UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,	)	Criminal Number 08 CR 10124 NG
v.	)	**VIOLATION:**
BIOVAIL PHARMACEUTICALS, INC.	)	18 U.S.C. § 371 - Conspiracy to Offer and Pay Illegal Remunerations to Physicians
	)	42 U.S.C. § 1320a-7(b)(b)(2) – Offers of Remuneration to Physicians
Defendants.	)	

INFORMATION

THE UNITED STATES ATTORNEY CHARGES THAT:

PRELIMINARY ALLEGATIONS

At all times material hereto, unless otherwise alleged:

1. Defendant **BIOVAIL PHARMACEUTICAL, INC.** ("**BPI**"), a Delaware corporation, had corporate headquarters in Morrisville, North Carolina.

The Drug Cardizem, L.A.

2. In January 2001, **BPI** acquired the Cardizem line of drugs from another company for $409.5 million dollars.

3. Cardizem is the brand name of a drug known as diltiazem, which is a heart medication used to control high blood pressure.

4. In or before 2003, the patent ran out on Cardizem, the then brand name version of diltiazem, and the drug faced generic competition.

5. In late 2002 and early 2003, **BPI** was preparing to introduce the product Cardizem, L.A. (CLA) to the market. Cardizem, L.A. was **BPI's** proprietary name for a new 24 hour time release, or long acting (L.A.), formulation of the brand name drug Cardizem.

6. **BPI** began selling Cardizem, L.A. on or about March 23, 2003. At that time, the generic version of Cardizem cost about one third less than the new drug, Cardizem, L.A.

The PLACE Program

7. As part of their promotion of Cardizem, L.A., beginning in March 2003, **BPI** implemented a program known as the PLACE (Proving Long Acting Through Experience) program.

8. The PLACE program paid physicians and other prescribers up to $1,000 for enrolling between 11-15 patients in the program, causing patients to fill prescriptions for Cardizem, L.A. These included prescriptions that were paid for by Medicaid.

9. The first phase of the PLACE program required the prescribing medical professionals (e.g. physicians, nurse practitioners, physician's assistants) to enroll in the program by signing a business reply card by which they agreed to participate, and by completing a 2 page, 10 multiple choice questionnaire. This questionnaire was not expected to take, and did not usually take, the prescribing professional more than 10 minutes to complete.

10. Under this initial part of the program, the prescribing medical professionals were paid $250 if they (a) signed the business reply card and thus agreed to participate in the program and write Cardizem, L.A. prescriptions for their patients, and (b) completed this brief questionnaire.

11. A payment of $250 for 10 to 15 minutes of these medical professionals' time exceeded the reasonable fair market value of their time.

12. In addition, if the business reply card was signed and the questionnaire completed and returned, an office manager or assistant received $50.00. In some cases, these assistants simply put the materials in an envelope. In other cases, the assistants did nothing at this stage.

13. The payments of $50 to these office assistants exceeded the reasonable fair market value of the assistants' actual time spent.

14. The second phase of the PLACE program provided that if the medical prescriber returned the final questionnaire, they would be paid, in addition to the initial $250 payment, as follows:

(1) an additional $250 if they enrolled between 1 and 5 patients;

(2) an additional $500 if they enrolled between 6 and 10 patients; and

(3) an additional $750 if they enrolled between 11 and 15 patients.

15. These payments of $250-$750 exceeded the reasonable fair market value of the medical prescribers' time necessary to enroll these patients and complete the final questionnaire.

16. In addition, if the final questionnaire was returned, the office assistant also received an additional $100.00. This payment also exceeded the fair market value of the office assistants' time necessary to complete the program.

17. To enroll a patient, the physician or other medicine prescriber was required to write a 30 day prescription for the patient and the patient had to fill the prescription. **BPI** provided a coupon or voucher, however, so that first thirty days of the drug would be free.

18. The physicians and other medicine prescribers were told that in order to receive the payment they also had to track the patients experience on Cardizem, L.A. for three regularly scheduled visits. These visits were nothing more than the routine visits and required no additional work for the prescriber.

19. **BPI** did not design or implement the PLACE program in a way calculated to provide new or meaningful scientific data about whether Cardizem, L.A. worked better than other available drugs.

20. **BPI** employees responsible for the PLACE program reported regularly on the number of prescriptions generated by the PLACE program and congratulated those involved for their success in using the PLACE program to generate prescriptions for Cardizem, L.A.

21. **BPI** paid and caused full payments to be made to medical prescribers and office assistants even if the information provided in the final study questionnaire was incomplete and/or not usable.

22. According to the final study report, nearly 64 percent of the final study questionnaires were not complete or contained inconsistent data.

23. The senior management of **BPI** and **BPI's** parent company communicated to the sales force that a successful launch of Cardizem, L.A. was critical to **BPI's** success and growth as a company, as well as to their own financial well-being. On February 28, 2003, a **BPI** parent company Vice President sent an email to the sales force with respect to the launch of Cardizem, L.A that stated:

> We have to deliver growth to Wall Street and everyone knows exactly what is expected from us. If we ever don't deliver, my net worth will shrink dramatically. I will suffer tremendously if this were to happen . . . We have made a huge

upfront commitment and now we expect you (the reps) to make a commitment in return.

24. **BPI** and its parent company management also congratulated the sales team on its success in using the PLACE program to drive prescriptions for Cardizem, L.A.

25. Thus, on or about April 11, 2003, the **BPI** Product Manager in charge of the PLACE program sent an email to all district sales managers that stated:

> Congratulations on doing an incredible job with the PLACE Program. The prescription generation has been phenomenal – Currently, we have 10,505RXs!!

26. Similarly, on June 23, 2003, this **BPI** Product Manager sent another email, including higher level sales and marketing managers, as follows:

> To date, a total of 89,092 Rxs have been recorded for Cardizem LA, as of June 6th 2003. Congratulations once again on all the success the PLACE Program is having in driving prescriptions and market share!!

27. In addition, on April 5, 2003, the CEO of **BPI's** parent company responded to a report of increasing Cardizem, L.A. prescriptions from the PLACE program with the following:

> This is a GREAT start. Now, who would care to venture a guess (don't we call them forecasts?) on what conversion we can expect to paying customers. I would really like to know what you think. Thanks and nice work.

28. Likewise, on April 8, 2003, the CEO of BPI's parent company responded to reports of 8356 faxed in prescription forms with "I have to tell you, I have NEVER seen this type of response!! CONGRATS!!!"

29. In preparing to launch Cardizem, L.A., **BPI** also contracted with R-Corp. to acquire a additional contracted sales representatives to promote Cardizem, L.A. at the time of its launch. Under the agreement, R-Corp. sales representatives were hired to help **BPI** sales representatives promote Cardizem, L.A. at its launch.

30. Prior to the launch of Cardizem, L.A., R-Corp. representatives raised a concern about whether the PLACE program complied with all laws, and specifically the Anti-Kickback laws and indicated that R-Corp. was unwilling to proceed without assurances that the program complied with the Anti-Kickback Act.

31. On or about March 21, 2003, an attorney for R-Corp. spoke with counsel for **BPI**'s parent company and informed the counsel for **BPI's** parent company about R-Corp.'s internal guidelines regarding the Anti-Kickback Act. These included the following:

> The purpose of the study cannot be to induce physicians to prescribe the product . . .
>
> The compensation cannot take into account the volume or value of any referrals or business generated between the parties . . .
>
> The recruitment of investigators needs to be aimed at practitioners that are experts in the field or leading researchers.
>
> Recruitment of investigators is not to be aimed at high prescribers. . . Participation in the research and any payments cannot be made contingent upon a practitioner prescribing a Reliant product. [Emphasis in original]

The Medicaid Program

32. Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 *et seq*., established a program to enable the states to furnish medical assistance to certain categories of persons whose income and resources were insufficient to meet the costs of necessary medical services. Commonly called Medicaid, the program was administered by the states, but was funded jointly by the federal and state governments.

33. To participate in the Medicaid program, a state was required to develop a plan that was approved by the Secretary of Health and Human Services as meeting federal

requirements. The state paid qualified providers for furnishing necessary services covered by the state plan to individuals who were eligible for medical assistance. The federal government contributed a portion of the costs that each participating state incurred in purchasing items and services from qualified providers on behalf of eligible persons. The state bore the remainder of the costs. At all times relevant hereto, Massachusetts was among the states that had Medicaid programs receiving federal funding.

34. Medicaid programs, including that in Massachusetts, were "federal health care programs" within the meaning of 18 U.S.C. § 24, in that they were public plans affecting commerce under which medical benefits, items and services were provided to individuals under the plans.

35. The federal government contributed to the costs of prescription drugs for persons who were Medicaid beneficiaries, including but not limited to persons receiving prescriptions for blood pressure treatment, such as Cardizem, L.A.

36. As discussed in this Information, prescribers D, E, G, R, S and W were each medical providers in Massachusetts who provided care and treatment for Medicaid-eligible patients for high blood pressure. Each of these prescribers prescribed Cardizem, L.A. for one or more patients who were Medicaid program beneficiaries in 2003. At all times relevant to this Information, the Medicaid program in Massachusetts reimbursed the Cardizem, L.A. prescriptions for the physicians' Medicaid eligible patients.

37. At all times relevant to this Information, federal law provided that it was illegal to knowingly and willfully offer or pay any remuneration (including any kickback, bribe or

rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person *to induce* such person to *order,* or arrange for or *recommend purchasing*, any item for which payment may be made in whole or in part under a Federal health care program.

38. **BPI** employees knew that Cardizem, L.A. prescriptions, including those induced through the PLACE program, would include prescriptions for Medicaid patients.

39. In 2003, Medicaid paid in excess of $3 million in reimbursement for prescriptions for Cardizem, L.A nationwide.

COUNT ONE
(CONSPIRACY - 18 U.S.C. § 371)

The Conspiracy

40. The allegations set forth in Paragraphs 1- 39 are herein realleged and incorporated by reference.

41. Commencing on or before August 2002, and continuing thereafter until in or about at least December 2003, the exact dates being unknown to the Grand Jury, in the District of Massachusetts and elsewhere, defendants

BIOVAIL PHARMACEUTICALS INC.,

and others known and unknown to the Grand Jury, did knowingly and willfully combine, conspire, and agree to commit an offense against the United States, to wit, 42 U.S.C. § 1320a-7b(b)(2)(A), by knowingly and willfully offering and paying remuneration, directly and indirectly, overtly and covertly, in cash and in kind, to physicians to induce them to prescribe Cardizem, L.A. for individuals, including Medicaid patients, for which payments were made in whole and in part under Medicaid and other Federal health care insurance programs.

Purpose of the Conspiracy

42. The purpose of the conspiracy was to target medical prescribers who were potential high prescribers of Cardizem, L.A. and to offer them payments and to pay them to induce them to prescribe Cardizem, L.A. for their patients, including their Medicaid patients.

Manner and Means of the Conspiracy

It was part of the conspiracy that :

43. From March 2003 through at least December 2003, **BPI** implemented the PLACE program to induce medical prescribers to prescribe Cardizem, L.A. for their patients.

44. From March 2003 through at least December 2003, **BPI** presented the PLACE program to medical prescribers and others as a scientific study of the performance of Cardizem, L.A., when the program was actually designed to induce prescribers to prescribe the product for their patients by paying prescribers up to $1,000.

45. From November 2002 through at least on or about March 2003, **BPI** confirmed their objectives for the Cardizem, L.A. program to include the following:

(1) Accelerate uptake among high prescribing PCPs;
(2) Engage physicians in evaluation of Cardizem [L.A.]; and
(3) Provide sales reps with an opportunity to reinforce/build relationships with key prescribers.

46. From March 2003 through at least December 2003, **BPI** paid the participants in the PLACE program more than the fair market value of their time in order to induce them to try Cardizem, L.A. on their patients.

47. From in or about October 2002 through on or about February 2003, **BPI** increased the payments to the physicians from the originally proposed honorarium of $100 (or a medically relevant item) to $300, then $500 and then $1,000 per prescriber.

48. In furtherance of the conspiracy, **BPI** paid the physicians up to $1,000 for their participation, without seeking attorney advice regarding the legality of the payments, even though **BPI** was advised by Q-Corp., the company helping **BPI** to help design and implement the PLACE program, that **BPI** would have to consult its own attorneys as to

the appropriateness and permissibility of increasing the payment to such a high honorarium.

49. From in or about March 2003 through at least July 2003, **BPI** created 25,000 PLACE kits and targeted approximately 17,000 prescribers for participation in the program and provided these target lists to their sales representatives.

50. From in or about March 2003 through at least July 2003, **BPI** targeted prescribers based upon their projected potential and likelihood of prescribing Cardizem, L.A.

51. From in or about March 2003 through at least May 2003, **BPI** falsely assured other participants, and specifically representatives of R-Corp., that the PLACE program had been reviewed by attorneys for compliance with the Anti-Kickback statutes as well as other laws, when in fact no such review had been done.

52. In or about March 2003, a Vice President of **BPI's** parent company dismissed R-Corp's concern about compliance with the Anti-Kickback Act as whining, indicated he did not really care what R-Corp had to say about it, and insisted that the program had to proceed to meet **BPI's** objectives.

53. In or about March 2003, this Vice President, when questioned further about how to deal with the objections concerning the program's potential lack of compliance with the Anti-Kickback Act, caused the program to go forward, concluding: "This is a formality anyway. The program has to proceed."

54. On or about April 10, 2003, **BPI** and a Vice President of its parent corporation signed a letter to R-Corp. in which **BPI** confirmed to R-Corp. the following:

> You have indicated, and assured us, that Biovail and [Q-Corp.] have carefully reviewed the program from an anti-kickback perspective . . . and firmly believe

that the program does not present an unreasonable risk of enforcement action. Further, you have indicated that the program has been reviewed by expert counsel well versed in these regulatory and enforcement matters and that counsel has confirmed your position. It is on the basis of your assurances, therefore, that we have agreed to enter an agreement directly with [Q-Corp]. to implement the Project.

You have agreed to indemnify and hold R-Corp. . . harmless from any losses . . . arising from or relating to the Project including any losses relating to any governmental or enforcement actions relating to the same.

55. On or about April 10, 2003, **BPI** executed this letter to persuade R-Corp. to go forward with the PLACE program, even though **BPI** had not obtained any review of the PLACE program's compliance with the Anti-Kickback Act, much less an expert counsel review of the PLACE program from an anti-kickback perspective.

56. From in or about March 2003 through in or about July 2003, **BPI** made the false representation that they had a legal advice as to the lawfulness of the PLACE program from an anti-kickback perspective in order to persuade R-Corp. to proceed with the program.

57. From in or about April 2003 through at least December 2003, **BPI** caused health insurers, including federal health care programs such as Medicaid, to pay for Cardizem, L.A. prescriptions generated by the PLACE program.

Overt Acts

58. In furtherance of the conspiracy, and to effect its objects, **BPI** and other co-conspirators known and unknown to the Grand Jury, committed numerous overt acts, including, but not omitted to, the following:

59. On various dates between March 2003 and in or about July 2003, **BPI** enrolled and caused to be enrolled approximately 15,000 prescribers in the PLACE program, including the six prescribers identified in the chart below.

60. On various dates between March 2003 and in or about September 2003, **BPI** caused approximately 5,000 prescribers, including the prescribers identified in the chart below, to be paid $250 for filling out the initial questionnaire.

61. On or about the dates set forth below and thereafter, **BPI** caused approximately 10,000 prescribers, including the prescribers identified in the chart below, to be paid and additional $750 for enrolling 11-15 patients.

62. In 2003, each of the prescribers identified in the chart below prescribed Cardizem, L.A. for patients for whom the prescriptions were reimbursed by Medicaid:

Prescriber	Enrollment Date On or About	$750 Payment Date On or About
Prescriber D Dartmouth MA	May 6, 2003	November 5, 2003
Prescriber E Braintree, MA	April 9, 2003	November 5, 2003
Prescriber G Bridgewater, MA	June 2, 2003	November 5, 2003
Prescriber R Springfield, MA	April 28, 2003	November 5, 2003
Prescriber S Agawam, MA	April 29, 2003	November 5, 2003
Prescriber W Long Meadow, MA	April 14, 2003	November 5, 2003

All in violation of Title 18, United States Code, Section 371.

COUNTS TWO - SEVEN
(OFFER OF REMUNERATION TO PHYSICIANS)
(42 U.S.C. § 1320a-7(b)(2)(A))

63. Paragraphs 1-62 are realleged and incorporated as if fully set forth herein.

64. From on or about March 21, 2003 through January 1, 2005, in the District of Massachusetts and elsewhere, defendant

BIOVAIL PHARMACEUTICALS, INC.,

did knowingly and willfully cause to be offered remuneration, directly and indirectly, overtly and covertly, in cash and in kind, to the physicians and other medical prescribers listed below to induce those prescribing medical professionals to prescribe Cardizem, L.A. for their patients, including their Medicaid patients, for which payments for prescriptions beyond the first month of free drug, would be made in whole and in part under state Medicaid programs, as follows:

Count	Date of Offer (On or About)	Medical Prescriber
2	May 6, 2003	Medical Prescriber D
3	April 9, 2003	Medical Prescriber E
4.	June 2, 2003	Medical Prescriber G
5	April 28, 2003	Medical Prescriber R
6	April 29, 2003	Medical Prescriber S
7	April 14, 2003	Medical Prescriber W

All in violation of Title 42, United States Code, Section 1320a-7b(b)(2)(A).

MICHAEL J. SULLIVAN
UNITED STATES ATTORNEY
DISTRICT OF MASSACHUSETTS

By: _____
SARA MIRON BLOOM
ASSISTANT UNITED STATES ATTORNEY

Date: 5/16/08