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UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

AT 0:00 M  
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THE UNITED STATES OF AMERICA,  
the states of CALIFORNIA, DELAWARE,  
FLORIDA, GEORGIA, HAWAII,  
ILLINOIS, INDIANA, LOUISIANA,  
MICHIGAN, NEVADA, NEW JERSEY,  
NEW HAMPSHIRE, NEW MEXICO,  
NEW YORK, OKLHOMA, RHODE  
ISLAND, TENNESSEE, TEXAS, and  
WISCONSIN, the COMMONWEALTHS of  
MASSACHUSETTS and VIRGINIA, and  
the DISTRICT OF COLUMBIA  
*ex rel.* JOHN DOE and JANE ROE,

Plaintiffs,

v.

PAR PHARMACEUTICAL COMPANIES,  
INC., PAR PHARMACEUTICALS, INC.,  
and STRATIVA PHARMACEUTICALS,

Defendants.

Civil Action No. 08- 3624  
(SRC)

Filed under seal pursuant to the  
False Claims Act, 31 U.S.C. § 3730(b)(2),  
and applicable state False Claims Acts

**COMPLAINT AND DEMAND FOR JURY TRIAL**

1. Plaintiff-Relators John Doe and Jane Roe ("relators") bring this action against defendants Par Pharmaceutical Companies, Inc. ("PPCI"), Par Pharmaceutical, Inc. ("PPI"), and Strativa Pharmaceutical on behalf of the United States under the federal False Claims Act ("FCA"), 31 U.S.C. § 3729 et seq., and on behalf of the states named above under their respective state False Claims Acts ("state FCAs") (together referred to as the "qui tam action"). Pursuant to 31 U.S.C. § 3730(b)(2), and comparable provisions in the state FCAs, this action is brought in camera and under seal.

2. In violation of the FCA and the respective state FCAs, the defendants (1) knowingly caused to be presented to the government of United States and of the respective states

false or fraudulent claims for payment or approval; and (2) knowingly made false statements to get false or fraudulent claims paid or approved by the respective governments.

3. Specifically, as alleged in further detail below, the defendants violated the respective false claims acts through aggressive illegal off-label marketing of their brand-name drug, Megace ES, in long-term care (LTC) facilities.

4. Megace ES is a form of megestrol, a drug which is medically indicated for weight loss in AIDS and for use in treating certain cancer patients. In spite of this limited medical indication, since in or about 2005, the defendants have aggressively marketed Megace ES to LTC facilities, all or most of whose patients are geriatric patients, without regard to their HIV or cancer status and without regard to unknown risks of using Megestrol in geriatric patients. As a result, on information and belief, prescriptions have been written for Megace ES, and fraudulent claims for Medicare and Medicaid reimbursement have been made for Megace ES prescriptions as a non-covered outpatient drug.

5. Defendant PPCI, through its wholly-owned subsidiary, defendant PPI, began supplying Megace ES, PPI's first brand product, in 2005. In 2007, PPCI began conducting its brand operations under the name Strativa Pharmaceuticals. From in or about June 2006 through March 2008, the defendants also marketed Megace ES in LTC facilities through a contract sales force supplied by Innovex, Inc., whose offices are located at 10 Waterview Boulevard, Parsippany, New Jersey 07054.

6. PPCI has reported revenues from the sale of Megace ES of approximately \$13.9 million in 2005; \$43.4 million in 2006; and \$75.3 million in 2007. As a result of the defendants' improper off-label marketing and sales practices, a substantial portion of the sales are for geriatric non-HIV, non-indicated cancer patients in LTC facilities.

## **PARTIES, JURISDICTION, AND VENUE**

7. The United States administers Medicare and Medicaid, a jointly funded federal-state program, through the Department of Health and Human Services, Centers for Medicare and Medicaid (“CMS”). The United States and the states named in this complaint are the real parties in interest in this action.

8. Relator John Doe is a resident of New Jersey and relator Jane Roe is a resident of New York. Both are sales representatives for PPI with assignments to LTC facilities in New York and New Jersey. Their true identities have been disclosed to the United States government separately from this complaint.

9. PPI is a wholly-owned subsidiary of PPCI and is in the business of developing, manufacturing, and distributing generic and branded drugs in the United States. PPI's offices are located at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

10. PPCI, is a Delaware holding company that operates primarily through PPI. The principal offices of PPCI are also located also at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677. Parent and subsidiary financial information of PPCI and PPI is reported on a consolidated basis, and the president and chief executive officer of PPCI is also the president and chief executive officer of PPI.

11. The court has subject matter jurisdiction over the federal claims alleged in this Complaint under 28 U.S.C. §§ 1331 (federal question) and 1345 (United States as plaintiff) and 31 U.S.C. § 3732(a) (FCA). Jurisdiction over the state law claims arises under 31 U.S.C. § 3732(b) (jurisdiction over state claims arising from the same transaction or occurrence as an action under the FCA), and 28 U.S.C. § 1367(a) (supplemental jurisdiction).

12. The court has personal jurisdiction over the defendants pursuant to 31 U.S.C. § 3732(a) because they can be found, reside, and transact business in the District of New Jersey and because an act proscribed by 31 U.S.C. § 3729 occurred within this district. Section 3732(a) further provides for nationwide service of process.

13. This action is not jurisdictionally precluded by the FCA's public disclosure bar, 31 U.S.C. § 3730(e)(4). Upon information and belief, there has been no public disclosure of the matters alleged herein and this action is not based upon any such disclosure. Notwithstanding the foregoing, through their employment with the defendants and interaction with the defendants; personnel and others, the relators have direct and independent knowledge of the instant allegations. Additionally, they have voluntarily provided, and offered to provide, this information to the United States government before filing this complaint. Therefore, to the extent any of these allegations is deemed to have been based upon a public disclosure, the relators are an original source of this information within the meaning of the False Claims Act and are expressly excepted from its public disclosure bar.

14. Venue is proper in this district under 28 U.S.C. §§ 1391(b) and (c), and 31 U.S.C. § 3732(a), because the defendants reside and transact business, and a substantial part of the events or omissions giving rise to the violations of 31 U.S.C. § 3729 alleged in this complaint occurred, in this district.

#### **DEFENDANT'S FALSE AND FRAUDULENT OFF-LABEL MARKETING SCHEME**

15. Under the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301-97, new drugs cannot be introduced into interstate commerce unless the Food and Drug Administration ("FDA") finds that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a),

(d). Although doctors are allowed to prescribe a drug for uses other than those which have been found by the FDA to be safe and effective ( "off-label uses"), the law prohibits drug manufacturers (except within narrow restrictions not applicable here), from marketing or promoting a drug for a use that the FDA has not approved. 21 U.S.C. §§ 331(d), 355(a).

16. In targeting LTC facilities, from at least in or about 2005 to the present, the defendants violated the restrictions on off-label marketing. As examples, defendants' executives and managers told sales reps to contact dieticians, administrators, and possibly others not licensed to prescribe drugs; provided information other than written safety/effectiveness information of the non-approved use; had no studies of the use of Megace ES in geriatric populations; and failed to provide sales reps with copies of any responses to physicians who inquire about such use. In addition, on information and belief, the defendants did not have a New Drug Application on file and did not intend to file a supplemental New Drug Application for the new use; did not file the required copies of information with FDA and include the required disclaimers; and provided information other than reprints of peer-reviewed articles and reference publication entries that are not false or misleading.

17. The defendants' managers instructed the relators and other sales representatives to "flip" as many LTC facilities to Megace ES as possible. The marketing materials, instructions, and practices they are being told to follow make no reference to the HIV or cancer status of the patients they are supposed to target. The studies provided by the company are expressly based on HIV patients; there are no studies or information about the use of Megace ES in geriatric populations; and their sales goals are to flip a percentage of the LTC business regardless of whether there are any HIV or indicated cancer patients. They are told to seek out the largest

nursing homes and those with the most patients with weight loss; look for favorable Medicare Part D plans in each state; and market to hospices, which are largely Medicaid funded.

18. The defendants' executives and managers who caused the sales force to engage in the off-label marketing of Megace ES for geriatric patients in LTC facilities include, as examples,

- Patrick Lepore, President and CEO, PPCI and PPI
- John MacPhee, President, Strativa, Branded Division of Par (reports to Lepore)
- Nefertiti Greene, Senior VP of Sales and Marketing, Strativa (reports to MacPhee)
- Brad Herschman, Area Director, East Coast Strativa (reports to Greene)
- Melissa Masterson, Director, Managed Markets (LTC) (reports to Greene)
- Beth Mills, National Account Manager - Managed Markets (LTC) (reports to Masterson)
- Fred Steinberg, Regional Account Manager (Innovex) (former employee; reported to Mills)
- Matthew Kryder, Regional Account Manager (Strativa; reports to Mills)
- Tracy Fulton - Regional Account Manager (Innovex), Area Business Manager (Strativa) (formerly reported to Mills)

18. The defendants' managers, including those named above, improperly promoted the sale of Megace ES in LTC facilities to cause physicians to write more prescriptions for Megace ES without regard to whether they were for AIDS patients (or indicated cancer patients) or not.

19. The defendants' sales materials lend an air of legitimacy to their marketing of Megace ES in LTC facilities by saying that HIV in LTC facilities is "underreported," but it is unlikely to impossible that the facilities the defendants are targeting have HIV patients on a scale commensurate with the company's goals and practices.

20. As examples, of five targeted nursing homes in Brooklyn and nearby New Jersey, with a total of 1,330 beds, the percent of HIV beds is zero.

<u>Facility</u>	<u>Location</u>	<u>Beds</u>	<u>HIV beds</u>	<u>Phys. on call panel</u>
Atlantis	Brooklyn	400	0	3

Sheepshead	Brooklyn	300	0	2
Hamilton Park	Jersey City	250	0	2
Delaire	Linden	240	0	2
Cusack Care	Jersey City	140	0	3

21. Many of the physicians on the sales representatives' call panels (such as the call panel listed above) have a high potential for conversion to prescribing Megace ES because they are medical directors in LTC facilities or have patients in several nursing homes. Management instructions for promoting sales of Megace ES no longer talks about "appropriate" patients. The sales representatives' goals and quotas are based on "flipping" a percentage of the business regardless of the patients' HIV (or cancer) status.

22. As a further example, from January 1 to May 30, 2007, the following physicians prescribed a total of 6,900 doses of Megace ES for patients in the Hamilton Park facility, which has zero HIV beds, on the following dates:

<u>Physician</u>	<u>Date</u>	<u>Qty.</u>
Akhtar, Shahnaz	5/31/2007	150
Bhatt, Pranay	4/11/2007	150
Bhatt, Pranay	5/26/2007	150
Booth, Linda	5/14/2007	150
Cardiello, Gary	4/16/2007	150
Cardiello, Gary	5/16/2007	150
Cardiello, Gary	5/23/2007	150
Carolino, Jerome	4/11/2007	150
Carolino, Jerome	4/18/2007	150
Carolino, Jerome	4/19/2007	150
Carolino, Jerome	5/1/2007	150
Carolino, Jerome	5/19/2007	150
Carolino, Jerome	5/23/2007	150
Dedousis, John	5/10/2007	150
Dedousis, John	5/10/2007	150
Dedousis, John	5/21/2007	150
Elias, Sameh	4/23/2007	150
Elias, Sameh	5/17/2007	150
Fogari, Robert	4/11/2007	150

Fogari, Robert	5/4/2007	150
Jurado, Jerry	4/18/2007	150
Lazo, Angel	5/17/2007	150
Levine, Howard	5/14/2007	150
Levine, Howard	5/15/2007	150
Milazzo, Carmelo	4/17/2007	150
Mutterperl, Mitchell	4/16/2007	150
Mutterperl, Mitchell	5/24/2007	150
Neibert, John	4/13/2007	150
Neibert, John	4/17/2007	150
Neibert, John	4/23/2007	150
Neibert, John	4/23/2007	150
Neibert, John	5/8/2007	150
Neibert, John	5/17/2007	150
Perera, Sharmalie	5/17/2007	150
Perveen, Mahmoodah	5/22/2007	150
Rajasekaran, Jeyachandran	4/23/2007	150
Rajasekaran, Jeyachandran	4/28/2007	150
Rajasekaran, Jeyachandran	5/24/2007	150
Reisner, Michelle	4/23/2007	150
Reisner, Michelle	5/29/2007	150
Reisner, Michelle	6/1/2007	150
Shukla, Paresh	4/19/2007	150
Shukla, Paresh	4/23/2007	150
Shukla, Paresh	6/1/2007	150
Wignarajan, Kanagarayer	5/30/2007	150
Wilcox, Ellis	1/19/2007	150
TOTAL		6,900

23. In presenting to nursing staffs and dietitians in LTC facilities, questions arise regarding potential risks to the geriatric patient population, such as, for example, deep vein thrombosis, diabetes, and adrenal suppression (which are among the known and reported potential adverse effects of Megace ES). The defendants' sales representatives have to downplay the risks without having supporting studies (published or not) to substantiate their statements.



24. The off-label use of Megace ES that was improperly promoted by the defendants for patients in LTC facilities is not for a “medically accepted indication,” and, as such, it is not reimbursable by Medicare and Medicaid.

25. To the relators’ knowledge, the prescriptions that the defendants caused to be written and the consequent requests for reimbursement for them did not disclose that the Megace ES prescriptions were for an off-label use. To the contrary, each prescription reimbursement claim impliedly certified that it was for an on-label use.

26. On-label use is an express condition for Medicare and Medicaid reimbursement. Because they are for an off-label use, each such claim was false.

27. Each prescription constitutes a false claim under the FCA and the state FCAs, which the defendants caused to be presented to the government by the patients, pharmacies, facilities, or others who submitted the requests for reimbursement. Each such prescription also constitutes a false or fraudulent record that the defendants caused to be used or made to get the claims paid or approved in violation of the FCA and the state FCAs.

28. The defendants knew and intended that Megace ES would be marketed to be prescribed for non-HIV and non-indicated cancer patients.

29. The defendants knew that many if not most of the prescriptions would be reimbursed by, or reimbursement for them would be sought from, Medicare and Medicaid.

## **MEDICAID AND MEDICARE**

### **Medicaid**

30. The Medicaid program provides “medical assistance to individuals and families whose resources are insufficient to meet the costs of necessary medical services.” 42 U.S.C.

§ 1396. This includes, where appropriate, reimbursement for the cost of outpatient drug prescriptions.

31. Medicaid providers, such as pharmacies, pay drug manufacturers for prescription drugs and, in turn, submit claims to state Medicaid agencies for reimbursement for prescriptions filled for eligible Medicaid beneficiaries. 42 U.S.C. § 1396a(a)(23), (a)(32).

32. Reimbursements for drugs prescribed to Medicaid beneficiaries are submitted by pharmacies to state Medicaid agencies. The federal government reimburses states for a substantial portion of the funds allotted. 42 U.S.C. § 1396. State Medicaid administrators obtain the federal government's share of such costs and expenses by submitting quarterly forms CMG 64 to CMS. For this reason, claims submitted to state Medicaid agencies are "presented" to the federal government within the meaning of the FCA.

33. The federal government pays Medicaid claims through a continuing line of credit certified to the Secretary of the Treasury in favor of the state payee. 42 C.F.R. § 430.30(d)(3), (4). The federal government authorizes the state payee "to draw Federal funds as needed to pay the Federal share of disbursements, 42 C.F.R. § 430.30(d)(3). The state can draw down on those funds only to pay the Medicaid claims of healthcare providers. 42 C.F.R. § 430.30(d). The funds made available to the state thus remain federal funds, in a Federal Reserve account, until they are drawn by the state and used to pay a provider's claim.

34. The federal government also "approves" within the meaning of the FCA the claims submitted and paid through the Medicaid program. When a state presents its Form CMS-64, i.e., the quarterly report of actual expenditures, to CMS the amounts of any fraudulent claims the state paid will be included in those reports. Based on the information in the reports, CMS determines and approves whether the claims that the state paid with federal funds were

appropriate. If CMS determines that certain claims paid by the state were improper, CMS may recoup the amount of the erroneously expended funds by reducing the amount of money provided to the state during the next quarter.

35. Because the Form CMS-64 constitutes the United States' means for approving and paying the amount of federal funds expended by the state, these reports overstate the amount of federal funds to which the state was entitled by the amount fraudulently paid. They are therefore false records or statements caused to be made or used to get false claims paid and approved by the United States.

36. Although physicians are allowed to prescribe a drug for off-label uses, Medicaid generally reimburses providers only for "covered outpatient drugs." 42 U.S.C. §§ 1396b(i)(10), 1396r-8(a)(3). "Covered drugs" do not include drugs "used for a medical indication which is not a medically accepted indication." 42 U.S.C. § 1396r-8(k)(3).

37. A medically accepted indication is one approved under the Federal Food, Drug, and Cosmetic Act or one included in certain, specified drug compendia. 42 U.S.C. § 1396r-8(k)(6). In effect, unless a particular off-label use for a drug is included in one of the identified drug compendia, a prescription for such use is not eligible for reimbursement by Medicaid.

38. Megace ES is not a "covered outpatient drug" when prescribed for anorexia, cachexia, or weight loss not associated with AIDS or indicated cancer uses.

### **Medicare**

39. The Medicare program provides medical assistance for the elderly. Medicare providers, such as pharmacies, pay drug manufacturers for prescription drugs and, in turn, submit

claims directly or through fiscal intermediaries and carriers for reimbursement for prescriptions filled for eligible beneficiaries.

40. The conditions for payment under Medicare Part B for covered outpatient drugs, 42 U.S.C. § 1395l(t)(14)(B), are generally as provided by the Medicaid statute.

41. The conditions for payment under Medicare Part D for covered outpatient drugs, 42 U.S.C. § 1395w-102(e), are generally as provided by the Medicaid statute. In addition, certain drugs and uses that fall under section 1396r-8(d)(2) are excluded, such as drugs “when used for anorexia, weight loss, or weight gain,” § 1396r-8(d)(2)(A).

#### **THE FEDERAL AND STATE FALSE CLAIMS ACTS**

42. The Federal FCA, 31 U.S.C. § 3729(a)(1), makes knowingly presenting or causing to be presented to the United States any false or fraudulent claim for payment, a violation of federal law for which the United States may recover three times the amount of the damages the government sustains and a civil monetary penalty of between \$5,500 and \$11,000 per claim for claims made on or after September 29, 1999. Section 3729(a)(2) makes knowingly making, using, or causing to be used or made, a false record or statement to get a false or fraudulent claim paid or approved by the Government, a violation of federal law for which the United States may recover three times the amount of the damages the Government sustains and a civil monetary penalty of between \$5,500 and \$11,000 per claim for claims made on or after September 29, 1999.

43. A person acts knowingly under the FCA when it “(1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof or specific intent to defraud is required.” 37 U.S.C. § 3729(b).

44. Several states have passed False Claims Act legislation, cited below, which in most instances closely tracks the federal FCA. Medicaid fraud losses caused by false Medicaid claims to the jointly federal-state funded Medicaid program are actionable under these statutes. Each of the state statutes contains *qui tam* provisions and provides for relators to share in the state's recovery.

**Count 1**  
**31 U.S.C. § 3729(a)(1)**  
**(Medicare)**

45. The relators reallege paragraphs 1 through 44 above.

46. From at least 2005 to the present, The defendants knowingly caused pharmacies, physicians, pharmacy benefit managers, and others to submit claims to Medicare for reimbursement for off-label prescriptions for Megace ES.

47. Each claim for reimbursement for such prescriptions represents a false or fraudulent claim for payment under section 3729(a)(1).

48. If the government of the United States had known that the claims for reimbursement were for non-covered drugs it would not have paid the claims.

49. The United States has been damaged by the defendants' wrongful conduct.

**Count 2**  
**31 U.S.C. § 3729(a)(2)**  
**(Medicare)**

50. The relators reallege paragraphs 1 through 44 above.

51. From at least 2005 to the present, the defendants knowingly caused physicians to write prescriptions for Medicare and Medicaid beneficiaries for off-label uses of Megace ES.

52. Each prescription that was written as a result of the defendants' illegal marketing practices, and the defendants' incomplete, misleading, or false sales and promotional materials,

represent false or fraudulent records or statements under section 3729(a)(2) that were used to get a false claim paid or approved.

53. If the government of the United States had known that the prescriptions were caused to be written to get false or fraudulent claims paid, it would not have paid the claims.

54. The United States has been damaged by the defendants' wrongful conduct.

**Count 3**  
**31 U.S.C. § 3729(a)(1)**  
**(Medicaid)**

55. The relators reallege paragraphs 1 through 44 above.

56. From at least 2005 to the present, the defendants knowingly caused pharmacies, physicians, pharmacy benefit managers, and others to submit claims to Medicaid for reimbursement for off-label prescriptions for Megace ES.

57. Each claim for reimbursement for such prescriptions represents a false or fraudulent claim for payment under Section 3729(a)(1).

58. If the government of the United States had known that the claims for reimbursement were for non-covered drugs it would not have paid the claims.

59. The United States has been damaged by the defendants' wrongful conduct.

**Count 4**  
**31 U.S.C. § 3729(a)(2)**  
**(Medicaid)**

60. The relators reallege paragraphs 1 through 44 above.

61. From at least 2005 to the present, the defendants knowingly caused physicians to write prescriptions for Medicaid beneficiaries for off-label uses of Megace ES.

61. Each prescription that was written as a result of the defendants' illegal marketing practices, and the defendants' incomplete, misleading, or false sales and promotional materials,

represent false or fraudulent records or statements under section 3729(a)(2) that were used to get a false claim paid or approved.

62. If the government of the United States had known that the prescriptions were caused to be written to get false or fraudulent claims paid, it would not have paid the claims.

63. The United States has been damaged by the defendants' wrongful conduct.

**Count 5**  
**Cal. Gov't Code § 12651(a)(1)**

64. The relators reallege paragraphs 1 through 44 above.

65. The California False Claims Act, Cal. Gov't Code § 12651(a)(1), provides:

(a) Any person who commits any of the following acts shall be liable to the state . . . for three times the amount of damages which the state . . . sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the state . . . for the costs of a civil action brought to recover any of those penalties or damages, and may be liable to the state . . . for a civil penalty of up to ten thousand (\$10,000) for each false claim:

Knowingly presents or causes to be presented to an officer or employee of the state . . . a false claim for payment or approval.

66. From at least 2005 to the present, the defendants knowingly caused pharmacies, physicians, pharmacy benefit managers, and others to submit claims to Medi-Cal, the California Medicaid program, for reimbursement for off-label prescriptions for Megace ES.

67. Each claim for reimbursement for such prescriptions represents a false or fraudulent claim for payment under the statute.

68. If the government of California had known that the claims for reimbursement were for non-covered drugs it would not have paid the claims.

69. The state of California has been damaged by the defendants' wrongful conduct.

**Count 6**  
**Cal. Gov't Code § 12651(a)(2)**

70. The relators reallege paragraphs 1 through 44 above.
71. The California False Claims Act, Cal. Gov't Code § 12651(a)(2), provides:

(a) Any person who commits any of the following acts shall be liable to the state . . . for three times the amount of damages which the state . . . sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the state... for the costs of a civil action brought to recover any of those penalties or damages, and may be liable to the state . . . for a civil penalty of up to ten thousand (\$10,000) for each false claim:

(2) Knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state . . . .

72. Each prescription that was written as a result of the defendants' illegal marketing practices, and the defendants' incomplete, misleading, or false sales and promotional materials, represent false or fraudulent records or statements under the statute that were used to get a false claim paid or approved.

73. If the government of California had known that the prescriptions were caused to be written to get false or fraudulent claims paid, it would not have paid the claims.

74. The state of California has been damaged by the defendants' wrongful conduct.

**Count 7**  
**Del. Code Tit. 6, § 1201(a)(1)**

75. The relators reallege paragraphs 1 through 44 above.

76. The Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1201(a)(1), provides that any person who:

(a)(1) Knowingly presents, or causes to be presented, directly or indirectly, to an officer or employee of the Government a false or fraudulent claim for payment or approval;

shall be liable to the Government for a civil penalty of not less than \$5,500 and not more than \$11,000 for each act constituting a violation of this section, plus 3 times the amount of actual damages which the Government sustains because of the act of that person.



77. From at least 2005 to the present, the defendants knowingly caused pharmacies, physicians, pharmacy benefit managers, and others to submit claims to the Delaware Medicaid program for reimbursement for off-label prescriptions for Megace ES.

78. Each claim for reimbursement for such prescriptions represents a false or fraudulent claim for payment under the statute.

79. If the government of Delaware had known that the claims for reimbursement were for non-covered drugs it would not have paid the claims.

80. The state of Delaware has been damaged by the defendants' wrongful conduct.

**Count 8**  
**Del. Code Tit. 6, § 1201(a)(2)**

81. The relators reallege paragraphs 1 through 44 above.

82. The Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1201(a)(2), provides that any person who:

(a)(2) Knowingly makes, uses or causes to be made or used, directly or indirectly, a false record or statement to get a false or fraudulent claim paid or approved;

shall be liable to the Government for a civil penalty of not less than \$5,500 and not more than \$11,000 for each act constituting a violation of this section, plus 3 times the amount of actual damages which the Government sustains because of the act of that person.

83. From at least 2005 to the present, the defendants knowingly caused physicians to write prescriptions for Delaware Medicaid beneficiaries for reimbursement for off-label prescriptions for Megace ES.

84. Each prescription that was written as a result of the defendants' illegal marketing practices, and the defendants' incomplete, misleading, or false sales and promotional materials,

represent false or fraudulent records or statements under the statute that were used to get a false claim paid or approved.

85. If the government of Delaware had known that the prescriptions were caused to be written to get false or fraudulent claims paid, it would not have paid the claims.

86. The state of Delaware has been damaged by the defendants' wrongful conduct.

**Count 9**  
**D.C. Code § 2-308.14(a)(1)**

87. The relators reallege paragraphs 1 through 44 above.

88. The District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.14(a)(1), provides:

(a) Any person who commits any of the following acts shall be liable to the District for 3 times the amount of damages which the District sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the District for the costs of a civil action brought to recover penalties or damages, and may be liable to the District for a civil penalty of not less than \$5,000, and not more than \$10,000, for each false claim for which the person:

(1) Knowingly presents, or causes to be presented, to an officer or employee of the District a false claim for payment or approval.

89. From at least 2005 to the present, the defendants knowingly caused pharmacies, physicians, pharmacy benefit managers, and others to submit claims to the D.C. Medical Assistance Administration, the D.C. Medicaid program, for reimbursement for off-label prescriptions for Megace ES.

90. Each claim for reimbursement for such prescriptions represents a false or fraudulent claim for payment under the statute.

91. If the government of the District of Columbia had known that the claims for reimbursement were for non-covered drugs it would not have paid the claims.

92. The District of Columbia has been damaged by the defendants' wrongful conduct.

**Count 10**  
**D.C. Code § 2-308.14(a)(2)**

93. The relators reallege paragraphs 1 through 44 above.

94. The District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.14(a)(2), provides:

(a) Any person who commits any of the following acts shall be liable to the District for 3 times the amount of damages which the District sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the District for the costs of a civil action brought to recover penalties or damages, and may be liable to the District for a civil penalty of not less than \$5,000, and not more than \$10,000, for each false claim for which the person:

(2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false claim paid or approved by the District;

95. From at least 2005 to the present, the defendants knowingly caused physicians to write prescriptions for D.C. Medical Assistance Administration beneficiaries for reimbursement for off-label prescriptions for Megace ES.

96. Each prescription that was written as a result of the defendants' illegal marketing practices, and the defendants' incomplete, misleading, or false sales and promotional materials, represent false or fraudulent records or statements under the statute that were used to get a false claim paid or approved.

97. If the government of the District of Columbia had known that the prescriptions were caused to be written to get false or fraudulent claims paid, it would not have paid the claims.

98. The District of Columbia has been damaged by the defendants' wrongful conduct.

**Count 11**  
**Fla. Stat. § 68.082(2)(a)**

99. The relators reallege paragraphs 1 through 44 above.

100. The Florida False Claims Act, Fla. Stat. § 68.082(2)(a), provides that any person who:

(a) Knowingly presents or causes to be presented to an officer or employee of an agency a false claim for payment or approval; ...is liable to the state for a civil penalty of not less than \$5,000 and not more than \$10,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

101. From at least 2005 to the present, the defendants knowingly caused pharmacies, physicians, pharmacy benefit managers, and others to submit claims to the Florida Medicaid program for reimbursement for off-label prescriptions for Megace ES.

102. Each claim for reimbursement for such prescriptions represents a false or fraudulent claim for payment under the statute.

103. If the government of Florida had known that the claims for reimbursement were for non-covered drugs it would not have paid the claims.

104. The state of Florida has been damaged by the defendants' wrongful conduct.

**Count 12**  
**Fla. Stat. § 68.082(2)(b)**

105. The relators reallege paragraphs 1 through 44 above.

106. The Florida False Claims Act, Fla. Stat. § 68.082(2)(b), provides that any person who:

(b) Knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by an agency; ...  
  
is liable to the state for a civil penalty of not less than \$5,000 and not more than \$10,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

107. From at least 2005 to the present, the defendants knowingly caused physicians to write prescriptions for Florida Medicaid beneficiaries for reimbursement for off-label prescriptions for Megace ES.

108. Each prescription that was written as a result of the defendants' illegal marketing practices, and the defendants' incomplete, misleading, or false sales and promotional materials, represent false or fraudulent records or statements under the statute that were used to get a false claim paid or approved.

109. If the government of Florida had known that the prescriptions were caused to be written to get false or fraudulent claims paid, it would not have paid the claims.

110. The state of Florida has been damaged by the defendants' wrongful conduct.

**Count 13**  
**Ga. Code Ann. Art. 7B, Ch. 4, Tit. 49**

111. The relators reallege paragraphs 1 through 44 above.

112. The Georgia State False Medicaid Claims Act, Ga. Code Ann. § 49-4-168, *et seq.*, provides at § 49-4-168.1, that:

(a) Any person who:

(1) Knowingly presents or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval;

shall be liable to the State of Georgia for a civil penalty of not less than \$5,500.00 and not more than \$11,000.00 for each false or fraudulent claim, plus three times the amount of damages which the Georgia Medicaid program sustains because of the act of such person.

113. From at least 2005 to the present, the defendants knowingly caused pharmacies, physicians, pharmacy benefit managers, and others to submit claims to the Georgia Medicaid program for reimbursement for off-label prescriptions for Megace ES.

114. Each claim for reimbursement for such prescriptions represents a false or fraudulent claim for payment under the statute..

115. If the government of Georgia had known that the claims for reimbursement were for non-covered drugs it would not have paid the claims.

116. The state of Georgia has been damaged by the defendants' wrongful conduct.

**Count 14**  
**Ga. Code Ann. Art. 7B, Ch. 4, Tit. 49**

117. The relators reallege paragraphs 1 through 44 above.

118. The Georgia State False Medicaid Claims Act, Ga. Code Ann. § 49-4-168, *et seq.*, provides at § 49-4-168.1, that:

(a) Any person who:

(2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Georgia Medicaid program;

shall be liable to the State of Georgia for a civil penalty of not less than \$5,500.00 and not more than \$11,000.00 for each false or fraudulent claim, plus three times the amount of damages which the Georgia Medicaid program sustains because of the act of such person.

119. From at least 2005 to the present, the defendants knowingly caused physicians to write prescriptions for Georgia beneficiaries for reimbursement for off-label prescriptions for Megace ES.

120. Each prescription that was written as a result of the defendants' illegal marketing practices, and the defendants' incomplete, misleading, or false sales and promotional materials, represent false or fraudulent records or statements under the statute that were used to get a false claim paid or approved.

121. If the government of Georgia had known that the prescriptions were caused to be written to get false or fraudulent claims paid, it would not have paid the claims.

122. The state of Georgia has been damaged by the defendants' wrongful conduct.

**Count 15**  
**740 Ill. Comp. Stat. § 175/3 (a)(1)**

123. The relators reallege paragraphs 1 through 44 above.

124. The Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat.

§ 175/3(a)(1), provides that any person who:

(1) knowingly presents, or causes to be presented, to an officer or employee of the State or member of the Guard a false or fraudulent claim for payment or approval;

...

is liable to the State for a civil penalty of not less than \$5,000 and not more than \$10,000, plus 3 times the amount of damages which the State sustains because of the act of that person.

125. From at least 2005 to the present, the defendants knowingly caused pharmacies, physicians, pharmacy benefit managers, and others to submit claims to the Illinois Medicaid program for reimbursement for off-label prescriptions for Megace ES.

126. Each claim for reimbursement for such prescriptions represents a false or fraudulent claim for payment under the statute.

127. If the government of Illinois had known that the claims for reimbursement were for non-covered drugs it would not have paid the claims.

128. The state of Illinois has been damaged by the defendants' wrongful conduct.

**Count 16**  
**740 Ill. Comp. Stat. § 175/3(a)(2)**

129. The relators reallege paragraphs 1 through 44 above.

130. The Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat.

§ 175/3(a)(2), provides that any person who:

(2) knowingly makes, uses or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;

...

is liable to the State for a civil penalty of not less than \$5,000 and not more than \$10,000, plus 3 times the amount of damages which the State sustains because of the act of that person.

131. From at least 2005 to the present, the defendants knowingly caused physicians to write prescriptions for Illinois Medicaid beneficiaries for reimbursement for off-label prescriptions for Megace ES.

132. Each prescription that was written as a result of the defendants' illegal marketing practices, and the defendants' incomplete, misleading, or false sales and promotional materials, represent false or fraudulent records or statements under the statute that were used to get a false claim paid or approved.

133. If the government of Illinois had known that the prescriptions were caused to be written to get false or fraudulent claims paid, it would not have paid the claims.

134. The state of Illinois has been damaged by the defendants' wrongful conduct.

**Count 17**  
**IC 5-11-5.5**

135. The relators reallege paragraphs 1 through 44 above.

136. The Indiana False Claims and Whistleblower Protection Act, IC 5-11-5.5-2(b) (2005), provides that by certain acts a person commits an unlawful act and shall be liable to the state for civil penalties and three times the amount of damages that the state sustains because of the act of that person [including]:



presents a false claim to the state for payment or approval;

137. From at least 2005 to the present, the defendants knowingly caused pharmacies, physicians, pharmacy benefit managers, and others to submit claims to the Indiana Medicaid program for reimbursement for off-label prescriptions for Megace ES.

138. Each claim for reimbursement for such prescriptions represents a false or fraudulent claim for payment under the statute.

139. If the government of Indiana had known that the claims for reimbursement were for non-covered drugs it would not have paid the claims.

140. The state of Indiana has been damaged by the defendants' wrongful conduct.

**Count 18**  
**I.C. 5-11-5.5**

141. The relators reallege paragraphs 1 through 44 above.

142. The Indiana False Claims and Whistleblower Protection Act, IC 5-11-5.5-2(b) (2005), provides that by certain acts a person commits an unlawful act and shall be liable to the state for civil penalties and three times the amount of damages that the state sustains because of the act of that person [including]:

makes or uses a false record or statement to obtain payment or approval of a false claims from the state; . . .

143. From at least 2005 to the present, the defendants knowingly caused physicians to write prescriptions for Indiana Medicaid beneficiaries for reimbursement for off-label prescriptions for Megace ES.

144. Each prescription that was written as a result of the defendants' illegal marketing practices, and the defendants' incomplete, misleading, or false sales and promotional materials,

represent false or fraudulent records or statements under the statute that were used to get a false claim paid or approved.

145. If the government of Indiana had known that the prescriptions were caused to be written to get false or fraudulent claims paid, it would not have paid the claims.

146. The state of Indiana has been damaged by the defendants' wrongful conduct.

**Count 19**  
**46 La. Rev. Stat. c. 3 § 438.3A**

147. The relators reallege paragraphs 1 through 44 above.

148. The Louisiana False Claims Act/Medical Assistance Programs Integrity Law ("Louisiana FCA"), 46 La. Rev. Stat. c. 3 § 438.3A, provides that: "No person shall knowingly present or cause to be presented a false or fraudulent claim".

149. From at least 2005 to the present, the defendants knowingly caused pharmacies, physicians, pharmacy benefit managers, and others to submit claims to the Louisiana Medicaid program for reimbursement for off-label prescriptions for Megace ES.

150. Each claim for reimbursement for such prescriptions represents a false or fraudulent claim for payment under the statute.

151. If the government of Louisiana had known that the claims for reimbursement were for non-covered drugs it would not have paid the claims.

152. The state of Louisiana has been damaged by the defendants' wrongful conduct.

**Count 20**  
**46 La. Rev. Stat. 1**

153. The relators reallege paragraphs 1 through 44 above.

154. The Louisiana FCA, 46 La. Rev. Stat. c. 3 § 438.3B, provides that:

No person shall knowingly engage in misrepresentation to obtain, or attempt to obtain, payment from medical assistance programs funds.

155. From at least 2005 to the present, the defendants knowingly caused physicians to write prescriptions for Louisiana Medicaid beneficiaries for reimbursement for off-label prescriptions for Megace ES.

156. Each prescription that was written as a result of the defendants' illegal marketing practices, and the defendants' incomplete, misleading, or false sales and promotional materials, represents a misrepresentation made to obtain or attempt to obtain payment from medical assistance programs funds.

157. If the government of Louisiana had known that the prescriptions were caused to be written to get false or fraudulent claims paid, it would not have paid the claims.

158. The state of Louisiana has been damaged by the defendants' wrongful conduct.

**Count 21**  
**Mass. Gen. Laws Ch. 12, § 5B(1)**

159. The relators reallege paragraphs 1 through 44 above.

160. The Massachusetts False Claims Act, M.G.L. Ch. 12, § 5B(1), provides that any person who:

(1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

...

shall be liable to the commonwealth or political subdivision for a civil penalty of not less than \$5,000 and not more than \$10,000 per violation, plus three times the amount of damages, including consequential damages, that the commonwealth or political subdivision sustains because of the act of that person.

161. From at least 2005 to the present, the defendants knowingly caused pharmacies, physicians, pharmacy benefit managers, and others to submit claims to MassHealth, the Massachusetts Medicaid program, for reimbursement for off-label prescriptions for Megace ES.

162. Each claim for reimbursement for such prescriptions represents a false or fraudulent claim for payment under the statute.

163. If the government of Massachusetts had known that the claims for reimbursement were for non-covered drugs it would not have paid the claims.

164. The Commonwealth of Massachusetts has been damaged by the defendants' wrongful conduct.

**Count 22**  
**Mass. Gen. Laws Ch. 12, § 5B(2)**

165. The relators reallege paragraphs 1 through 44 above.

166. The Massachusetts False Claims Act, M.G.L. Ch. 12, § 5B(2), provides that any person who:

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth or any political subdivision thereof;

...

shall be liable to the commonwealth or political subdivision for a civil penalty of not less than \$5,000 and not more than \$10,000 per violation, plus three times the amount of damages, including consequential damages, that the commonwealth or political subdivision sustains because of the act of that person.

167. From at least 2005 to the present, the defendants knowingly caused physicians to write prescriptions for Massachusetts Medicaid beneficiaries for reimbursement for off-label prescriptions for Megace ES.

168. Each prescription that was written as a result of the defendants' illegal marketing practices, and the defendants' incomplete, misleading, or false sales and promotional materials, represent false or fraudulent records or statements under the statute that were used to get a false claim paid or approved.

169. If the government of Massachusetts had known that the prescriptions were caused to be written to get false or fraudulent claims paid, it would not have paid the claims.

170. The Commonwealth of Massachusetts has been damaged by the defendants' wrongful conduct.

**Count 23**  
**Mich. Comp. Laws Ch. 400**

171. The relators reallege paragraphs 1 through 44 above.

172. The Michigan Medicaid False Claims Act, MCL § 400.603, provides:

A person shall not knowingly make or cause to be made a false statement or false representation of a material fact in an application for Medicaid benefits... [or] for use in determining rights to a Medicaid benefit.

173. It further provides that

A person, having knowledge of the occurrence of an event affecting ...[the] initial or continued right of any other person on whose behalf he has applied...shall not conceal or fail to disclose that event with intent to obtain a benefit to which the person or any other person is not entitled or in an amount greater than that to which the person or any other person is entitled.

174. Under section 400.612,

A person who receives a benefit which the person is not entitled to receive by reason of fraud or making a fraudulent statement or knowingly concealing a material fact shall forfeit and pay to the state a civil penalty equal to the full amount received plus triple the amount of damages suffered by the state as a result of the conduct by the person."

175. From at least 2005 to the present, the defendants knowingly caused pharmacies, physicians, pharmacy benefit managers, and others to misrepresent material facts and to make false statements for use in determining rights to a Medicaid benefit.

176. Each claim for reimbursement for such prescriptions represents a false or fraudulent claim statement under the statute.

177. If the government of Michigan had known that the claims for reimbursement were for non-covered drugs it would not have paid the claims.

178. The state of Michigan has been damaged by the defendants' wrongful conduct.

**Count 24**  
**Mich. Comp. Laws Ch. 400**

179. The relators reallege paragraphs 1 through 44 above.

180. The Michigan Medicaid False Claim Act, MCL § 400.607, provides :

A person shall not make or present or cause to be made or presented to an employee or officer [of the state] a claim . . . upon or against the state, knowing the claim to be false . . . .

A person shall not make or present or cause to be made or presented a claim . . . which he or she knows falsely represents that the goods or services for which the claim is made were medically necessary . . . .

181. Under section 400.612,

A person who receives a benefit which the person is not entitled to receive by reason of fraud or making a fraudulent statement or knowingly concealing a material fact shall forfeit and pay to the state a civil penalty equal to the full amount received plus triple the amount of damages suffered by the state as a result of the conduct by the person.

182. From at least 2005 to the present, the defendants knowingly caused pharmacies, physicians, pharmacy benefit managers, and others make or present false claims to the Michigan Medicaid program for reimbursement.

183. Each prescription that was written as a result of the defendants' illegal marketing practices represents such a false claim.

184. If the government of Michigan had known that the prescriptions were caused to be written to get false or fraudulent claims paid, it would not have paid the claims.

185. The state of Michigan has been damaged by the defendants' wrongful conduct.

186. The relators reallege paragraphs 1 through 44 above.

187. The Nevada False Claims Act, Nev. Rev. Stat. § 357.040(1)(a), provides that a person who:

With or without specific intent to defraud, does any of the following listed acts is liable to the state or a political subdivision, whichever is affected, for three times the amount of damages sustained by the state or political subdivision because of the act of that person, for the costs of a civil action brought to recover those damages and for a civil penalty of not less than \$2,000 or more than \$10,000 for each act:

Knowingly presents or causes to be presented a false claim for payment or approval.

188. From at least 2005 to the present, the defendants knowingly caused pharmacies, physicians, pharmacy benefit managers, and others to submit claims to the Nevada Medicaid program for reimbursement for off-label prescriptions for Megace ES.

189. Each claim for reimbursement for such prescriptions represents a false or fraudulent claim for payment under the statute.

190. If the government of Nevada had known that the claims for reimbursement were for non-covered drugs it would not have paid the claims.

191. The state of Nevada has been damaged by the defendants' wrongful conduct.

**Count 25**  
**Nev. Rev. Stat. § 357.040(1)(b)**

192. The relators reallege paragraphs 1 through 44 above.

193. The Nevada False Claims Act, Nev. Rev. Stat. § 357.040(1)(b), provides that a person who:

With or without specific intent to defraud, does any of the following listed acts is liable to the state or a political subdivision, whichever is affected, for three times the amount of damages sustained by the state or political subdivision because of the act of that person, for the costs of a civil action brought to recover those damages and for a civil penalty of not less than \$2,000 or more than \$10,000 for each act:

...

Knowingly makes or uses, or causes to be made or used, a false record or statement to obtain payment or approval of a false claim.

194. From at least 2005 to the present, the defendants knowingly caused physicians to write prescriptions for Nevada Medicaid beneficiaries for reimbursement for off-label prescriptions for Megace ES.

195. Each prescription that was written as a result of the defendants' illegal marketing practices, and the defendants' incomplete, misleading, or false sales and promotional materials, represent false or fraudulent records or statements under the statute that were made or used to get a false claim paid or approved.

196. If the government of Nevada had known that the prescriptions were caused to be written to get false or fraudulent claims paid, it would not have paid the claims.

197. The state of Nevada has been damaged by the defendants' wrongful conduct.



**Count 26**  
**N.H. Rev. Stat. Ann. §§ 167:61-b et seq.**

198. The relators reallege paragraphs 1 through 44 above.

199. The New Hampshire Medicaid False Claims Act, N.H. Rev. Stat. Ann. §§ 167:61-b *et seq.* (2005), provides that by certain acts a person commits an unlawful act and shall be liable to the state for a civil penalty and three times the amount of damages that the state sustains because of the act if that person:

(a) presents, or causes to be presented, to the state a claim for payment under the Medicaid program knowing that such claim is false or fraudulent claim;

200. From at least 2005 to the present, the defendants knowingly caused pharmacies, physicians, pharmacy benefit managers, and others to submit claims to the New Hampshire Medicaid program for reimbursement for off-label perscriptions for Megace ES.

201. Each claim for reimbursement for such prescriptions represents a false or fraudulent claim for payment under the statute.

202. If the government of New Hampshire had known that the claims for reimbursement were for non-covered drugs it would not have paid the claims.

203. The state of New Hampshire has been damaged by the defendants' wrongful conduct.

**Count 27**  
**N.H. Rev. Stat. Ann. §§ 167:61-b et seq.**

204. The relators reallege paragraphs 1 through 44 above.

205. The New Hampshire Medicaid False Claims Act, N.H. Rev. Stat. Ann. §§ 167:61-b *et seq.* (2005), provides that by certain acts a person commits an unlawful act and shall be liable to the state for a civil penalty and three times the amount of damages that the state sustains because of the act if that person:

(b) makes, uses or causes to be made or used a record or statement to get a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false;

206. From at least 2005 to the present, the defendants knowingly caused pharmacies, physicians, pharmacy benefit managers, and others to submit claims to the New Hampshire Medicaid program for reimbursement for off-label prescriptions for Megace ES.

207. Each prescription that was written as a result of the defendants' illegal marketing practices, and the defendants' incomplete, misleading, or false sales and promotional materials, represent false or fraudulent records or statements under the statute that were used to get a false claim paid or approved.

208. If the government of New Hampshire had known that the claims for reimbursement were for non-covered drugs it would not have paid the claims.

209. The state of New Hampshire has been damaged by the defendants' wrongful conduct.

**Count 28**  
**N.J. Rev. Stat. Ann. § 2A:32C-3(a)**

210. The relators reallege paragraphs 1 through 44 above.

211. The New Jersey False Claims Act, N.J. Rev. Stat. Ann. § 2a:32C-3, provides:

A person shall be jointly and severally liable to the State for a civil penalty of not less than and not more than the civil penalty allowed under the federal False Claims Act (31 U.S.C.s.3729 et seq.), as may be adjusted in accordance with the inflation adjustment procedures prescribed in the Federal Civil Penalties Inflation Adjustment Act of 1990, Pub.L.101-410, for each false or fraudulent claim, plus three times the amount of damages which the State sustains, if the person commits any of the following acts:

a. Knowingly presents or causes to be presented to an employee, officer or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval;

212. From at least 2005 to the present, the defendants knowingly caused pharmacies, physicians, pharmacy benefit managers, and others to submit claims to the New Jersey Medicaid program for reimbursement for off-label prescriptions for Megace ES.

213. Each claim for reimbursement for such prescriptions represents a false or fraudulent claim for payment under the statute.

214. If the government of New Jersey had known that the claims for reimbursement were for non-covered drugs it would not have paid the claims.

215. The state of New Jersey has been damaged by the defendants' wrongful conduct.

**Count 29**  
**N.J. Rev. Stat. Ann. § 2A:32C-3(b)**

216. The relators reallege paragraphs 1 through 44 above.

217. The New Jersey False Claims Act, N.J. Rev. Stat. Ann. § 2a:32C-3, provides:

A person shall be jointly and severally liable to the State for a civil penalty of not less than and not more than the civil penalty allowed under the federal False Claims Act (31 U.S.C.s.3729 et seq.), as may be adjusted in accordance with the inflation adjustment procedures prescribed in the Federal Civil Penalties Inflation Adjustment Act of 1990, Pub.L.101-410, for each false or fraudulent claim, plus three times the amount of damages which the State sustains, if the person commits any of the following acts:

b. Knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State;

218. From at least 2005 to the present, the defendants knowingly caused physicians to write prescriptions for New Jersey Medicaid beneficiaries for reimbursement for off-label prescriptions for Megace ES.

219. Each prescription that was written as a result of the defendants' illegal marketing practices, and the defendants' incomplete, misleading, or false sales and promotional materials,

represent false or fraudulent records or statements under the statute that were used to get a false claim paid or approved.

220. If the government of New Jersey had known that the prescriptions were caused to be written to get false or fraudulent claims paid, it would not have paid the claims.

221. The state of New Jersey has been damaged by the defendants' wrongful conduct.

**Count 30**  
**N.M. Stat. § 27-14-1 et seq.**

222. The relators reallege paragraphs 1 through 44 above.

223. The New Mexico Medicaid False Claims Act, N.M. Stat. § 27-14-4(A) provides that by certain acts

a person commits an unlawful act and shall be liable to the state for three times the amount of damages that the state sustains because of the act if that person [including]:

4A. presents, or causes to be presented, to the state a claim for payment under the Medicaid program knowing that such claims is false or fraudulent claim;

4B. presents, or causes to be presented, to the state a claim for payment under the Medicaid program knowing that the person receiving a Medicaid benefit or payment is not authorized or is not eligible for a benefit under the Medicaid program;

224. From at least 2005 to the present, the defendants knowingly caused pharmacies, physicians, pharmacy benefit managers, and others to submit claims to the New Mexico Medicaid program for reimbursement for off-label perscriptions for Megace ES.

225. Each claim for reimbursement for such prescriptions represents a false or fraudulent claim for payment under the statute.

226. If the government of New Mexico had known that the claims for reimbursement were for non-covered drugs it would not have paid the claims.

227. The state of New Mexico has been damaged by the defendants' wrongful conduct.

**Count 31**  
**N.M. Stat. § 27-14-1 et seq.**

228. The relators reallege paragraphs 1 through 44 above.

229. The New Mexico Medicaid False Claims Act, N.M. Stat. § 27-14-4(C) et seq., provides that by certain acts

a person commits an unlawful act and shall be liable to the state for three times the amount of damages that the state sustains because of the act if that person [including]:

4C. makes, uses or causes to be made or used a record or statement to obtain a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false;

230. From at least 2005 to the present, the defendants knowingly caused physicians to write prescriptions for New Mexico Medicaid beneficiaries for reimbursement for off-label perscriptions for Megace ES.

231. Each prescription that was written as a result of the defendants' illegal marketing practices, and the defendants' incomplete, misleading, or false sales and promotional materials, represent false or fraudulent records or statements under the statute that were used to get a false claim paid or approved.

232. If the government of New Mexico had known that the prescriptions were caused to be written to get false or fraudulent claims paid, it would not have paid the claims.

233. The state of New Mexico has been damaged by the defendants' wrongful conduct.

**Count 32**  
**N.Y. St. Fin. Law § 189(1)(a)**

234. The relators reallege paragraphs 1 through 44 above.

235. The New York False Claims Act, N.Y. St. Fin. Law § 189(1)(a), provides that:

any person who:

knowingly presents, or causes to be presented, to any employee, officer or agent of the state or a local government, a false or fraudulent claim for payment or approval;

shall be liable (I) to the state for a civil penalty of not less than six thousand dollars and not more than twelve thousand dollars, plus three times the amount of damages which the state sustains because of the act of that person;

236. From at least 2005 to the present, the defendants knowingly caused pharmacies, physicians, pharmacy benefit managers, and others to submit claims to the New York Medicaid program for reimbursement for off-label prescriptions for Megace ES.

237. Each claim for reimbursement for such prescriptions represents a false or fraudulent claim for payment under the statute.

238. If the government of New York had known that the claims for reimbursement were for non-covered drugs it would not have paid the claims.

239. The state of New York has been damaged by the defendants' wrongful conduct.

**Count 33**  
**N.Y. St. Fin. Law § 189(1)(b)**

240. The relators reallege paragraphs 1 through 44 above.

241. The New York False Claims Act, N.Y. St. Fin. Law § 189(1)(b) provides, with exceptions not pertinent to this complaint, that:

any person who:

(b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state or a local government;

shall be liable: (I) to the state for a civil penalty of not less than six thousand dollars and not more than twelve thousand dollars, plus three times the amount of damages which the state sustains because of the act of that person;

242. From at least 2005 to the present, the defendants knowingly caused physicians to write prescriptions for New York Medicaid beneficiaries for reimbursement for off-label perscriptions for Megace ES.

243. Each prescription that was written as a result of the defendants' illegal marketing practices, and the defendants' incomplete, misleading, or false sales and promotional materials, represent false or fraudulent records or statements under the statute that were used to get a false claim paid or approved.

244. If the government of New York had known that the prescriptions were caused to be written to get false or fraudulent claims paid, it would not have paid the claims.

245. The state of New York has been damaged by the defendants' wrongful conduct.

**Count 34**  
**Oklahoma Medicaid False Claims Act, 63 Okl. St. Ann. § 5053 et seq.**

246. The relators reallege paragraphs 1 through 44 above.

247. The Oklahoma Medicaid False Claims Act, 63 Okl. St. Ann. § 5053.1(B)(1) provides:

Any person who:

1. Knowingly presents, or causes to be presented, to an officer or employee of the State of Oklahoma, a false or fraudulent claim for payment or approval; . . .

is liable to the State of Oklahoma for a civil penalty of not less than Five Thousand Dollars (\$5,000.00) and not more than Ten Thousand Dollars (\$10,000.00), unless a penalty is imposed for the act of that person in violation of this subsection under the federal False Claims Act for the same or a prior action, plus three times the amount of damages which the state sustains because of the act of that person.

248. From at least 2005 to the present, the defendants knowingly caused pharmacies, physicians, pharmacy benefit managers, and others to submit claims to the Oklahoma Medicaid program, for reimbursement for off-label prescriptions for Megace ES.

249. Each claim for reimbursement for such prescriptions represents a false or fraudulent claim for payment under the statute.

250. If the government of Oklahoma had known that the claims for reimbursement were for non-covered drugs it would not have paid the claims.

251. The state of Oklahoma has been damaged by the defendants' wrongful conduct.

**Count 35**

**Oklahoma Medicaid False Claims Act, 63 Okl. St. Ann. § 5053(1) et seq.**

252. The relators reallege paragraphs 1 through 44 above.

253. The Oklahoma Medicaid False Claims Act, 63 Okl. St. Ann. § 5053.1(B)(2), provides:

Any person who:

2. Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state; . . .

is liable to the State of Oklahoma for a civil penalty of not less than Five Thousand Dollars (\$5,000.00) and not more than Ten Thousand Dollars (\$10,000.00), unless a penalty is imposed for the act of that person in violation of this subsection under the federal False Claims Act for the same or a prior action, plus three times the amount of damages which the state sustains because of the act of that person.

254. Each prescription that was written as a result of the defendants' illegal marketing practices, and the defendants' incomplete, misleading, or false sales and promotional materials, represent false or fraudulent records or statements under the statute that were used to get a false claim paid or approved.

255. If the government of Oklahoma had known that the prescriptions were caused to be written to get false or fraudulent claims paid, it would not have paid the claims.

256. The state of Oklahoma has been damaged by the defendants' wrongful conduct.



**Count 36**  
**Tenn. Code Ann. § 71-5-182(a)(1)(A)**

257. The relators reallege paragraphs 1 through 44 above.

258. The Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-182(a)(1)(A),

provides that any person who:

(A) Presents, or causes to be presented, to the state a claim for payment under the Medicaid program knowing such claim is false or fraudulent;

...

is liable to the state for a civil penalty of not less than five thousand dollars (\$5,000) and not more than ten thousand dollars (\$10,000), plus three (3) times the amount of damages which the state sustains because of the act of that person.

259. From at least 2005 to the present, the defendants knowingly caused pharmacies, physicians, pharmacy benefit managers, and others to submit claims to the Tennessee Medicaid program for reimbursement for off-label perscriptions for Megace ES.

260. Each claim for reimbursement for such prescriptions represents a false or fraudulent claim for payment under the statute.

261. If the government of Tennessee had known that the claims for reimbursement were for non-covered drugs it would not have paid the claims.

262. The state of Tennessee has been damaged by the defendants' wrongful conduct.

**Count 37**  
**Rhode Island False Claim Act, R.I.G.L. § 9-1.1-3(a)(1)**

263. The relators reallege paragraphs 1 through 44 above.

264. The Rhode Island False Claim Act, R.I.G.L. § 9-1.1-3(a)(1) provides:

Any person who:

(1) knowingly presents, or causes to be presented, to an officer or employee of the state or a member of the guard a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state; . . .

is liable to the state for a civil penalty of not less than five thousand dollars (\$5,000) and not more than ten thousand dollars (\$10,000), plus three (3) times the amount of damages which the state sustains because of the act of that person. A person violating this subsection (a) shall also be liable to the state for the costs of a civil action brought to recover any such penalty or damages.

265. From at least 2005 to the present, the defendants knowingly caused pharmacies, physicians, pharmacy benefit managers, and others to submit claims to the Oklahoma Medicaid program, for reimbursement for off-label perscriptions for Megace ES.

266. Each claim for reimbursement for such prescriptions represents a false or fraudulent claim for payment under the statute.

267. If the government of Rhode Island had known that the claims for reimbursement were for non-covered drugs it would not have paid the claims.

268. The state of Rhode Island has been damaged by the defendants' wrongful conduct.

**Count 38**  
**Rhode Island False Claim Act, R.I.G.L. § 9-1.1-3(a)(2)**

269. The relators reallege paragraphs 1 through 44 above.

270. The Rhode Island False Claim Act, R.I.G.L. § 9-1.1-3(a)(2) provides:

a) Any person who:

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state; . . .

is liable to the state for a civil penalty of not less than five thousand dollars (\$5,000) and not more than ten thousand dollars (\$10,000), plus three (3) times the amount of damages which the state sustains because of the act of that person. A person violating

this subsection (a) shall also be liable to the state for the costs of a civil action brought to recover any such penalty or damages.

271. Each prescription that was written as a result of the defendants' illegal marketing practices, and the defendants' incomplete, misleading, or false sales and promotional materials, represent false or fraudulent records or statements under the statute that were used to get a false claim paid or approved.

272. If the government of Rhode Island had known that the prescriptions were caused to be written to get false or fraudulent claims paid, it would not have paid the claims.

273. The state of Rhode Island has been damaged by the defendants' wrongful conduct.

**Count 39**  
**Tenn. Code Ann. § 71-5-182(a)(1)(B)**

274. The relators reallege paragraphs 1 through 44 above.

275. The Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-182(a)(1)(B), provides that any person who:

(B) Makes, uses, or causes to made or used, a record or statement to get a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false;

...

is liable to the state for a civil penalty of not less than five thousand dollars (\$5,000) and not more than ten thousand dollars (\$10,000), plus three (3) times the amount of damages which the state sustains because of the act of that person.

276. From at least 2005 to the present, the defendants knowingly caused physicians to write prescriptions for Tennessee Medicaid beneficiaries for reimbursement for off-label perscriptions for Megace ES.

277. Each prescription that was written as a result of the defendants' illegal marketing practices, and the defendants' incomplete, misleading, or false sales and promotional materials,

represent false or fraudulent records or statements under the statute that were used to get a false claim paid or approved.

278. If the government of Tennessee had known that the prescriptions were caused to be written to get false or fraudulent claims paid, it would not have paid the claims.

279. The state of Tennessee has been damaged by the defendants' wrongful conduct.

**Count 40**  
**Tex. Hum. Res. Code § 36.002(1)-(2)**

280. The relators reallege paragraphs 1 through 44 above.

281. The Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.001(1), provides that a person commits an unlawful act if the person:

(1) knowingly or intentionally makes or causes to be made a false statement or misrepresentation of a material fact:

on an application for a contract, benefit, or payment under the Medicaid program; or

(B) that is intended to be used to determine a person's eligibility for a benefit or payment under the Medicaid program.

282. From at least 2005 to the present, the defendants knowingly caused pharmacies, physicians, pharmacy benefit managers, and others to submit claims to the Texas Medicaid program for reimbursement for off-label prescriptions for Megace ES.

283. Each claim for reimbursement for such prescriptions represents a false or fraudulent claim for payment under the statute.

284. If the government of Texas had known that the claims for reimbursement were for non-covered drugs it would not have paid the claims.

285. The state of Texas has been damaged by the defendants' wrongful conduct.

**Count 41**

**Tex. Hum. Res. Code § 36.002(4)(B)**

286. The relators reallege paragraphs 1 through 44 above.

287. The Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.002(4)(B),

provides that a person commits an unlawful act if the person:

(4) knowingly or intentionally makes, causes to be made, induces, or seeks to induce the making of a false statement or misrepresentation of material fact concerning:

...

(B) Information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program;

288. From at least 2005 to the present, the defendants knowingly caused physicians to write prescriptions for Texas Medicaid beneficiaries for reimbursement for off-label perscriptions for Megace ES.

289. Each prescription that was written as a result of the defendants' illegal marketing practices, and the defendants' incomplete, misleading, or false sales and promotional materials, represent false or fraudulent records or statements under the statute that were used to get a false claim paid or approved.

290. If the government of Texas had known that the prescriptions were caused to be ritten to get false or fraudulent claims paid, it would not have paid the claims.

291. The state of Texas has been damaged by the defendants' wrongful conduct.

**Count 42**

**Va. Code Ann. § 8.01-216.3(A)(1)**

292. The relators reallege paragraphs 1 through 44 above.

293. The Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(A)(1), provides that any person who:

1. Knowingly presents, or causes to be presented, to an officer or employee of the Commonwealth a false or fraudulent claim for payment or approval;

...

shall be liable to the Commonwealth for a civil penalty of not less than \$5,000 and not more than \$10,000, plus three times the amount of damages sustained by the Commonwealth.

294. From at least 2005 to the present, the defendants knowingly caused pharmacies, physicians, pharmacy benefit managers, and others to submit claims to the Virginia Medicaid program for reimbursement for off-label prescriptions for Megace ES.

295. Each claim for reimbursement for such prescriptions represents a false or fraudulent claim for payment under the statute.

296. If the government of Virginia had known that the claims for reimbursement were for non-covered drugs it would not have paid the claims.

297. The Commonwealth of Virginia has been damaged by the defendants' wrongful conduct.

**Count 43**  
**Va. Code Ann. § 8.01-216.3(A)(2)**

298. The relators reallege paragraphs 1 through 44 above.

299. The Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3(A)(2), provides that any person who:

2. Knowingly makes, uses or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth;

...

shall be liable to the Commonwealth for a civil penalty of not less than \$5,000 and not more than \$10,000, plus three times the amount of damages sustained by the Commonwealth.

300. From at least 2005 to the present, the defendants knowingly caused physicians to write prescriptions for Virginia Medicaid beneficiaries for reimbursement for off-label perscriptions for Megace ES.

301. Each prescription that was written as a result of the defendants' illegal marketing practices, and the defendants' incomplete, misleading, or false sales and promotional materials, represent false or fraudulent records or statements under the statute that were used to get a false claim paid or approved.

302. If the government of Virginia had known that the prescriptions were caused to be written to get false or fraudulent claims paid, it would not have paid the claims.

303. The Commonwealth of Virginia has been damaged by the defendants' wrongful conduct.

#### **Count 44**

#### **Wisconsin False Claims for Medical Assistance Law, Wis. Stat. § 20.931(2)(a)**

304. The relators reallege paragraphs 1 through 44 above.

305. The Wisconsin False Claims for Medical Assistance Law, Wis. Stat. § 20.931(2)(a) provides in pertinent part:

. . . any person who does any of the following is liable to this state for 3 times the amount of the damages sustained by this state because of the actions of the person, and shall forfeit not less than \$5,000 nor more than \$10,000 for each violation:

(a) Knowingly presents or causes to be presented to any officer, employee, or agent of this state a false claim for medical assistance.

(b) Knowingly makes, uses, or causes to be made or used a false record or statement to obtain approval or payment of a false claim for medical assistance.

306. From at least 2005 to the present, the defendants knowingly caused pharmacies, physicians, pharmacy benefit managers, and others to submit claims to the Wisconsin Medicaid program, for reimbursement for off-label prescriptions for Megace ES.

307. Each claim for reimbursement for such prescriptions represents a false or fraudulent claim for payment under the statute.

308. If the government of Wisconsin had known that the claims for reimbursement were for non-covered drugs it would not have paid the claims.

309. The state of Wisconsin has been damaged by the defendants' wrongful conduct.

#### **Count 45**

#### **Wisconsin False Claims for Medical Assistance Law, Wis. Stat. § 20.931(2)(b)**

310. The relators reallege paragraphs 1 through 44 above.

311. The Wisconsin False Claims for Medical Assistance Law, Wis. Stat.

§ 20.931(2)(b) provides in pertinent part:

. . . any person who does any of the following is liable to this state for 3 times the amount of the damages sustained by this state because of the actions of the person, and shall forfeit not less than \$5,000 nor more than \$10,000 for each violation:

(b) Knowingly makes, uses, or causes to be made or used a false record or statement to obtain approval or payment of a false claim for medical assistance.

312. Each prescription that was written as a result of the defendants' illegal marketing practices, and the defendants' incomplete, misleading, or false sales and promotional materials, represent false or fraudulent records or statements under the statute that were used to get a false claim paid or approved.

313. If the government of Wisconsin had known that the prescriptions were caused to be written to get false or fraudulent claims paid, it would not have paid the claims.



314. The state of Wisconsin has been damaged by the defendants' wrongful conduct.

**RELIEF DEMANDED**

WHEREFOR the relators, acting on behalf of and in the name of the United States of America and the state plaintiffs, and on their own behalf, demand judgment as follows against the defendants under the federal FCA and under the supplemental state FCAs as follows:

- A. For the United States against the defendants for treble the amount of damages to Government Health Care Programs from the fraudulent schemes alleged above, plus maximum civil penalties of Eleven Thousand Dollars (\$11,000.00) for each false claim;
- B. For the United States against the defendants for disgorgement of the profits earned a result of its illegal conduct;
- C. For the relators for the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) to include reasonable expenses, attorney fees and costs incurred by Relator;
- D. For all costs of the federal FCA civil action;
- E. For the relators and the United States for such other and further relief as the court deems appropriate;
- F. For the relators and the state Plaintiffs against the defendants jointly and severally in an amount equal to three times the amount of damages that California, Delaware, the District of Columbia, Florida, Georgia, Indiana, Illinois, Louisiana, Massachusetts, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oklahoma Rhode Island Tennessee, Virginia, and Wisconsin have sustained, respectively, as a result of the defendants' actions, as well as the applicable statutory maximum civil penalty against the defendants for each violation of each state's FCA;

G. For the relators and the state of Texas against the defendants in an amount equal to two times the amount of damages that Texas has sustained as a result of the defendants' actions, as well as a civil penalty against the defendants of a statutory maximum for each violation of Tex. Hum. Res. Code § 36.002;

H. For the relators and the state of Michigan against the defendants for a civil penalty equal to one time the loss caused to the Michigan Medicaid program as a result of the defendants' actions, plus damages equal to three times such loss;

I. For the relators for the maximum amount allowed as a relators' share pursuant to the state FCAs as follows:

- (1) Cal. Gov't Code § 12652(g)
- (2) D.C. Code § 2-308.14(f)
- (3) Del. Code Ann. Tit. 6, § 1205
- (4) Fla. Stat. § 68.085
- (5) Ga. Code Ann. § 49-4-168.2(i)
- (6) 740 Ill. Comp. Stat. § 175/4(d); IC 5-11-5.5
- (7) 46 La. Rev. Stat. c. 3, § 437.1 et seq.
- (8) Mass. Gen. Laws Ch. 12, § 5F
- (9) Mich. Comp. L. Ch. 400
- (10) N.H. Rev. Stat. Ann. §§ 167:61-b
- (11) N.J. Rev. Stat. S.A. § 2A:32C-7(a) and (d)
- (12) N.M. Legis. 49 (2004)
- (13) N.Y. St. Fin. Law §190(6)
- (14) Nev. Rev. Stat. § 357.210
- (15) 63 Okl. St. Ann. § 5053.4
- (16) R.I.G.L. § 9-1.1-4(d)
- (17) Tenn. Code Ann. § 71-5-183(c)
- (18) Tex. Hum. Res. Code § 36.110
- (19) Va. Code Ann. § 8.01-216.7
- (20) Wis. Stat. § 20.931(11)

J. For the relators for all costs and expenses associated with the supplemental state claims, including attorneys' fees and costs; and

K. For the state plaintiffs and the relators for all such other relief as the court deems appropriate.

**DEMAND FOR JURY TRIAL**

The relators, pursuant to Fed.R.Civ.P. 38, hereby demand trial by jury.

Dated: River Edge, New Jersey  
July 16, 2008

Respectfully submitted,

BRICKFIELD & DONAHUE  
ATTORNEYS

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*Attorneys for relators*  
*Pro hac vice admission to be applied for*