UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

FILED JUL 09 2004

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UNITED STATES OF AMERICA
ex rel. JOAN GALLAGHER,

Plaintiff,

- against -

INTERMUNE, INC.,

Defendant.

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04cv4323

COMPLAINT

PLAINTIFF DEMANDS
A TRIAL BY JURY

**FILED UNDER SEAL
PURSUANT TO
31 U.S.C. § 3730**

I.
PARTIES

1. Joan Gallagher ("plaintiff," "Relator" or "Gallagher"), is a resident of the Commonwealth of Pennsylvania and a former employee of InterMune, Inc. ("InterMune," the "Company," or "defendant"). Joan Gallagher is the original source of the facts and information hereinafter set forth concerning the activities of the defendant. The facts averred herein are based upon her personal observation and documents in her possession, unless otherwise noted.

2. InterMune is a corporation with its principal place of business in Brisbane, California. InterMune is principally engaged in the sale of pharmaceuticals including prescription pharmaceuticals falling under the jurisdiction and regulation of the U.S. Food and Drug Administration.

II.
JURISDICTION AND VENUE

3. Jurisdiction is based on 31 U.S.C. § 3730.

4. At all times material hereto InterMune regularly conducted substantial business within the Commonwealth of Pennsylvania, maintained permanent employees, and made and is making significant sales within Pennsylvania, and is thus subject to personal jurisdiction in the Commonwealth of Pennsylvania pursuant to 42 Pa. Cons. Stat. Ann. § 5322.

5. The facts complained in occurred for the most part in this district and therefore, the venue of this matter is the Eastern District of Pennsylvania.

6. The relator has prepared, and will serve with this complaint, a disclosure pursuant to 31 U.S.C. § 3730(2) of information in her possession and of which she is the original source.

III.
FACTS

7. Prior to InterMune's acquisition of the patent rights for a drug known as Interferon Gamma-1B ("interferon"), the Food and Drug Administration ("FDA") had approved the drug for two indications, Chronic Granulomatous Disease and severe, malignant Osteopetrosis. Genentech, Inc., which developed Interferon, sold the rights to InterMune; those rights will expire in or about 2013.

8. After acquiring the patent rights to Interferon, the Company began marketing the drug under the brand name "Actimmune." (For clarity, Interferon will be referred to as Actimmune throughout the remainder of the Complaint.) At the time of the acquisition, Actimmune was still only approved for treatment of Chronic Granulomatous Disease and severe, malignant Osteopetrosis. The two diseases are quite rare, together affecting approximately 800 individuals per year. Thus, the market

for sales of Actimmune for FDA-approved purposes was, and remains, extremely limited.

9. Under applicable statutes and regulations, the manufacturer of a prescription drug regulated by the FDA may not promote or market the use of the drug for purposes or in dosages other than those approved by the FDA. 21 U.S.C. § 331 et seq. Uses of a prescription drug for purposes other than those approved by the FDA are referred to as "off-label" uses. Promotion by a drug manufacturer of "off-label" uses of prescription drugs is strictly illegal and contrary to the explicit policies and regulations of the United States Government.

10. Although Actimmune was FDA-approved for limited purposes only, InterMune formed a scheme to increase the sales of Actimmune while awaiting approval of expanded or additional uses of the drug. The scheme consisted of an elaborate, fraudulent and clandestine promotion of at least one off-label use of Actimmune, in direct contravention of rules and regulations of the FDA and the Health Care Finance Agency. In particular, InterMune created a scheme for marketing Actimmune for the off-label use of treating Idiopathic Pulmonary Fibrosis ("IPF").

11. At the same time that InterMune was engaged in the third phase of clinical trials to determine if Actimmune was effective for the treatment of IPF, and if so, to obtain FDA approval, it sought to increase its off-label sales of Actimmune and short-circuit legitimate scientific monitoring of the drug by creating a Registry, the "Actimmune Safe and Appropriate Use Program" ("ASAP" or the "Registry").

12. The Registry was ostensibly created to assess the safety and effectiveness of Actimmune for IPF patients treated with the drug and to provide

participating physicians with information regarding the management of their patients treated with Actimmune compared to the aggregate experience of all physicians participating in the Registry.

13. In actuality, on information and belief, defendant used the ASAP Registry to increase sales of Actimmune for the treatment of IPF and to circumvent the ban on off-label marketing of the drug.

14. InterMune encouraged its sales representatives to solicit physicians to participate in the Registry and have their patients take Actimmune, by, among other things, creating dissatisfaction among physicians with other treatment options, informing physicians that there would be no harm in placing patients in the Registry and that they and their patients had "nothing to lose" by participating in the Registry, and promising (and following through on the promise) that InterMune would arrange to take care of all paperwork and insurance reimbursement for their patients enrolled in the Registry, including Medicaid reimbursement.

15. Unlike in clinical trials for which sponsoring companies are required to pay for the drug that is being tested, patients enrolled in the ASAP Registry taking Actimmune paid for it in the same manner as would any other patient taking the drug, e.g., private insurance and/or Medicaid. As described in more detail herein, defendant caused false claims to be submitted to Medicaid for patients enrolled in the ASAP Registry.

16. Defendant used its sales force to increase the number of patients in the Registry, rewarding them with bonuses and stock options.

17. Defendant placed many more patients in the Registry than were

participating in the clinical trials.

18. InterMune did not follow requisite protocols with respect to patients studied in the Registry. For example, InterMune frequently failed to obtain FDA-required patient consents for individuals placed in the ASAP Registry. (The FDA requires that patients give their consent before being placed in a study.) In violation of Health Insurance Portability and Accountability Act ("HIPPA") guidelines and confidentiality requirements, sales representatives obtained identification and contact information relating to patients, and contacted ASAP Registry patients at home to ensure individuals were continuing to take Actimmune for IPF. Although InterMune went to great lengths to ensure patients remained enrolled in the Registry (and thereby purchased the drug), in contrast, Relator is unaware of InterMune actually providing any information to participating physicians regarding outcomes of their patients in comparison to outcomes of patients of other participating physicians.

19. The scheme to increase sales, some details of which are set forth in plaintiff's disclosure statement, some details of which are peculiarly within defendant's control, was carried out by engaging in activities to deliberately circumvent FDA restrictions against off-label marketing, including:

a. Directing its employees to knowingly make false statements to physicians and pharmacists concerning the efficacy and safety of Actimmune for IPF. The false statements to physicians included representing that scientific evidence existed that Actimmune is effective in treating IPF, despite a lack of scientific basis to make such representations; overstating the effectiveness of Actimmune

while the Phase III clinical trials were proceeding, including instructing sales representatives to speak to physicians about the effectiveness of Actimmune in mild to moderate IPF cases; and then, after the Phase III clinical trials showed that there was no medically-proven long-term benefit resulting from use of Actimmune in treatment of IPF, continuing to claim its efficacy. InterMune officials knew that their employees' statements were unsupported by legitimate scientific evidence. Additionally, InterMune instructed and caused its Clinical Specialists to cover-up, downplay and/or ignore the results of a study that linked the deaths of end-stage IPF sufferers to Actimmune.

b. Initiating contacts with physicians relating to the use of Actimmune in treatment of IPF, and directly soliciting physicians to prescribe Actimmune for IPF.

c. Initiating discussions with physicians relating to the state of the medical evidence relating to the effectiveness of Actimmune in treatment of IPF.

d. Providing physicians with medical information beyond FDA-approved materials, including but not limited to summarizing studies purporting to show the effectiveness of Actimmune for IPF.

e. Instructing sales representatives as to the best way to approach discussions with doctors both before and after the results of the Phase III clinical trials were made public, including instructing sales

representatives to stress early diagnosis of IPF and to stress the effectiveness of Actimmune in mild to moderate cases of IPF.

f. Instructing sales representatives to avoid discussions of a European study that linked the use of Actimmune to deaths in four IPF patients, and further instructing sales representatives to refer any physicians who raised the study to the Company's medical affairs department.

g. Making illegal kickbacks in the form of large incentives to physicians who prescribed Actimmune for "off-label" purposes to patients, some of whose prescriptions were paid for by Medicaid. The kickbacks included honoraria paid to doctors speaking at medical education dinners and seminars about the off-label uses of Actimmune, in the range of $2,500 per dinner or seminar.

h. Making illegal kickbacks in the form of $250 incentives to physicians for each patient placed in the ASAP Registry, some of whose prescriptions were paid for by Medicaid.

i. From 2000 until December 2002, employing a dedicated pulmonology sales staff of 60 employees, despite having no FDA-approved pulmonology drug.

j. As of December 2002, setting up a nationwide network of sales representatives misleadingly referred to as "Clinical Specialists," whose assigned duties consisted entirely of conventional direct sales activities and not any legitimate scientific activity, and

"Medical Science Liaisons," who acted as support staff to the Clinical Specialist, in an effort to increase Actimmune sales.

k. Paying or offering gratuities to InterMune employees in the form of stock options and bonuses to increase sales of Actimmune, and requiring sales representatives to sell at least one new prescription per week of Actimmune, all the while knowing that the drug would have to be used for off-label purposes for such an increase in sales to be possible.

l. Training InterMune employees in methods of avoiding detection of their activities by the FDA, such as recording lunches and dinners with doctors relating to sales of Actimmune as "Amphotec" lunches and dinners rather than "Actimmune" lunches and dinners.

20. Defendant's scheme to increase sales of Actimmune was highly successful. During the period 2001 through 2004, InterMune's sales of Actimmune grew from $35 million in 2001 to more than $140 million in 2003. InterMune recently projected sales of Actimmune for 2004 to range between $130-$155 million. Although this projection was withdrawn, during the first quarter of 2004 sales of Actimmune exceeded $33 million. In 2003, 96.5% of InterMune's sales of Actimmune were for off-label uses, primarily for treatment of IPF.

21. If each individual afflicted with one of the two diseases for which Actimmune has an FDA-approved indication paid full price for the drug, sales of the drug would not exceed approximately $20 million. The rapid growth in off-label use of Actimmune is a direct result of InterMune's illegal marketing activities.

22. Of all the off-label use of Actimmune, some percentage is accounted for by patients whose prescriptions are paid for, directly or indirectly, by the United States, in the form of reimbursements through Medicaid and Medicare, although primarily through Medicaid. (Actimmune is an injectable drug, which is not reimbursable by Medicare unless injected in a doctor's office.)

23. The off-label use of Actimmune for IPF, actively promoted by InterMune, is not recognized as a medically accepted usage, because it is not FDA approved, and is not recognized for treatment of IPF by the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information, American Medical Association Drug Evaluations, DrugDex, or by any peer-reviewed medical literature. Thus, these off-label uses are beyond the scope of uses designated by federal law and regulation, in particular 42 U.S.C. § 1396r-8, as eligible for coverage by the Medicaid programs.

24. There is no valid scientific evidence to support the contention that Actimmune is safe and effective for IPF. InterMune is currently conducting trials investigating the use of Actimmune for treatment of IPF; however, these trials are incomplete and do not support its safe and effective use for that purpose.

COUNT I - VIOLATION OF 31 U.S.C. 3729(a)(1) - ILLEGAL MARKETING, FRAUDULENT AND FALSE STATEMENTS AND ILLEGAL KICKBACKS

25. Plaintiff repeats and realleges each and every allegation contained in paragraphs one through 24 of this Complaint with the same force and effect as if set forth herein.

26. Under the statutes and regulations establishing the Medicaid program, the individual states are permitted to establish drug utilization review boards and formularies which define those prescription drugs and their uses for which a state agency will make reimbursement under their Medicaid programs. Federal law, in particular 42 U.S.C. §1396r-8, permits reimbursement of covered outpatient drugs. Such drugs do not include drugs used for a non-medically accepted indication. A medically accepted indication includes a use which is approved under the Federal Food Drug and Cosmetic Act, or which is included in specified drug compendia.

27. IPF is not a medically accepted use for Actimmune because it is not an approved use under the FDCA, and is not included in a specified drug compendia.

28. Many, if not all, states lack the technical ability to monitor precisely for medical diagnoses in the case of individual prescriptions, and thus lack the technical ability to reject reimbursement for off-label uses of prescription drugs which are not medically accepted according to the federally specified publications.

29. InterMune has recognized and aggressively exploited the fact that states will not reject reimbursement for off-label uses by utilizing a direct, illegal, nationwide program of promotion of off-label use of Actimmune by physicians, including all the conduct set forth above. InterMune has conducted this program of promotion knowing that off-label prescriptions for Actimmune were not eligible for Medicaid reimbursement.

30. Notwithstanding InterMune's knowledge that use of Actimmune for IPF was not a medically accepted use eligible for Medicaid reimbursement, InterMune knowingly and intentionally took steps to increase the number of off-label Actimmune prescriptions submitted to Medicaid.

31. These steps included: making false and/or fraudulent statements to physicians to induce them to write prescriptions of Actimmune for IPF; providing kickbacks to physicians to induce them to write prescriptions of Actimmune for IPF; providing special assistance, through a "Reimbursement Hotline," to physicians, pharmacies and individuals in an effort to ensure reimbursement for prescriptions, whether through governmental programs or private insurance, and ensuring that patients and physicians are aware that public assistance, including Medicaid, may be available to pay for prescriptions of Actimmune; and requiring prescriptions of Actimmune to be filled through Priority Healthcare to further enable InterMune to track the number of prescriptions written, track which physicians wrote the highest number of prescriptions, and track whether payment for Actimmune was made by public and private insurers.

32. But for InterMune's conduct, most of the claims submitted for payment by Medicaid for off-label Actimmune prescriptions would never have been filed.

33. InterMune's aggressive, illegal scheme of off-label promotion, false statements, kickbacks and insurance assistance, induced federal payments through a pattern of fraudulent conduct by causing the states, and thus the federal government, to pay out sums to claimants they did not intend to benefit. InterMune's conduct constituted a pattern of fraud, was designed to induce payments by the federal government, caused physicians to submit claims that were not eligible for payment by the government under Medicaid (but which were nevertheless paid) and constitute False Claims within the meaning of 31 U.S.C. § 3729(a)(1).

COUNT II - 31 U.S.C. 3729(a)(1): ILLEGAL KICKBACKS

34. Plaintiff repeats and realleges each and every allegation contained in paragraphs one through 33 of this Complaint with the same force and effect as if set forth herein.

35. Federal laws and regulations governing the Medicaid program prohibit kick-backs to physicians and medical care providers, in particular, 42 U.S.C. § 1320a-7 and 42 C.F.R. § 1001. "Kick-backs" have been defined as including payments, gratuities, and other benefits paid to physicians who prescribe prescription drugs by the manufacturers of the drugs.

36. All states, as part of their Medicaid programs, require prospective Medicaid providers to agree to comply with all Medicaid requirements, including the fraud and abuse provisions and anti-kickback provisions.

37. In some states, this takes the form of an express certification to comply with the rules and regulations of Medicaid; in others, certification is a condition precedent to receiving reimbursement for services.

38. As part of its nationwide program of off-label promotion of Actimmune, InterMune has established a system of kick-backs to physicians who are prescribers of large amounts of Actimmune. These kick-backs are administered by the InterMune sales department, and are frequently disguised as consultantships although unrelated to any scientific or educational activity. The kick-backs take the form of cash payments, entertainment, and other benefits.

39. InterMune tracks the number of prescriptions of Actimmune written by each physician, and seeks to have the large prescription writers give medical education

talks, ostensibly about IPF, but in reality which promote Actimmune, all in exchange for payment.

40. InterMune rewarded the physicians who wrote large numbers of prescriptions of Actimmune with offers to speak at medical education seminars and Advisory Board meetings, in exchange for large cash incentives in the range of $2,500 per talk. Doctors speaking at national meetings received as much as $5,000 per talk. These so-called medical education seminars were in reality seminars marketing Actimmune for IPF.

41. By receiving kickbacks at the same time they were writing Actimmune prescriptions for Medicaid patients and seeking Medicaid payments for their services, physicians falsely certified compliance with the rules and regulations of Medicaid.

42. InterMune knew that its payments to physicians, as set forth above, were kickbacks and that any of those physicians who participated in the Medicaid program would file false claims. Had InterMune not paid kickbacks, physicians would not have falsely certified compliance with the anti-kickback statute.

43. InterMune tracked the prescription writing of all doctors, particularly after they received kickbacks, in essence gauging the effectiveness of the kickbacks.

44. These kickbacks are strictly illegal and have had the effect of greatly increasing the amount of Actimmune prescriptions, and indirectly, the amount of money spent by the federal government for reimbursement of prescriptions covered by Medicaid. The payment of these kickbacks represents the inducement of federal payments through a pattern of fraudulent conduct, and constitute False Claims within the meaning of 31 U.S.C. § 3729.

COUNT III- 31 U.S.C. § 3729(a)(3) - CONSPIRACY TO DEFRAUD

45. Plaintiff repeats and realleges each and every allegation contained in paragraphs one through 44 of this Complaint with the same force and effect as if set forth herein.

46. The False Claims Act prohibits conspiracies to defraud the Government by having a false or fraudulent claim allowed or paid.

47. InterMune retained Covance, Inc., a Delaware corporation, to provide training to its employees in an effort to obtain insurance reimbursement, including Medicaid and Medicare, for Actimmune.

48. InterMune retained Priority Healthcare, Inc. ("Priority"), a Pennsylvania corporation, to track prescriptions of Actimmune for IPF, and to administer the "Actimmune Reimbursement Hotline," which provides assistance to patients and providers in obtaining reimbursement for prescriptions of Actimmune for IPF. Reimbursement services included assisting providers and patients in resolving problem insurance claims and screening patients as potential applicants to Medicaid and Medicare programs.

49. InterMune and Priority knew that Actimmune was not FDA-approved for IPF. InterMune and Priority knew that Actimmune was not in any of the aforementioned compendia. InterMune and Priority knew that prescriptions of Actimmune for IPF were not eligible for Medicaid reimbursement. Nevertheless, InterMune and Priority conspired to have a false or fraudulent claim allowed or paid by the Government, by providing the Reimbursement Hotline to assist patients and doctors in submitting Medicaid claims for reimbursement, and actively took steps to ensure payment by

Medicaid for Actimmune prescriptions for IPF. As a result of InterMune's and Priority's conduct, designed to induce payments by the federal government, claims were submitted that were not eligible for payment by the government under Medicaid (but which were paid), and constitute False Claims within the meaning of 31 U.S.C. § 3729(a)(1).

JURY TRIAL DEMAND

50. Plaintiff demands a trial by jury.

WHEREFORE, the plaintiff/relator prays for judgment against defendant as follows:

(1) That defendant cease and desist from violating 31 U.S.C.§ 3729 et seq.;

(2) That the Court enter judgment against defendant in an amount equal to three times the amount of damages the United States has sustained as a result of defendant's actions, as well as a civil penalty against each defendant of $10,000 for each violation of 31 U.S.C. 3729;

(3) That plaintiff/relator be awarded the maximum amount allowed pursuant to § 3730(d) of the Federal Civil False Claims Act;

(4) That plaintiff/relator be awarded all costs and expenses of this action, including attorneys' fees; and

(5) That the United States and plaintiff/relator receive all such other relief as the Court deems just and proper.

Dated: July 8, 2004
New York, New York

BERANBAUM MENKEN BEN-ASHER & BIERMAN LLP

By: _____

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UNDER SEAL

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA ex rel. JOAN GALLAGHER	:	CIVIL ACTION
v.	:	
INTERMUNE, INC.	:	NO. 04-3249

ORDER

Pursuant to Federal Rules of Civil Procedure 16(b)(1)-(3) and 26(f), a pretrial conference in this matter will be held on **September 22, 2004, at 11:00 a.m.** before the Honorable M. Faith Angell, United States Magistrate Judge, Room 3030, Third Floor, United States Courthouse, 601 Market Street, Philadelphia, PA 19106.

It is the obligation of counsel for the plaintiff to serve a copy of this Order upon counsel for all of the defendants and upon counsel for any other parties joined prior to the date of the conference, as soon as the identity of such counsel is learned.

Date: July 23, 2004

BY THE COURT:

M. FAITH ANGELL
UNITED STATES MAGISTRATE JUDGE

Date: 7-23-04
By ~~Fax and/or~~ Mail: See the Attached List