriate. With respect to any such materials that constitute "matters occurring before the grand jury" within the meaning of Rule 6(e) of the Federal Rules of Criminal Procedure, InterMune further consents to a) any order sought by the Department permitting such disclosure and b) the Department's ex parte or in camera application for such orders. The Department agrees that any material which comprises trade secrets or other proprietary information shall, prior to disclosure to any governmental entity, be redacted of such information, or be accompanied by a prominent warning notifying the agency of the protected status of the material. Nothing in this paragraph shall be construed as a waiver of InterMune's rights in the materials it provides to the Department, and such materials shall not be provided to non-governmental entities without InterMune's prior written consent.

12. InterMune agrees that it will use its best efforts to not make any public statements, in litigation or otherwise, materially contradicting the facts set forth in Attachment A, or its representations in this Agreement. Any such statements shall constitute a breach of this Agreement, and InterMune thereafter would be subject to prosecution unless it cures its breach as set forth below. Upon the Department's providing written notice to InterMune of such a

contradictory statement, InterMune may avoid a breach of this Agreement by publicly repudiating such statement within 72 hours after receipt of written notification by the Department.

13. InterMune is simultaneously entering into an agreement with the Department's Civil Division (the "Civil Settlement Agreement") regarding the payment of money to settle certain civil claims. InterMune is also simultaneously entering into a Corporate Integrity Agreement ("CIA") with the Office of Inspector General of the Department of Health and Human Services ("OIG-HHS") to implement certain specified compliance measures. Failure by InterMune to comply fully with those material terms of the Civil Settlement Agreement called to occur during the Effective Period of this Agreement may constitute a breach of this Agreement, provided, however, that a breach of the CIA referenced in the Civil Settlement Agreement does not constitute a breach of this Agreement. Any disputes arising under the CIA shall be resolved exclusively through the dispute resolution provisions of the CIA. The parties understand that nothing in this paragraph shall be construed to enlarge the Effective Period of this Agreement, or to delay the dismissal of the Information as described in paragraph 7 if at the time specified therein, InterMune is in full compliance with its obligations under the Civil Settlement Agreement. The parties further understand and agree that this paragraph does not deprive InterMune of its rights under the Civil Settlement Agreement or the common law to contest the existence of a breach of the Civil Settlement Agreement in the Northern District of California. The Department further agrees that nothing in this paragraph shall be construed by the United States as affecting the underlying nature of InterMune's obligations under the Civil Settlement Agreement.

14. It is further understood that should it be determined that InterMune has deliberately given materially false, incomplete, or misleading information under this Agreement, or has committed any criminal health care fraud offense during the Effective Period, or that InterMune has otherwise knowingly, intentionally and materially violated any provision of this Agreement, InterMune shall, in the Department's reasonable discretion and in good faith, thereafter be

subject to prosecution for any federal criminal violation of which the Department has knowledge. Any such prosecutions may be premised on information provided by InterMune to the Department. Moreover, InterMune agrees that any criminal prosecutions relating to the unlawful promotion of Actimmune from 2000 through 2003 that are not time-barred by the applicable statute of limitations on the effective date of this Agreement may be commenced against InterMune in accordance with this Agreement, notwithstanding the expiration of the statute of limitations between the effective date of this Agreement and its expiration date two years after the date this Agreement is accepted by the Court. By this Agreement, InterMune expressly intends to and does waive any rights with respect to the statute of limitations as described in the preceding sentence.

15. It is further agreed that should it be determined that InterMune has knowingly, intentionally and materially violated any provision of this Agreement:

A. all statements made by InterMune to the Department, FDA, HHS-OIG, the FBI or any other federal agency, or any testimony given by InterMune before a grand jury, the United States Congress, the SEC, or elsewhere, whether prior or subsequent to this Agreement, including this Agreement and the statement of facts in Attachment A, shall be admissible in evidence in any and all criminal proceedings brought by the Department against InterMune;

B. nothing in this agreement shall prohibit the admission in such proceedings of any evidence derived from such statements or testimony; and

C. InterMune shall not assert any claim under the United States Constitution, Rule 11(f) of the Federal Rules of Criminal Procedure, Rule 410 of the Federal Rules of Evidence, or any other federal rule, that statements made by InterMune prior to or subsequent to this Agreement, or any leads therefrom, should be suppressed.

16. In the event the Department asserts that InterMune has breached any provision of this Agreement, the Department shall provide written notice to InterMune and will provide InterMune with a two-week period from receipt of such notice, except as otherwise specified

herein, in which to make a presentation to the Department, or its designee, to demonstrate that no breach has occurred, or, to the extent applicable, that the breach was not knowing, intentional or material, or has been cured. The Department shall have four weeks from providing written notice to InterMune asserting a breach to file a motion with the Court asserting the breach and seeking a finding of a breach; however, this motion shall not be filed less than 15 days from the day the Department provides InterMune written notice asserting the breach. In the event a motion is filed by the Department, the Court shall determine whether a breach occurred by a preponderance of the evidence.

17. InterMune agrees to not enter into any joint defense agreements relating to the Department's investigation during the Effective Period of this Agreement without Department approval, and InterMune further agrees to withdraw from current joint defense agreements, if any exist, for which the Department does not approve of InterMune's continuing participation. The Department agrees that its approval pursuant to this paragraph will not be unreasonably withheld.

18. The Company agrees that if it sells or merges all or substantially all of its business operations as they exist as of the date of this Agreement to or into a single purchaser or group of affiliated purchasers during the term of this Agreement, it shall provide the Government with reasonable prior notice and it shall include in any contract for sale or merger a provision binding the purchaser-successor to the obligations described in this Agreement.

19. With respect to the matters described in this Agreement, and with the exception of the agreements described in paragraph 13, and the letter from Ethan M. Posner to the Department dated October 9th, 2006, this Agreement supersedes all prior, if any, understandings, promises, and/or conditions between the Department and InterMune. This Agreement may not be modified except in writing signed by all the parties.

20. InterMune hereby warrants and represents that the Board of Directors of InterMune has duly authorized, in a specific resolution, the execution and delivery of this Agreement by InterMune, and that the person signing the Agreement has authority to bind InterMune. InterMune agrees that either a duly authorized corporate officer or a duly authorized attorney for

InterMune, at the discretion of the Court, shall appear on behalf of InterMune to enter into this Agreement.

On Behalf of the United States Department of Justice:

10·24·06
DATE

Kevin V. Ryan
United States Attorney
Northern District of California

Ioana Petrou
Assistant United States Attorney

On Behalf Of InterMune, Inc.

DATE

Robin Steele
Senior Vice President and General Counsel
InterMune, Inc.
3280 Bayshore Boulevard
Brisbane, CA 94005

DATE

Ethan Posner
Covington & Burling
Counsel to InterMune, Inc.

On Behalf of the United States Department of Justice:

DATE

Kevin V. Ryan
United States Attorney
Northern District of California

Ioana Petrou
Assistant United States Attorney

On Behalf Of InterMune, Inc.

October 24, 2006
DATE

Robin Steele
Senior Vice President and General Counsel
InterMune, Inc.
3280 Bayshore Blvd
Brisbane, CA 94005

10-24-06
DATE

Ethan M. Posner
Covington & Burling
Counsel to InterMune, Inc.

Attachment A

Attachment A

Introduction

InterMune, Inc., first incorporated in 1998, is a biopharmaceutical company focused on developing and commercializing innovative therapies in pulmonology and hepatology.

During the Investigative Period (August 2002 through January 2003), InterMune derived the majority of its revenue from Actimmune® (interferon gamma-1b). Actimmune was approved by the United States Food and Drug Administration ("FDA") for the treatment of chronic granulomatous disease and severe, malignant osteopetrosis. These diseases affect very small patient populations. The vast majority of Actimmune sales during the Investigative Period were attributable to prescriptions for the treatment of idiopathic pulmonary fibrosis ("IPF"), a debilitating, fatal lung disease for which there is no FDA-approved treatment and which afflicts approximately 83,000 Americans.

Dissemination of Misleading Information Regarding Phase III Trial of Actimmune

1. Commencing in October 2000 and through 2002 InterMune conducted a global Phase III clinical trial of Actimmune for the treatment of IPF that was designed to study whether Actimmune extended the time to disease progression or death. The primary endpoint was progression-free survival , measured from randomization of the test subjects either to disease progression or death, and, in addition, there were a number of secondary endpoints, including overall patient survival. In this clinical study, 330 IPF patients were studied in a double-blind, placebo-controlled trial conducted at 58 centers in the United States and Europe. Study participants received either a placebo or 200 micrograms of Actimmune injected subcutaneously three times per week. All patients were to remain in the trial until the last patient received 48 weeks of therapy. Median treatment duration was 60 weeks.

2. On August 16, 2002, a select number of InterMune personnel received data from the clinical trial. On August 19, 2002, the data was also provided to the Data Monitoring Committee ("DMC"), which had been established in accordance with the protocol of the trial as

an independent committee that monitored safety and efficacy data throughout the trial in order to determine if it was scientifically and ethically appropriate to continue the trial, and to review data from the completed trial. The data showed that the trial failed to achieve statistical significance on the primary endpoint agreed between InterMune and the FDA, or any agreed upon secondary endpoint, including overall survival. After receiving the data, InterMune conducted some additional analysis of the mortality data that involved breaking the patient population into subgroups.

3. Certain senior InterMune personnel discussed these preliminary trial results, including the exploratory subgroup analysis, with representatives of the FDA in an informal telephone conference on August 27, 2002. The purpose of the call was to provide InterMune with the FDA reviewers' preliminary impressions of the data. The FDA representatives told InterMune that any substantive comments represented their own opinions and did not reflect the official opinion of the FDA. During the telephone conference, one FDA representative noted that the study failed to demonstrate efficacy on its primary endpoint. The FDA representative suggested that while the data appeared to show an optimistic trend on overall survival, because the data had failed to achieve statistical significance in the primary endpoint previously agreed with the FDA at the outset of the trial, it was the representative's opinion that the FDA was unlikely to approve the use of Actimmune for the treatment of IPF without further rigorous clinical testing.

4. On August 28, 2002, InterMune publicly announced the results of the Phase III clinical trial of Actimmune for the treatment of IPF in the form of a press release. Former employees of InterMune approved the press release, which was headlined "InterMune Announces Phase III Data Demonstrating Survival Benefit of Actimmune in IPF, with the subheading "Reduces Mortality by 70% in Patients With Mild to Moderate Disease." In the release, InterMune's then-President and CEO characterized the clinical trial results as indicating that "Actimmune may extend the lives of patients suffering from this debilitating disease" and further

stated that "Actimmune is the only available treatment demonstrated to have clinical benefit in IPF, with improved survival data in two controlled clinical trials."

5. By letter dated September 5, 2002 to InterMune, the Chair of the DMC expressed his "serious concerns" with the August 28, 2002 press release. The letter reminded InterMune of, "the DMC's assessment that the trial had failed to establish benefit on the primary endpoint" and that there was no statistically significant evidence of benefit for any of the secondary endpoints. The letter also stated that the press release provided a "serious misrepresentation of results obtained from exploratory data subgroup analyses," referring specifically to the subheading and other statements concerning a survival benefit in the mild to moderate subgroup.

6. In approximately mid-October 2002, a specialty pharmacy that distributed Actimmune disseminated a fax concerning Actimmune for IPF to more than 2,000 pulmonologists. Distribution of the fax had been approved by a former InterMune employee. The fax, like the August 28, 2002 press release, began with the headline, "InterMune Announces Phase III Data Demonstrating Survival Benefit of Actimmune in IPF," and continued with the subheading, "Reduces Mortality by 70% in Patients with Mild to Moderate Disease." The fax also included a copy of the InterMune press release.

7. During approximately September to October 2002, the same specialty pharmacy, again with the approval of a former InterMune employee, distributed a patient letter by mail to Actimmune patients, which was sent along with their Actimmune prescriptions. The patient letter was prepared by the specialty pharmacy's clinical staff from information, including the press release, provided by former InterMune personnel and provided the same misleading information about the results of the Phase III Actimmune trial results. The letter stated that "On August 28, 2002, InterMune, Inc. announced that preliminary data from its Phase III clinical trial of Actimmune (Interferon gamma-1b) injection for the treatment of [IPF] showed a statistically significant reduction in mortality by 70% in patients with mild to moderate IPF. Interferon gamma-1b is the first treatment ever to show any meaningful impact in this disease in clinical trials. These results indicate that Actimmune should be used early in the course of treatment of

this disease in order to realize the most favorable long-term survival benefit." A former InterMune employee approved the final version of the patient letter.

8. Notwithstanding the fact that the Phase III trial failed to establish statistically significant benefits on its primary endpoint or any of its secondary endpoints, including overall survival, and notwithstanding the evaluation of the results by the FDA and DMC, certain former InterMune employees encouraged InterMune sales force personnel to inform physicians that Actimmune demonstrated a survival benefit in mild to moderate IPF patient populations, and certain former sales force personnel did so. Certain former sales personnel also distributed or showed the specialty pharmacy documents to physicians during sales visits.

ASAP Registry

9. In 2001, InterMune established the "Actimmune Safe and Appropriate Use Program" (the "ASAP Registry" or the "Registry"), a registry that collected information about IPF patients taking Actimmune. As described in the Registry Services Agreement between InterMune and the third-party administrator of the Registry, the ASAP Registry was an observational database designed to obtain data on "variation in current diagnostic and therapeutic management of patients receiving Actimmune." Information from the Registry was to be available to InterMune and to participating physicians for research and analysis and "as a basis for scientific presentations and publications."

10. During the Investigative Period, the ASAP Registry was operated substantially by InterMune sales and marketing personnel. During the Investigative Period, InterMune sales representatives were the principal source of Registry enrollment, and were also the principal points of contact for physicians and their offices with respect to the Registry. Sales representatives received incentive payments for patients they enrolled.

11. Although one purpose the ASAP Registry was to gather data on Actimmune patients and make that data available to physicians who had patients enrolled in the Registry, InterMune did not share the data directly with physicians. InterMune provided a brief summary presentation at a scientific meeting in late 2002 in San Diego.

12. During the Investigative Period, there were a number of regulatory and operational issues raised by the third-party administrator concerning the ASAP Registry, including various issues relating to good clinical practices and the extent of InterMune sales representatives' participation in the operation of the Registry.

13. In the spring of 2002, an outside consultant was retained by InterMune to assess the ASAP Registry. In June 2002, the consultant issued a final audit report, which identified a number of problems with the Registry and concluded that absent significant changes, data from the Registry would most likely not be accepted by the regulatory authorities.

Sales Force

14. InterMune employed approximately sixty sales representatives focusing on pulmonology and, in particular, Actimmune, during the Investigative Period. The FDA had not approved Actimmune for the treatment of pulmonary disorders at that time.

15. In January 2001, InterMune acquired rights to Amphotec®, an anti-fungal drug approved by the FDA for the treatment of aspergillosis, including pulmonary aspergillosis. Amphotec was primarily administered in a hospital setting. Prior to the fall of 2002, InterMune's sales representatives had not marketed Amphotec for pulmonary aspergillosis outside the hospital setting. However, in the fall of 2002, sales force personnel relied on Amphotec for access to pulmonologists' offices, where the primary purpose for access to the offices was to discuss Actimmune for IPF.

16. InterMune's Sales Incentive Compensation Plan for 2002 provided that sales representatives would receive a quarterly bonus based on 7% of incremental Actimmune sales and 3.5% of incremental Amphotec sales. The Plan also provided that the bonuses paid to Regional Sales Directors were derived in part from the total earnings of the sales representatives in their regions.

17. During the Investigative Period several sales force personnel sometimes created and used their own marketing aids in discussions with physicians concerning Actimmune for IPF. For example, one former sales representative wrote and distributed an invitation letter to an

educational program, which one physician recipient characterized as "against the spirit of FDA regulations."

Attachment B

CIVIL SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement ("Agreement") is entered into by and between the United States of America, acting through the United States Department of Justice and the United States Attorney's Office for the Northern District of California, on behalf of the Office of Inspector General ("OIG-HHS") of the United States Department of Health and Human Services ("HHS"); the United States Office of Personnel Management ("OPM"); the United States Department of Defense TRICARE Management Activity ("TMA"); the United States Department of Defense, Defense Logistics Agency ("DLA"), on behalf of the Defense Supply Center- Philadelphia ("DSCP") (collectively "the United States"); InterMune, Inc. ("InterMune"), a Delaware corporation with its principal place of business in Brisbane, California; and Joan Gallagher ("Relator") (hereafter referred to as "the Parties"), through their authorized representatives.

II. PREAMBLE

As a preamble to this Agreement, the Parties agree to the following:

A. WHEREAS, at all relevant times, InterMune distributed, marketed and sold pharmaceutical products in the United States, including a drug it sold under the trade name Actimmune®;

B. WHEREAS, on or about July 9, 2004, Relator Joan Gallagher filed a qui tam action in the United States District Court for the Eastern District of Pennsylvania, captioned United States of America ex rel. Joan Gallagher v. InterMune, Inc., Civil Action No. 04 CV 3249 (E.D. Pa.). On October 7, 2004, the qui tam action was transferred to the United States District Court for the Northern District of California ("Court"), now captioned United States of America

ex rel. Joan Gallagher v. InterMune, Inc., C 04-4323 MHP (N.D. Cal.)(the "Civil Action");

C. WHEREAS InterMune has agreed to enter into a Deferred Prosecution Agreement ("DPA") with the United States Attorney for the Northern District of California. The United States has filed an Information in the United States District Court for the Northern District of California (the "Court") charging InterMune with One Count of doing an act, with intent to defraud or mislead, with respect to a drug while the drug was held for sale after shipment in interstate commerce that results in the drug being misbranded, in violation of Title 21, United States Code, Section 331(k) (the "Information");

D. WHEREAS, the United States and InterMune will file with the Court the DPA, which states that the Department of Justice will recommend to the Court that prosecution of InterMune for the conduct charged in the Information be deferred for a period of 2 years from the date the Court approves the DPA and that the Department of Justice will seek dismissal with release of the Information thereafter if InterMune is in compliance with all of its obligations under the DPA;

E. WHEREAS, InterMune has entered into or will be entering into separate settlement agreements ("Medicaid State Settlement Agreements") with the states which will be receiving settlement funds from InterMune pursuant to Paragraph 1(c) below for the Covered Conduct described in Paragraph G below (hereinafter referred to as the "Medicaid Participating States");

F. WHEREAS, the United States and the Medicaid Participating States allege that InterMune caused to be submitted claims for payment for Actimmune to Medicaid Programs,

established pursuant to or in connection with Title XIX of the Social Security Act ("Act"), 42 U.S.C. §§ 1396-1396y (the "Medicaid Program"); and the United States further alleges that InterMune caused to be submitted claims for payment of Actimmune to the Medicare Program, 42 U.S.C. §§ 1395-1395hhh, TRICARE Program (formerly known as the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS")), 10 U.S.C. §§ 1071-1110, which is administered by the Department of Defense through TMA, and to the Federal Employees Health Benefits Program ("FEHBP"), 5 U.S.C. §§ 8901-8914, and that InterMune caused purchases of Actimmune by the Department of Veterans Affairs ("DVA") and DSCP;

G. WHEREAS, the United States contends that it has claims under the False Claims Act, 31 U.S.C. §§ 3729-3733, and that it and the Medicaid Participating States (hereinafter collectively referred to as the "Government") have certain other civil claims against InterMune for allegedly engaging in the following conduct with respect to the marketing, promotion and sale of Actimmune:

(i) The Government contends that between January 1, 2001 and June 30, 2003, InterMune knowingly and willfully promoted the sale and use of Actimmune for the treatment of idiopathic pulmonary fibrosis ("IPF"), a use for which Actimmune had not been approved by the United States Food and Drug Administration ("FDA"), and knowingly caused the submission of claims to the Government as described in subparagraph (v) below. Actimmune has only been approved by the FDA to treat two rare diseases, chronic granulomatous disease and severe, malignant osteopetrosis;

(ii) The Government contends that notwithstanding the fact that InterMune's

Phase III clinical trial of Actimmune for the treatment of IPF failed to establish statistically significant benefits on its primary endpoint or any of its secondary endpoints, including overall survival, certain former InterMune employees encouraged InterMune sales force personnel to inform physicians that Actimmune demonstrated a survival benefit in mild to moderate IPF patient populations, and certain former sales force personnel did so;

(iii) The Government contends that InterMune's promotion of Actimmune for IPF violated the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 331(a) & (d);

(iv) The Government contends that the use of Actimmune for IPF was not a "medically accepted indication" pursuant to 42 U.S.C. § 1396r-8(k)(6);

(v) The Government further contends that the conduct described in the foregoing subparagraphs (i) through (iv) resulted in claims for Actimmune being submitted to the Medicaid, Medicare, FEHBP and TRICARE Programs, and in DVA and DSCP purchasing Actimmune for dispensing to patients for an unapproved indication, between January 1, 2001 and June 30, 2005, in violation of the False Claims Act, 31 U.S.C. §§ 3729-3733.

InterMune's conduct as described in the Civil Action, the DPA and in Preamble Paragraph G of this Agreement is hereafter referred to as the "Covered Conduct."

H. WHEREAS, the United States also contends that it has certain administrative claims against InterMune for engaging in the Covered Conduct, as specified in Paragraphs 5-8 below;

I. WHEREAS, the United States and the Relator have reached an agreement with

respect to the Relator's claim of entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Agreement;

J. WHEREAS, the Relator and InterMune have reached an agreement with respect to the Relator's claim of entitlement under 31 U.S.C. § 3730(d) to attorneys' fees and costs;

K. WHEREAS, this Agreement is neither an admission of facts or liability by InterMune (with the exception of such admissions as InterMune makes in connection with the DPA referenced in Paragraph C above and accepted by the Court) nor a concession by the Government that its claims are not well founded; and

L. WHEREAS, to avoid the delay, expense, inconvenience and uncertainty of protracted litigation of these claims, the Parties mutually desire to reach a full and final settlement as set forth in this Agreement.

III. TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants, and obligations in this Agreement, and for good and valuable consideration, receipt of which is hereby acknowledged, the Parties agree as follows:

1. InterMune shall pay to the United States and the Medicaid Participating States, collectively, the sum of thirty-six million, nine hundred forty-four thousand, forty-three dollars ($36,944,043), plus any interest that may have accrued between November 1, 2006 and the Effective Date of this Agreement at a rate of 5% per annum ("Settlement Amount"). On the

Effective Date of this Agreement, as defined in paragraph 32 herein, this sum shall constitute a debt due and immediately owing to the United States and the Participating States. InterMune shall discharge its debt to the United States and the Medicaid Participating States under the following terms and conditions:

a. InterMune shall pay to the United States the principal sum of $30,249,229 (the "Federal Settlement Amount"). InterMune shall pay the Federal Settlement Amount, plus interest accrued thereon at the rate of 5% per annum, in accordance with the payment schedule attached hereto as Exhibit A ("Payment Schedule"). Within 10 days after the Effective Date of this Agreement, InterMune shall pay the United States the initial fixed payment in the amount of $4,093,925 ("Initial Payment"), plus any interest that may have accrued between November 1, 2006 and the Effective Date, and thereafter make principal payments with interest according to the schedule in Exhibit A.

b. All payments set forth in this Paragraph 1(a) shall be made to the United States by electronic funds transfer pursuant to written instructions provided by the Office of the United States Attorney for the Northern District of California. The entire principal balance of the Federal Settlement Amount or any portion thereof, plus any interest accrued on the principal as of the date of any prepayment, may be prepaid without penalty.

c. InterMune shall pay to the Medicaid Participating States the sum of $6,694,814 ("Medicaid State Settlement Amount"). InterMune shall pay the Medicaid State Settlement Amount, plus interest accrued thereon at the rate of 5% per annum, in accordance with the Payment Schedule found at Exhibit A. Within 10 days after the Effective Date of this

Agreement, InterMune shall set aside $906,075, plus any interest that may have accrued between November 1, 2006 and the Effective Date, into an interest-bearing account of its own choosing ("deposit account") as agreed upon between InterMune and the National Association of Medicaid Fraud Control Units Settlement Team (the "NAMFCU Team") and, upon reaching agreements with, and obtaining release from each of the Medicaid Participating States and receipt of written payment instructions from the NAMFCU Team, shall pay the State Settlement Amount plus any additional interest earned in the deposit account as directed by each settling Medicaid Participating State. Upon reaching final agreements with, and obtaining release from the Medicaid Participating States, Intermune shall thereafter make fixed pro rata payments according to the schedule in Exhibit A and as directed by each settling Medicaid Participating State. The entire principal balance of the Medicaid State Settlement Amount or any portion thereof, plus any interest accrued on the principal as of the date of any prepayment, may be prepaid without penalty.

d. InterMune shall pay attorneys' fees to the Relator in the amount of

$40,000. This amount shall be paid as an electronic funds transfer to the Relator's attorney (to be allocated in accordance with their instructions) no later than seven (7) business days after the stipulations of dismissal are filed as set forth in Paragraph 13.

2. If the Court does not accept the DPA as described in Preamble Paragraph D or refuses to impose the agreed upon disposition for whatever reason, this Agreement shall be null and void at the option of either the United States or InterMune. If either the United States or InterMune exercises this option, which option shall be exercised by notifying all Parties, through

counsel, in writing within ten (10) business days of the Court's decision, the Parties will not object to the voiding of this Agreement and the Agreement will be deemed rescinded. If this Agreement is rescinded, InterMune will not plead, argue or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel or similar theories, to any such civil or administrative claims, actions or proceedings relating to the Covered Conduct which are brought by the United States within 90 calendar days of notification to all other Parties of that rescission, except to the extent such defenses were available before the Effective Date of this Agreement.

3. Subject to the exceptions in Paragraphs 4, 5, 6, 7 and 8, in consideration of the obligations of InterMune set forth in this Agreement, conditioned upon InterMune's payment in full of the Settlement Amount, subject to Paragraph 20 below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement, as defined below), and subject to the Court's approval of the DPA described in Preamble Paragraph D, the United States, on behalf of itself, and its officers, agents, agencies, and departments, as set forth above, hereby fully and finally releases InterMune, its predecessors, subsidiaries, corporate

parents and affiliates, successors and assigns, and current or former officers, directors, and employees, except as excluded in Paragraph 4, below, from any civil or administrative monetary claim that the United States has against InterMune under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; any statutory provision applicable to the federally-funded programs in this Agreement for which the Civil Division, United States Department of Justice, has actual and present authority to assert and compromise pursuant to 28 C.F.R. Part 0, Subpart I,

§ 0.45(d); and common law claims for fraud, payment by mistake, unjust enrichment or disgorgement for the Covered Conduct.

4. Notwithstanding any term of this Agreement, the United States specifically does not herein release any person or entity from any of the following claims or liabilities: (a) any potential criminal, civil or administrative claims arising under Title 26, U.S. Code (Internal Revenue Code); (b) any criminal liability; (c) any potential liability to the United States (or any agencies thereof) for any conduct other than the Covered Conduct; (d) any claims based upon obligations created by this Agreement; (e) except as explicitly stated in Paragraphs 5, 6, 7 and 8 of this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs; (f) any express or implied warranty claims or other claims for defective or deficient products and services; (g) any claims for personal injury or property damage or for other consequential damages arising from the Covered Conduct; (h) any claim based on a failure to deliver items or services due; or (i) any civil or administrative claims against individuals, including current and former directors, officers, and employees of InterMune, its predecessors,

subsidiaries, and its corporate parent and affiliates, who, related to the Covered Conduct, receive written notification that they are the target of a criminal investigation, are criminally indicted or charged, or are convicted, or who enter into a criminal plea agreement.

5. In consideration of the obligations of InterMune set forth in this Agreement and in the Corporate Integrity Agreement ("CIA"), conditioned upon InterMune's payment in full of the Settlement Amount, and subject to Paragraph 20 below (concerning bankruptcy proceedings commenced within 91 days of the effective date of this Agreement), the OIG-HHS agrees to

release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion against InterMune from Medicare, Medicaid or other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law), or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities), for the Covered Conduct except as reserved in Paragraph 4 above, and as reserved in this Paragraph. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude InterMune from the Medicare, Medicaid, or other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 4, above. InterMune will immediately begin implementing its obligations under the CIA upon execution of this Agreement.

6. In consideration of the obligations of InterMune set forth in this Agreement, conditioned upon InterMune's full payment of the Settlement Amount, and subject to Paragraph

20 below (concerning bankruptcy proceedings commenced within 91 days of the effective date of this Agreement or any payment under this Agreement), TMA agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion or suspension from the TRICARE Program against InterMune and its predecessors, subsidiaries, corporate parents, affiliates, successors and assigns, or its current directors, officers or employees under 32 C.F.R. § 199.9 for the Covered Conduct, except as reserved in Paragraph 4 above, and as reserved in this Paragraph. TMA expressly reserves its authority to exclude InterMune under 32

C.F.R. § 199.9 (f)(1)(i)(A), (f)(1)(i)(B), and (f)(1)(iii), based upon the Covered Conduct. Nothing in this Paragraph precludes TMA or the TRICARE Program from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 4, above.

7. In consideration of the obligations of InterMune in this Agreement, conditioned upon InterMune's full payment of the Settlement Amount, and subject to Paragraph 20 below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment under this Agreement), OPM agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking debarment from FEHBP against InterMune and its predecessors, subsidiaries, corporate parents, affiliates, successors and assigns, or its current directors, officers or employees under 5 U.S.C. § 8902a or 5 C.F.R. Part 970 for the Covered Conduct, except as reserved in Paragraph 4, above. OPM expressly reserves all rights to comply with any statutory obligations to debar InterMune from the FEHBP under 5 U.S.C. § 8902a(b) (mandatory debarment) based upon the Covered Conduct. Nothing in this Paragraph precludes OPM from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 4, above.

8. In consideration of the obligations of InterMune set forth in this Agreement, conditioned upon InterMune's full payment of the Settlement Amount, and subject to Paragraph 20 below (concerning bankruptcy proceedings commenced within 91 days of the effective date of this Agreement or any payment under this Agreement), DSCP/DLA agrees to defer to the OIG-HHS for any contractor integrity issues arising from this settlement and the Covered Conduct.

Nothing in this Paragraph precludes DLA from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 4, above.

9. Relator and her heirs, successors, attorneys, agents, and assigns agree not to object to this Agreement and agree and confirm that settlement of this Civil Action, and the payment schedule set forth in Exhibit A, is fair, adequate and reasonable under all the circumstances, agree not to challenge this Agreement pursuant to 31 U.S.C. § 3730(c)(2)(B), and expressly waive the opportunity for a hearing on any objection to this Agreement pursuant to 31 U.S.C. § 3730(c)(2)(B).

10. Upon her receipt of the pro rata share of the Initial Payment, the Relator, individually, and for her heirs, successors, agents and assigns, fully and finally releases, waives, and forever discharges the United States, its agencies (including, but not limited to, the OIG-HHS, TMA, OPM, DVA, and DLA), employees, servants, and agents from any claims arising from or relating to 31 U.S.C. § 3730 from any claims arising from the filing of the qui tam civil action, and from any other claims for a share of the Federal Settlement Amount, and in full settlement of any claims Relator may have under this Agreement. This Agreement does not resolve or in any manner affect any claims the United States has or may have against the Relator arising under Title 26, U.S. Code (Internal Revenue Code), or any claims arising under this Agreement.

11. The United States agrees to pay the Relator $5,748,160 as her share of the proceeds pursuant to 31 U.S.C. § 3730(d)(the "Relator's Share"). The United States will pay the Relator her pro rata share of each payment that InterMune pays the United States under the

Payment Schedule set forth in Exhibit A. The United States will pay the Relator her pro rata share within 21 days of the United States' receipt of each payment from InterMune. The Relator expressly understands and agrees that the United States is only liable to the Relator for funds actually received or collected by the United States.

12. Conditioned upon InterMune's full payment of the Settlement Amount, the Relator, individually, and for her heirs, successors, agents and assigns, fully and finally releases, waives, and forever discharges InterMune, its predecessors, subsidiaries, corporate parents and affiliates, successors and assigns, and current or former officers, directors, and employees, from any claims that the Relator has or may have that arises under or relates to any of the allegations in the Civil Action and/or the Covered Conduct, including claims for attorney's fees, expense and costs pursuant to 31 U.S.C. § 3730(d). The Relator hereby represents and warrants that no other individual is entitled to assert any matter released in this paragraph in or through the Relator's right.

13. Upon execution of this Agreement by all parties, the United States will file a notice of intervention in the qui tam action and advise the Court that the parties have reached a civil settlement. Upon receipt of the full payments described in Paragraph 1(a) and (c) above and in Exhibit A, the United States and Relator shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal with prejudice of the Civil Action pursuant to the terms of the Agreement.

14. In consideration of the obligations of the United States set forth in this Agreement, InterMune and its predecessors, subsidiaries, corporate parents and affiliates fully

and finally release the United States, its agencies (including, but not limited to, HHS, TMA, OPM and DVA), employees, servants, and agents from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) which they have asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to or arising from the United States' criminal and civil investigations of the Civil Action and the Covered Conduct.

15. In consideration of the obligations of the Relator set forth in this Agreement, InterMune, and its predecessors, subsidiaries, corporate parents and affiliates, and all of their agents, successors and assigns, hereby fully and finally release the Relator and her respective heirs, successors, assigns, agents and attorneys from any claims they have asserted, could have asserted, or may assert in the future against the Relator arising from the filing of the Civil Action and the United States' criminal and civil investigations of the Civil Action and the Covered Conduct.

16. The Settlement Amount shall not be decreased as a result of the denial of claims

for payment now being withheld from payment by any Federal or State payer, related to the Covered Conduct; and InterMune shall not resubmit to any Federal or State payer any previously denied claims related to the Covered Conduct, and shall not appeal any such denials of claims.

17. InterMune agrees to the following:

a. Unallowable Costs Defined: that all costs (as defined in the Federal Acquisition Regulations (FAR) 48 C.F.R. § 31.205-47 and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395hhh and 1396-1396y, and the regulations and official

program directives promulgated thereunder) incurred by or on behalf on InterMune, its present or former officers, directors, employees, shareholders, and agents in connection with: (1) the matters covered by this Agreement and the related DPA; (2) the United States' civil and criminal investigation of the matters covered by this Agreement; (3) InterMune's investigation, defense, and any corrective actions undertaken in direct response to the United States' civil and criminal investigations in connection with the matters covered by this Agreement (including attorneys' fees); (4) the negotiation and performance of this Agreement, the DPA, and the Medicaid State Settlement Agreement, (5) the payments made to the United States or any State pursuant to this Agreement, the DPA, or the Medicaid State Settlement Agreement and any payments that InterMune may make to Relator; (6) the negotiation of, and the obligations undertaken pursuant to the CIA, including to (i) retain an independent review organization to perform annual reviews as described in Section III.D of the CIA; and (ii) prepare and submit reports to the OIG-HHS, are unallowable costs on Government contracts with DVA, DLA and other agencies and under the Medicare Program, Medicaid Program, TRICARE Program, and FEHBP. However, nothing in this Paragraph affects the status of costs that are not allowable based on any other authority applicable to InterMune. (All costs described or set forth in this Paragraph 17(a) are hereafter, "unallowable costs").

b. Future Treatment of Unallowable Costs: If applicable, these unallowable costs will be separately estimated and accounted for by InterMune, and it will not charge such unallowable costs directly or indirectly to any contracts with the United States or any State Medicaid Program, or seek payment for such unallowable costs through any cost report, cost

statement, information statement, or payment request submitted by them or any of their subsidiaries to Medicare, Medicaid, TRICARE, FEHBP, DLA or DVA.

c. Treatment of Unallowable Costs Previously Submitted for Payment: If applicable, InterMune further agrees that within 90 days of the Effective Date of this Agreement, it will identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid, DLA, DVA, and FEHBP fiscal agents, any unallowable costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid Program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by InterMune or any of its subsidiaries, and will request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. InterMune agrees that the United States, at a minimum, will be entitled to recoup from InterMune any overpayment plus applicable interest as a result of the inclusion of such unallowable costs on previously-submitted cost reports, information reports,

cost statements, or requests for payment. Any payment due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice, and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by InterMune or any of its subsidiaries on the effect of inclusion of unallowable costs (as defined in this Paragraph) on InterMune's or any of its subsidiaries' cost reports, cost statements, or information reports. Nothing in this Agreement shall constitute a waiver of the rights of the United States to examine or reexamine the unallowable costs

described in this Paragraph.

18. InterMune agrees that it will not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents or sponsors. InterMune waives any causes of action against these beneficiaries or their parents or sponsors based upon the claims for payment covered by this Agreement.

19. InterMune expressly warrants that it has reviewed its financial situation and that it is currently solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and expects to remain solvent following the payments to the United States hereunder. Further, the Parties expressly warrant that, in evaluating whether to execute this Agreement, the Parties (a) have intended that the mutual promises, covenants and obligations set forth herein constitute a contemporaneous exchange for new value given to InterMune, within the meaning of 11 U.S.C. § 547(c)(1), and (b) have concluded that these mutual promises, covenants and obligations do, in fact, constitute such a contemporaneous exchange.

20. In the event InterMune or any other party commences, within 91 days of the

Effective Date of this Agreement (defined below), or of any payment made hereunder, any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization or relief of debtors, (a) seeking to have any order for relief of InterMune's debts, or seeking to adjudicate InterMune as bankrupt or insolvent, or (b) seeking appointment of a receiver, trustee, custodian or other similar official for InterMune for all or any substantial part of its assets, InterMune agrees as follows:

a. InterMune's obligations under this Agreement may not be avoided

pursuant to 11 U.S.C. § 547 or 548, and InterMune will not argue or otherwise take the position in any such case, proceeding or action that: (i) InterMune's obligations under this Agreement may be avoided under 11 U.S.C. § 547 or 548; (ii) InterMune was insolvent at the time this Agreement was entered into, or became insolvent as a result of the payment made to the United States hereunder; or (iii) the mutual promises, covenants and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to InterMune;

b. In the event that InterMune's obligations hereunder are avoided for any reason, including, but not limited to, the exercise of a trustee's avoidance powers under the Bankruptcy Code, the United States, at its sole option, may rescind the releases in this Agreement, and bring any civil and/or administrative claim, action or proceeding against InterMune for the claims that would otherwise be covered by the releases provided in this Agreement. If the United States chooses to do so, InterMune agrees that, for purposes only of any case, action, or proceeding referenced in the first clause of this Paragraph, (i) any such claims, actions or proceedings brought by the United States (including any proceedings to

exclude InterMune from participation in Medicare, Medicaid, or other Federal Health Care programs) are not subject to an "automatic stay" pursuant to 11 U.S.C. Section 362(a) as a result of the action, case or proceeding described in the first clause of this Paragraph, and that InterMune will not argue or otherwise contend that the United States' claims, actions or proceedings are subject to an automatic stay; (ii) that InterMune will not plead, argue or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel or similar theories, to any such civil or administrative claims, actions or proceedings which are

brought by the United States within 30 calendar days of written notification to InterMune that the releases herein have been rescinded pursuant to this Paragraph, except to the extent such defenses were available before the Effective Data of this Agreement; and (iii) the United States and the Participating States have valid claims against InterMune in at least the aggregate amount of the Settlement Amount and they may pursue their claims, inter alia, in the case, action or proceeding referenced in the first clause of this Paragraph, as well as in any other case, action, or proceeding; and

c. InterMune acknowledges that its agreement in this Paragraph is provided in exchange for valuable consideration provided in this Agreement.

21. In the event that InterMune fails to pay any and all of the payments owed pursuant to this Agreement within 30 calendar days of the due date ("Default"), any dismissals as to InterMune shall, at the United States' option, be null and void, and the Settlement Amount referenced in Paragraph 1 above, less any payments already made, shall become immediately due and payable and shall bear interest at the Medicare interest rate (per 42 C.F.R. part 405.378) as of

the date of Default until payment of the Settlement Amount is made in full.

Furthermore, in the event of a breach of the payment provisions as described in the preceding paragraph, the United States may at its option: 1) rescind its releases; 2) offset the remaining unpaid balance of the Settlement Amount from any amounts due and owing to InterMune by any department, agency, or agent of the United States at the time of Default; 3) reinstitute an action or actions against InterMune in this Court; and 4) InterMune agrees not to contest any draw, offset, or collection action undertaken by the United States pursuant to this

Paragraph, either administratively or in any court.

In the event of a Default of any payment under this Agreement, InterMune agrees to pay the United States all reasonable costs of collection and enforcement of this Agreement, including attorneys' fees and expenses. In the event the United States reinstitutes an action under this Paragraph, InterMune expressly agrees not to plead, argue, or otherwise raise any defense under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims, which: (a) are filed by the United States within 30 calendar days of written notification to InterMune that this Agreement has been made a nullity, and (b) relates to the Covered Conduct, except to the extent these defenses were available on September 4, 2006.

22. In the event of Default as defined in Paragraph 21 above, OIG-HHS may exclude InterMune from participating in all Federal health care programs until InterMune pays the Settlement Amount and reasonable costs as set forth in Paragraphs 1 and 21 above. OIG-HHS will provide written notice of any such exclusion to InterMune. InterMune waives any further notice of the exclusion under 42 U.S.C. § 1320a-7(b)(7), and agrees not to contest such exclusion either administratively or in any state or federal court. Reinstatement to program participation is not automatic. If at the end of the period of exclusion InterMune wishes to apply for reinstatement, InterMune must submit a written request for reinstatement to the OIG in accordance with the provisions of 42 C.F.R. §§ 1001.3001-.3005. InterMune will not be reinstated unless and until the OIG approves such request for reinstatement.

23. InterMune has provided financial statements to the United States and the United States has relied on the accuracy and completeness of these financial statements in reaching this

Agreement. If the United States learns that the historical financial statements contained in InterMune SEC filings made between May 2005, and the Effective Date, either (a) failed to disclose a material non-contingent asset or assets in which InterMune had an interest (a "Material Nondisclosure"); or (b) contained any other knowing, material misrepresentation or omission regarding the financial condition of InterMune (a "Knowing Material Misrepresentation"), the United States may at its option pursue relief under this Paragraph 23 as follows: (a) the United States shall provide InterMune with written notice of the nature of the Material Nondisclosure or Knowing Material Misrepresentation; (b) within ten (10) calendar days of the date of the written notice, InterMune shall provide the United States, in writing, with any explanation it may have regarding the Material Nondisclosure or Knowing Material Misrepresentation referenced in the written notice; (c) if unsatisfied with InterMune's explanation, as determined in its sole and absolute discretion, the United States may file an action seeking relief under this Paragraph 23 in which action the United States shall bear the burden of establishing by a preponderance of the evidence the Material Nondisclosure or Knowing Material Misrepresentation; (d) if the court finds a Material Nondisclosure or Knowing Material Misrepresentation, then – (i) the Settlement Amount shall be increased by one hundred percent (100%) of the amount of the Material Nondisclosure or Knowing Material Misrepresentation; (ii) the remaining unpaid principal portion of the Settlement Amount (including the increase specified in subparagraph (d)(i) above) shall become accelerated and immediately due and payable, with interest at a simple rate of 5% from the Effective Date of this Agreement to the date of the court finding, and at the Medicare interest rate (per 42 C.F.R. part 405.378) from the date of the court finding until the date of

payment; (iii) the United States may offset the remaining unpaid balance of the Settlement Amount (inclusive of interest and the increase specified in subparagraph (d)(i) above) from any amounts due and owing to InterMune by any department, agency, or agent of the United States; and (iv) InterMune shall immediately pay the United States all reasonable costs incurred in the action seeking relief under this Paragraph 23, including attorney's fees and expenses.

24. If, after the Effective Date of this agreement and before the company has made all payments required pursuant to Paragraph 1 of this Agreement, the company obtains a cumulative total of more than $150,000,000.00 in cash financing from (1) license fees and milestone payments paid to the company pursuant to partnering agreements, (2) external debt financing, and/or (3) external equity financing, the company shall notify the United States and apply twenty percent (20%) of the excess over $150,000,000.00 ("excess cash amount") to make advance payments against the Settlement Amount. The company shall make the advance payment(s) first by paying the outstanding principal owed (plus any interest accrued on that principal through the advance payment date) in 2011 and shall continue to make such advance payments in reverse

chronological order until the excess cash amount is reduced to zero. The payment schedule referenced in Exhibit A shall remain in effect until the balance of the Settlement Amount is paid off. Cash financing, for purposes of this paragraph, is limited to the sources enumerated in the first sentence of this paragraph and shall expressly exclude any increase in operating revenues after the Effective Date or reimbursement of research or development expenses from a partner. Advance payments made by the company pursuant to this paragraph shall not exceed $10,000,000.00 in any single calendar year. Further, in the event InterMune is sold (either

through an asset sale or an equity sale) or merged into another non-affiliated entity, then all remaining payments owed pursuant to the Settlement Agreement, are accelerated and become immediately due and payable.

In addition to notifying the United States when it has obtained more than $150,000,000 in cash financing, Intermune will be required to provide the United States with notice within ten days of each financing arrangement or agreement (agreement) it obtains after the Effective Date of the settlement after the cumulative financing described in the preceding paragraph totals $150,000,000, along with a copy of each such financing agreement. InterMune further agrees that it shall pay the U.S. all amounts required under this provision within 10 days following receipt of external financing which causes a prepayment under this paragraph. Amounts that are due under this paragraph and not paid when due will be considered amounts in Default. Default amounts are subject to the Default provisions (except that Default will be effective immediately and not within 30 days of the due date) contained in this Settlement Agreement as specified in paragraph 21, including the Default rate of interest at the Medicare

interest rate (per 42 C.F.R. part 405.378) beginning as of the date of Default until payment of the Settlement Amount is made in full.

25. InterMune waives and will not assert any defenses it may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

26. The Parties each represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

27. Except as otherwise stated herein, this Agreement is intended to be for the benefit of the Parties only, and by this instrument the Parties do not release any claims against any other person or entity.

28. Nothing in any provision of this Agreement constitutes an agreement by the United States, InterMune or the Relator concerning the characterization of the Settlement Amount or the relator's share for purposes of the Internal Revenue Laws, Title 26 of the United States Code.

29. Except as expressly provided in this Agreement, each party to this Agreement will bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

30. This Agreement is governed by the laws of the United States. The Parties agree that the United States District Court for the Northern District of California shall retain

jurisdiction over this Agreement until all the terms and conditions have been completely satisfied. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement will be the United States District Court for the Northern District of California, including any dispute regarding Relator's share of the settlement, except that disputes arising under the CIA shall be resolved through the dispute resolution provisions set forth in the CIA.

31. The undersigned InterMune signatories represent and warrant that they are

authorized by their Board of Directors to execute this Agreement. The undersigned signatory or signatories for the Relator represents and warrants that he is authorized to execute this Agreement on behalf of the Relator. The undersigned United States signatories represent that they are signing this Agreement in their official capacities and they are authorized to execute this Agreement on behalf of the United States through their respective agencies and departments, and, in the case of the OIG-HHS and TMA, on behalf of their respective Departments.

32. This Agreement is effective on the later of (1) the date of signature of the last signatory to the Agreement, or (2) the date the Court approves the DPA as described in Preamble Paragraph D (the "Effective Date"). Facsimiles of signatures shall constitute acceptable binding signatures for purposes of this Agreement.

33. This Agreement shall be binding on all successors, transferees, heirs and assigns of the Parties.

34. This Agreement and Exhibit A attached hereto, together with the CIA, and the DPA described in Preamble Paragraphs C and D, constitute the complete agreement between the Parties with regard to the Covered Conduct. This Agreement may not be amended except by written consent of all the Parties, except that only InterMune and OIG-HHS must agree in writing to a modification of the CIA, without the consent of any other party to this Agreement or the DPA.

35. InterMune and the Relator hereby consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

36. This Agreement may be executed in counterparts, each of which shall constitute an original and all of which shall constitute one and the same Agreement.

UNITED STATES OF AMERICA

By: _____

ALEX G. TSE
Assistant United States Attorney
United States Attorney's Office
Northern District of California

Dated: 10/24/06

By: _____

ANDY J. MAO
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

Dated:

By: _____

GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services

Dated:

By: _____

LAUREL C. GILLESPIE
Deputy General Counsel
TRICARE Management Activity
United States Department of Defense

Dated:

UNITED STATES OF AMERICA

By: _____
ALEX G. TSE
Assistant United States Attorney
United States Attorney's Office
Northern District of California

Dated:

By: _____
ANDY J. MAO
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

Dated: 10/25/06

By: _____
GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services

Dated:

UNITED STATES OF AMERICA

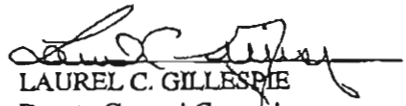
By: _____
ALEX G. TSE
Assistant United States Attorney
United States Attorney's Office
Northern District of California
Dated:

By: _____
ANDY J. MAO
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice
Dated:

By: _____
GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Dated: 10/25/06

By: _____ Dated: 10/20/2006
KATHLEEN McGETTIGAN
Deputy Associate Director
Center for Retirement & Insurance Services United States Office of Personnel Management

By: _____ Dated: 10/20/2006
J. DAVID COPE
Assistant Inspector General for Legal Affairs \
United States Office of Personnel Management

By: 

LAUREL C. GILLESPIE
Deputy General Counsel
TRICARE Management Activity
United States Department of Defense

Dated: 24 Oct 06

By: _____

SUSAN CHADICK
Deputy General Counsel
Defense Logistics Agency

Dated:

By: _____ Dated:
LAUREL C. GILLESPIE
Deputy General Counsel
TRICARE Management Activity
United States Department of Defense

By: Susan Chadick Dated: October 25, 2006
SUSAN CHADICK
Deputy General Counsel
Defense Logistics Agency

INTERMUNE, INC.

By: _____ Dated: October 24, 2006.
Robin Steele, General Counsel
Intermune, Inc.

By: _____ Dated: 10-24-06
ETHAN M POSNER
Covington & Burling LLP

RELATOR

By: Joan Gallagher
JOAN GALLAGHER Dated: October 24, 2006

By: _____
JOHN A. BERANBAUM Dated:
Beranbaum Menken Ben-Asher & Bierman LLP

RELATOR

By: _____
JOAN GALLAGHER Dated:

By: _____
JOHN A. BERANBAUM Dated: 10-24-06
Beranbaum Menken Ben-Asher & Bierman LLP

EXHIBIT A: PAYMENT SCHEDULE

TOTAL PAYMENT

Year	Payment	Interest at 5%	Principal	Balance
				36,944,043.50
11/1/2006	5,000,000.00	-	5,000,000.00	31,944,043.50
11/1/2007	5,000,000.00	1,597,202.18	3,402,797.83	28,541,245.68
11/3/2008	6,500,000.00	1,427,062.28	5,072,937.72	23,468,307.96
11/2/2009	7,000,000.00	1,173,415.40	5,826,584.60	17,641,723.36
11/1/2010	9,000,000.00	882,086.17	8,117,913.83	9,523,809.52
11/1/2011	10,000,000.00	476,190.48	9,523,809.52	0.00
Total	42,500,000.00		36,944,043.50	

PAYMENT TO THE UNITED STATES

Year	Payment	Interest at 5%	Principal	Balance
				30,249,228.50
11/1/2006	4,093,924.98	-	4,093,924.98	26,155,303.52
11/1/2007	4,093,924.98	$1,307,765	2,786,159.80	23,369,143.72
11/3/2008	5,322,102.47	$1,168,457	4,153,645.29	19,215,498.43
11/2/2009	5,731,494.97	$960,775	4,770,720.05	14,444,778.38
11/1/2010	7,369,064.96	$722,239	6,646,826.04	7,797,952.34
11/1/2011	8,187,849.96	$389,898	7,797,952.34	0.00
Total	34,798,361.32	4,548,333	30,249,228.50	

PAYMENT TO THE MEDICAID PARTICIPATING STATES

Year	Payment	Interest at 5%	Principal	Balance
				6,694,815.00
11/1/2006	906,075.02	-	906,075.02	5,788,739.98
11/1/2007	906,075.02	$289,437	616,638.02	5,172,101.96
11/3/2008	1,177,897.53	$258,605	919,292.43	4,252,809.53
11/2/2009	1,268,505.03	$212,640	1,055,864.55	3,196,944.97
11/1/2010	1,630,935.04	$159,847	1,471,087.79	1,725,857.18
11/1/2011	1,812,150.04	$86,293	1,725,857.18	0.00
Total	7,701,637.68	1,006,822.68	6,694,815.00	

Attachment C

Attachment C - Acknowledgment of Agreement

This Agreement supersedes all prior, if any, written or oral understandings, promises, and/or conditions between the Department and InterMune, Inc., with the exception of the Civil Settlement Agreement incorporated herein, the Corporate Integrity Agreement referred to herein, and the letter from Ethan Posner to the Department dated October 9, 2006. No additional promises, agreements, and conditions have been entered into and none will be entered into unless in writing and signed by all the parties.

On Behalf of the United States Department of Justice:

10.24.06
DATE

Kevin V. Ryan
United States Attorney
Northern District of California

Ioana Petrou
Assistant United States Attorney

On Behalf Of InterMune, Inc.

DATE

Robin Steele
Senior Vice President and General Counsel
InterMune, Inc.
3280 Bayshore Boulevard
Brisbane, CA 94005

DATE

Ethan Posner
Covington & Burling
Counsel to InterMune, Inc.

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This Agreement supersedes all prior, if any, written or oral understandings, promises, and/or conditions between the Department and InterMune, Inc., with the exception of the Civil Settlement Agreement incorporated herein, the Corporate Integrity Agreement referred to herein, and the letter from Ethan M. Posner to the Department dated October 9, 2006. No additional promises, agreements, and conditions have been entered into and none will be entered into unless in writing and signed by all the parties.

On Behalf of the United States Department of Justice:

DATE

Kevin V. Ryan
United States Attorney
Northern District of California

Ioana Petrou
Assistant United States Attorney

On Behalf Of InterMune, Inc.

October 24, 2006
DATE

Robin Steele
Senior Vice President and General Counsel
InterMune, Inc.
3280 Bayshore Boulevard
Brisbane, CA 94005

10-24-06
DATE

Ethan M. Posner
Covington & Burling
Counsel to InterMune, Inc.