UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WISCONSIN
MILWAUKEE DIVISION

UNITED STATES *ex rel.* KURT KROENING

STATE OF ARKANSAS *ex rel.* KURT KROENING

STATE OF CALIFORNIA *ex rel.* KURT KROENING

STATE OF COLORADO *ex rel.* KURT KROENING

STATE OF CONNECTICUT *ex rel.* KURT KROENING

STATE OF DELAWARE *ex rel.* KURT KROENING

DISTRICT OF COLUMBIA *ex rel.* KURT KROENING

STATE OF FLORIDA *ex rel.* KURT KROENING

STATE OF GEORGIA *ex rel.* KURT KROENING

STATE OF HAWAII *ex rel.* KURT KROENING

STATE OF ILLINOIS *ex rel.* KURT KROENING

STATE OF INDIANA *ex rel.* KURT KROENING

STATE OF IOWA *ex rel.* KURT KROENING

STATE OF LOUISIANA *ex rel.* KURT KROENING

STATE OF MAINE *ex rel.* KURT KROENING

STATE OF MARYLAND *ex rel.* KURT KROENING

COMMONWEALTH OF MASSACHUSETTS *ex rel.* KURT KROENING

STATE OF MICHIGAN *ex rel.* KURT KROENING

STATE OF MINNESOTA *ex rel.* KURT KROENING

STATE OF MONTANA *ex rel.* KURT KROENING

Filed *In Camera* pursuant to 31 U.S.C.§3730(b)(2)

Civil Action File No.

COMPLAINT FOR DAMAGES AND INJUNCTIVE RELIEF UNDER 31 U.S.C. § 3730 FEDERAL FALSE CLAIMS ACT AND VARIOUS STATE FALSE CLAIMS ACTS

Jury Trial Demanded

STATE OF NEVADA *ex rel.* KURT KROENING

STATE OF NEW HAMPSHIRE *ex rel.* KURT KROENING

STATE OF NEW JERSEY *ex rel.* KURT KROENING

STATE OF NEW MEXICO *ex rel.* KURT KROENING

STATE OF NEW YORK *ex rel.* KURT KROENING

STATE OF NORTH CAROLINA *ex rel.* KURT KROENING

STATE OF OKLAHOMA *ex rel.* KURT KROENING

STATE OF RHODE ISLAND *ex rel.* KURT KROENING

STATE OF TENNESSEE *ex rel.* KURT KROENING

STATE OF TEXAS *ex rel.* KURT KROENING

COMMONWEALTH OF VIRGINIA *ex rel.* KURT KROENING

STATE OF WISCONSIN *ex rel.* KURT KROENING

Plaintiffs/Relator,

v.

FOREST PHARMACEUTICALS, INC.,

FOREST LABORATORIES, INC.

Defendants

INTRODUCTION

NOW COMES Kurt Kroening, Plaintiff/Relator, through his attorneys, Cross Law Firm, S.C., by Nola J. Hitchcock Cross and Noah Reinstein, and states that this is an action brought on behalf of THE UNITED STATES OF AMERICA by KURT KROENING (hereinafter "Relator") against FOREST LABORATORIES, INC. (hereinafter referred to as "FLI") and

FOREST PHARMACEUTICALS, INC. (hereinafter referred to as "FPI"), (collectively referred to as "Defendants") pursuant to the Federal Civil False Claims Act, 31 U.S.C. §§ 3729, *et seq.* ("FCA"), and on behalf of the above named states under the following statutes: Arkansas, Ark. Code Ann § 20-77-901 *et seq.*; California, Cal. Gov't. Code §12650 *et seq.;* Colorado, Colo. Rev. Stat. § 25.5-4-304 *et seq.*;Connecticut, Conn. Gen. Stat. §176-301a *et seq;*. Delaware, Del. Code Ann. Title 6 § 1201 *et seq.*; District of Columbia, D.C. Code Ann. § 2-308.13 *et seq.*; Florida Fla. Stat. § 68.081 *et seq.*; Georgia, GA. Stat. Ann. § 49-4-168 *et seq.*; Hawaii Haw. Rev. Stat. § 661-21 *et seq.*; Illinois, 740 ILCS 175/1 *et seq.*; Indiana, Ind. Code §5-11-5.5-1 *et seq.*; Iowa, Iowa Code § 685.1 *et seq*; Louisiana, La. Rev. Stat. Ann. § 46-437.1 *et seq.*, Maine, Me. Rev. Stat. tit. 5 § 215 *et seq.*; Maryland, Md. Code Ann. Health-Gen. §2-601 *et seq.;* Massachusetts Mass. Gen. Laws Ch. 12 § 5A *et seq.*; Michigan MCL 400.601 *et seq.*; Minnesota Minn. Stat. § 15C.01 *et seq.*; Montana, Mon. Code Ann. § 17-8-401 *et seq.*; Nevada, Nev. Rev. Stat. § 357.010 *et seq.*; New Hampshire, N.H. Rev. Stat. Ann. § 167:61-b *et seq.*; New Jersey, N.J. Rev. Stat. § 2A:32C-1 *et seq.*; New Mexico, N.M. Stat. Ann §§ 27-14-1 *et seq.*; New York, NY State Fin. Law Ch. §187 *et seq.*; North Carolina, NC. Gen. Stat. Ann. § 1-605 *et seq.*; Oklahoma, Okla. Stat. tit. 63 § 5053.1 *et seq.*; Rhode Island, R.I. Gen. Laws § 9-1.1-1 *et seq.*; Tennessee Tenn. Code Ann. § 71-5-181 *et seq.*; Texas, Tex. Hum. Res. Code Ann. § 36.001 *et seq.*; Virginia Va. Code Ann. § 8.01-216.1 *et seq.*; Wisconsin, Wis. Stat. § 20.931 *et seq.* (collectively "State False Claims Act" or "State FCA"), to recover for knowingly false claims submitted for payment to the United States and various States through the federal Center for Medicare and Medicaid Services ("CMS").

PARTIES

1. Plaintiff/Relator Kurt Kroening ("Kroening" or "Relator") is a citizen of the United States. He is a resident of Germantown, Wisconsin residing within the Eastern District of Wisconsin. Relator is and was at all times material employed as a pharmaceutical sales representative by Defendant Forest Pharmaceuticals, Inc. He brings this *qui tam* action based upon direct and unique information personally obtained by him during his employment as a Sales Representative with Defendant Forest Pharmaceuticals, Inc. Kroening has direct and independent knowledge on which the allegations set forth in this Complaint are based. Relator has knowledge of the information on which his allegations are based that is independent from any public discourse about the matter and that materially adds to any such public disclosures. None of the allegations set forth in this Complaint are based on a public disclosure of allegations or transactions in a criminal, civil or administrative hearing, in a congressional administrative or General Accounting Office report, hearing, audit or investigation or from the news media.

2. Defendant Forest Laboratories, Inc. ("FLI") is a Delaware corporation with its principal place of business at 909 Third Avenue, New York, New York 10022. FLI maintains an office in the State of Wisconsin and does business in every state within the United States.

3. Defendant Forest Pharmaceuticals, Inc. ("FPI") is a wholly owned subsidiary of Defendant Forest Laboratories, Inc. and is a Delaware corporation with its principal offices located 13600 Shoreline Drive, St. Louis, Missouri 63045. FPI is the marketing and sales business unit of Defendant FLI.

STATUTORY AND REGULATORY PROVISIONS APPLICABLE TO FLI AND FPI'S FALSE CLAIMS ACT VIOLATIONS

A. Federal Government Health Programs

1. Medicare

4. The Medicare Program ("Medicare") was created in 1965 as part of the Social Security Act,.42 U.S.C. §§ 1395 *et seq.*, as a health insurance program administered by the government of the United States and funded by taxpayer revenue. The Center for Medicare and Medicaid Service ("CMS"), a component of the Department of Health and Human Services ("HHS"), administers the Medicare program.

5. Medicare was designed to be a health insurance program and to provide for the payment of medical services primarily for the benefit of persons over sixty-five (65) years of age.

6. A primary benefit of Medicare is the payment for certain prescription drugs; including the drugs at issue in this Complaint, Savella, Viibryd, and Bystolic. Reimbursement for Medicare claims is made by the United States through CMS which contracts with private insurance carriers to administer and pay claims from the Medicare Trust Fund. 42 U.S.C. § 1395u.

2. Medicaid

7. The Medicaid Program ("Medicaid") was also created as part of the Social Security Act, 42 U.S.C. §§ 1396-1396v, as a health insurance program administered by the government of the United States and funded by State and Federal taxpayer revenue.

B. The False Claims Act and the Medicare Fraud & Abuse Anti-Kickback Statute

1. False Claims Act

8. The FCA, 31 U.S.C. § 3729(a)(1)(A) provides that any person who knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval is liable for a civil penalty of up to $11,000 and not less than $5,500 plus three (3) times the amount of damages which the Government sustains because of the act of that person.

9. The FCA 31 U.S.C. § 3729(a)(1)(B) provides that any person who knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim is liable for a civil penalty of up to $11,000 and not less than $5,500 plus three (3) times the amount of damages which the Government sustains because of the act of that person.

10. The FCA, 31 U.S.C. § 3729(a)(1)(C) makes any person who conspires to commit a violation of the FCA liable for three times the amount of the damages the Government sustains and a civil monetary penalty of up to $11,000 and not less than $5,500.

11. The FCA, 31 U.S.C. § 3729(a)(1)(G) makes any person who knowingly makes, uses or causes to be made or used a false record or statement material to an obligation to pay or transmit money or property to the Government, knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government, liable for three (3) times the amount of damages the Government sustains and a civil monetary penalty of up to $11,000 and not less than $5,500.

2. Medicare Fraud & Abuse Anti-Kickback Statute

12. The Medicare Anti-Kickback Statute, 42 U.S.C. § 1320a-7b ("Anti-Kickback Statute") provides for penalties for certain acts impacting Medicare and Medicaid reimbursable

services. Specifically the statute prohibits persons who knowingly and willfully solicit or pay remuneration in return for referring or prescribing any prescription which payment may be made by Medicare or Medicaid. *See* 42 U.S.C. § 1320a-7b(1)(B). A person found in violation of this law shall be guilty of a felony and shall be fined up to $25,000 and imprisoned for up to five years. *Id.*

13. The Balanced Budget Act of 1997 amended the Anti-Kickback Statute to include administrative civil penalties of $50,000 for each act violating the Anti-Kickback Statute, as well as an assessment of not more than three (3) times the amount of remuneration offered, paid, solicited, or received, without regard to whether a portion of that amount was offered, paid, or received for a lawful purpose. *See* 42 U.S.C. § 1320a-7a(a).

14. Compliance with the Anti-Kickback Statute is a precondition to participation as a health care provider under a Government Health Care Program, including Medicare and the state Medicaid programs. Moreover, compliance with the Anti-Kickback Statute is a *condition of payment* for drug claims administered by physicians for which Medicare or Medicaid reimbursement is sought. Reimbursement practices under all Government Health Care Programs closely align with the rules and regulations governing Medicare reimbursement. Each of the Government Health Care Programs requires every provider who seeks payment from the program to promise and ensure compliance with the provisions of the Anti-Kickback Statute and with other federal laws governing the provision of health care services in the United States. As such, if a provider informs CMS or its agent that it provided services in violation of the Anti-Kickback Statute (or another relevant law including off label indications), CMS will not pay the claim.

15. Healthcare providers enter into a Provider Agreement with CMS in order to establish their eligibility to seek reimbursement from the Medicare Program. They do so through completing a paper CMS-855 form or the Internet-based Provider Enrollment, Chain and Ownership System ("PECOS"). CMS-855 form requires certification of, in part, the following:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to this provider. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the provider's compliance with all applicable conditions or participation in Medicare.
>
> I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and I will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

Form CMS-855A (updated 07/11).

16. Submission for individual claims requires similar provider certification through the CMS-1500 form which states in part, "Anyone who misrepresents or falsifies essential information to receive payment from Federal funds requested by this form may upon conviction be subject to fine and imprisonment under applicable Federal laws."

17. The Patient Protection and Affordable Care Act ("PPACA"), Public Law No. 111-148, Sec. 6402(g), amended the Anti-Kickback Statute or "Social Security Act," 42 U.S.C. § 1320a-7b(b), to specifically allow violations of its "anti-kickback" provisions to be enforced under the FCA. The PPACA also amended the Social Security Act's "intent requirement" to make clear that violations of the Social Security Act's anti-kickback provisions, like violations of the FCA, may occur even if an individual does "not have actual knowledge" or "specific intent to commit a violation." *Id.* at Sec. 6402(h).

C. Federal Food and Drug Administration Regulations

18. To be properly reimbursable by Medicare or Medicaid, a prescription drug must also meet certain other requirements involving whether the drug is prescribed for an "on label" versus an "off-label" use or indications. The Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301, *et seq.*, prohibits the distribution of new pharmaceutical drugs in interstate commerce unless the Food and Drug Administration ("FDA") has determined that the drug is safe and effective for its intended use. 21 U.S.C. § 355(a) and (d).

19. If the manufacturer intends to promote the drug for a new unapproved use, an application for the proposed new use must be filed with the FDA, or an exemption therefrom must be obtained, and any promotional materials concerning unapproved uses must meet strict statutory and regulatory requirements. *See* 21 U.S.C. §§ 360aaa.

20. Government health programs such as Medicare and Medicaid rely on FDA determinations of what is a safe and effective use of a prescription drug. If a particular use clearly is not indicated on the FDA-approved product label ("Package Insert"), and if the use has not been determined to be safe and effective in authoritative studies, the federal government will reject payment for such medication and consider such demand for payment a "false" claim.

21. Medicaid provides prescription drug reimbursement only for statutorily defined "covered" outpatient prescription drugs. 42 U.S.C. § 1396b(i)(10) Covered drugs are defined as those used for a "medically accepted indication." 42 U.S.C. § 1396r-8(k)(3). A medically accepted indication is defined as either an FDA-approved use, or a use supported by citations included in, or approved for inclusion in the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information, or its successor publications, or the DRUGDEX Information System. 42 U.S.C. § 1396r-8(k)(6) and (g)(1)(B)(i). Thus, unless a

particular off-label use for a drug is included in one of the identified drug compendia, a prescription for the off-label use of the drug is not eligible for reimbursement under Medicaid.

22. Federal regulations further provide that a state Medicaid program may restrict coverage of covered outpatient drugs when the prescribed use in not for a medically accepted indication. In certain circumstances Medicaid will reimburse the prescription of certain single-source or multi-source innovator drugs for an "off-label" use where the individual State has determined, *inter alia*, that the drug is essential to the health of the beneficiaries. 42 U.S.C. § 1396r8(a)(3).

23. The FDCA provides criminal penalties for the dissemination of written information to health care providers regarding the safety, effectiveness, or benefit of the use of a drug that is not described in the FDA approved labeling of the drug, if that written information fails to conform to the law's requirements. 21 U.S.C. §§ 331(z), 333(a)(1)-(2), 360aaa. A manufacturer may disseminate information on a new use of a drug only if it meets the specific requirements set forth in 21 U.S.C. § 360aaa.

D. FPI and FLI's violations

24. The Defendants have violated the Federal and various named State FCAs, the Anti-Kickback Statute and the FDCA by engaging in the conduct described herein involving the marketing, selling, prescribing, and billing of Savella (from in or about the January 2009 FDA approval through the present), Bystolic (from in or about the December 2007 FDA approval through the present), and Viibryd (from January 2011 through the present), drugs which Defendants knew were paid for by state and federal health care programs and paid by taxpayer funds, and which drugs Defendants expected health care providers around the United States to prescribe and administer to their patients and thereafter illegally bill or cause to be billed to state

and federal health care programs. Defendants' schemes, included, but are not limited to the following actions, all of which violate the Federal and State FCAs and Anti-Kickback Statute:

(a) Knowingly engaging in illegal off-label marketing of Savella for the non FDA-approved purpose of treating non-narcotic pain relief, thereby causing false claims to be made;

(b) Knowingly engaging in illegal off-label marketing of Bystolic for the non FDA-approved purpose of treating congestive heart failure and headaches

(c) Knowingly and unlawfully promoting Savella, Viibryd and Bystolic in violation of the Anti-Kickback Statute by providing payments and other incentives to induce doctors to promote and prescribe Savella, Viibryd and Bystolic including for off-label uses;

(d) Knowingly paying money and providing gifts to physicians for the purpose of inducing physicians to prescribe medications manufactured and sold by FLI and FPI;

(e) Knowingly engaging in return on investment ("ROI") tracking of Continuing Medical Education ("CME") consultants and advisors, whereby Defendants analyze whether such CMEs are successful in influencing attendees to change their prescription writing practices;

(f) Conspiring to create unlawful incentives to provide in exchange for patient referral and prescription business;

(g) Conspiracy to pay money to physicians and others in order to seek assistance from the person(s) receiving the kickbacks and/or gifts in influencing other

physicians to prescribe medications manufactured and sold by FPI and FLI; and

(h) Other unlawful activities as described herein in this Complaint.

FACTUAL BACKGROUND

A. FDA Uses and Restrictions of Defendants' Prescription Drugs Savella, Bystolic and Viibryd

1. Savella

25. FLI manufactures a prescription drug known as Savella (generic name milnacipran HCl). FPI sells and markets Savella. Savella is a prescription drug first approved for sale in the United States in January 2009. Savella's principal competing drugs are Cymbalta and Lyrica. Savella is a selective serotonin and norepinephrine reuptake inhibitor ("SNRI"), FDA-approved for the management of fibromyalgia.

26. According to FLI's 2011 Annual Report, Savella sales for fiscal year 2011 were $90,000,000.00 with a growth rate of thirty percent (30%).

27. Savella is a preferred Wisconsin Medicaid drug. When prescribed, the cost to the Medicaid recipient is $3.00 per month for a thirty (30) day supply.

28. Fibromyalgia is a syndrome in which a person has long-term, body-wide pain and tenderness in the joints, muscles, tendons, and other soft tissues. Fibromyalgia is also linked to fatigue, sleep problems, headaches, depression, and anxiety. Fibromyalgia patients are often placed on prescription medication to relieve these symptoms. Savella is one such prescription drug.

29. Savella has never been approved for use in connection with non-narcotic pain reduction, depression or anxiety. The FDA has not approved use of Savella in conjunction with any other SRNI or any other non-narcotic pain reducer or anti-depressant.

30. In order to maximize Savella's earning potential Defendants, among other things, marketed, promoted and caused the prescribing of Savella for non-approved, non-indicated uses or purposes including, without limitation the following: (a) use as a non-narcotic pain reliever; (b) use as an anti-depressant; (c) use in combination with Lyrica (generic name pregabalin); (e) as a substitute pain medication for patients seeking narcotics (f) as a preferred low cost Medicaid covered prescription non-narcotic pain reliever.

2. Bystolic

31. FLI manufactures a prescription drug known as Bystolic (generic name nebivolol.) FPI sells and markets Bystolic. Bystolic was approved by the United States FDA in 2007 for the treatment of hypertension.

32. According to FLI's 2011 Annual Report, Bystolic sales for fiscal year 2011 were $264,000,000.00 with a growth rate of thirty percent (30%). Defendants predict that 2012 sales growth for the drug will be thirty-five percent (35%) for a sales total of $356,000,000.00.

33. In August 2008, FLI received a warning letter from the FDA for failure to show the risks of its high blood pressure medication when promoting Bystolic to physicians.

34. Bystolic has never been FDA approved for use in connection with any other use such as congestive heart failure or headaches.

35. In order to maximize Bystolic's earning potential Defendants marketed, promoted and caused the prescribing of Bystolic for non-approved, non-indicated uses or purposes including the following: (a) using the term "novel" when describing the drug; (b) promoting the mechanism of action of Bystolic which decreases nitrous oxide as being a benefit to people with congestive heart failure when the FDA has not approved Bystolic for that indication; and (c) promoting Bystolic as an effective beta blocker in the treatment and prevention of migraine headaches when the FDA has not approved Bystolic for that indication.

B. Defendants' Sales and Marketing Training and Directives to Sales Force

36. Defendants' corporate Executive Vice President of Marketing is Elaine Hockberg. Defendants maintain a corporate strategy of marketing, training and sales which they disseminate to the FPI sales force in its various districts through corporate training or regional managers, who, in turn, instruct their subordinate managers and supervisors. Defendants also disseminate their strategies through corporate sales and marketing conventions and other training events and materials.

37. Defendants' pharmaceutical sales division is separated into five (5) geographic areas across the United States. Relator works in Area 5. Relator's Area Business Director, Cary Renner oversees the Regional Director of the North Star Region Josh Cox. The North Star Region consists of Wisconsin, Minnesota, the Upper Peninsula of Michigan, North Dakota, South Dakota, Iowa, and parts of Illinois. Cox oversees Relator's immediate supervisor District Manager Jessie Edwards. Edwards oversees the Forest Therapeutic Representative Team. Relator is a member of this team that markets and promotes Savella, Bystolic and Viibryd.

38. Relator has frequent interaction with sales representatives who market the same basket of drugs: Savella, Bystolic and Viibryd. Relator meets with FPI sales representatives at national conferences repeatedly throughout each year and maintains on-going communications with many of these sales representatives throughout the country in order to discuss and compare the sales directives of FPI management and to discuss sales strategies, results, performance and discipline issues.

39. Defendants' Forest Therapeutic Representative Teams' Wisconsin districts include West Milwaukee, East Milwaukee, Upper Peninsula, Oshkosh, La Crosse, Waukesha, Green Bay Eau Claire, and Madison.

40. Beginning in June of 2007, Relator became employed by FPI as a Sales Representative. Relator initially marketed Lexapro and Namenda until Lexapro became generic and Defendants made a company-wide change from Namenda to Savella.

41. Beginning in 2009, Relator started to market Savella for Defendants.

42. Relator currently markets Savella, Bystolic and Viibryd in the Oshkosh – Neenah Menasha area.

43. On June 1, 2010, Relator received an email from Edwards regarding messaging of Savella which states in part, "[h]ow are we going to convey Savella's progressive ability to only address pain, but the other true 'functional' aspects that are critical for these patients?"

44. The "functional" aspects mentioned in the email relate to increase in energy and an improved mood. In the email, Edwards did not mention the indicated use of Savella as a treatment for the management of fibromyalgia.

45. On or around April 28, 2011, Regulatory Review Officer Mathilda Fienkeng of the FDA's Division of Drug Marketing, Advertising, and Communications ("DDMAC"), sent via facsimile to John Driscoll, Senior Manager of Regulatory Affairs for FLI, a communication stating that on May 12, 2010, false or misleading oral statements were made by a FPI sales representative to a healthcare professional regarding Savella.

46. On information and belief, the healthcare professional in question was Dr. Steven J. Donatello of the Columbia St. Mary's - Glendale Clinic, 9233 North Green Bay Road Brown Deer, WI.

47. On information and belief, Defendants focused their investigation on FPI sales representative Kate Baumann. Baumann was a sales representative for the West Milwaukee area used as a scapegoat for the actual sales representative guilty of Donatello's allegations.

48. On information and belief, the FPI sales representative that Donatello reported was Specialty Representative Gina Lamer, the number one "Specialty Representative" in the country.

49. FPI's Specialty Representatives are responsible for two territories and solely target physicians that write a higher number of prescription. Lamer is responsible for Eastern and Western Milwaukee, the highest selling territories in Wisconsin.

50. The healthcare professional submitted a complaint to DDMAC on or around September 10, 2010 alleging that sales representative's statements "promote unapproved uses for Savella, make unsubstantiated superiority and mechanism of action claims about the drug, and minimize the serious risks associated with Savella."

51. The above referenced letter from DDMAC requested that Defendants immediately cease these practices and submit a written response by May 12, 2011 to those allegations contained therein.

52. On May 11, 2011, human resource employee, Brian McKenna contacted Relator and scheduled a meeting for 10:00 a.m. on May 12, 2011, with McKenna, Director of Compliance Germaine Matti, and two corporate attorneys at the Hyatt Regency in Milwaukee. The FPI personnel held similar meetings with all six sales reps from the West Milwaukee area that sell Savella.

53. The May 12, 2011 meeting was specifically in regards to whether Relator was promoting and marketing the prescription drug Savella for off-label purposes.

54. At the time of this meeting, Relator was ranked 7th out of 100 sales representatives for the sale of Savella.

55. On May 13, 2011, during a team meeting that included district manager Edwards and FPI sales representative Katie Kropp and Brad Jensen, Edwards told Relator to continue to sell Savella for "non-narcotic pain relief." This was a direct contradiction to Relator's May 12, 2011 meeting with Matti and McKenna.

56. After Relator's May 13, 2011 team meeting he contacted Matti and explained that Edwards instructed him to continue to promote Savella as a non-narcotic pain reliever.

57. There was no response by Defendants' compliance office after Relator provided this information until June of 2011.

58. On June 6, 2011 through June 9, 2011, Relator participated at a "Scientific Launch" of drugs Viibryd and Daliresp. This national conference included sales representatives and their supervisors from all parts of the country. Defendants' Vice President of Sales, Jerry Lynch and Chief Executive Officer Howard Solomon both presented speeches at the conference.

59. At the said "Scientific Launch" sales representatives receive FDA approved package inserts for newly approved drugs. The FDA regulates these package inserts and sales representatives are only legally permitted to promote a drug in accordance with the package insert.

60. Sales representatives attend conferences, presentations, and "break-out" sessions during these launches.

61. During breakfast, dinners, and while socializing, Relator and sales representatives from around the country discuss their off-label marketing and successful sales pitches that do not follow the package inserts. This included promotion of drug uses approved of in Europe and promotion of other off-label drug usages. Relator participated in such discussions regarding Savella and Bystolic between June 6, 2011 and June 9, 2011.

62. On August 22, 2011 through August 25, 2011, Relator participated at the "Branded Launch" of Viibryd and Dalisrep in Anaheim, California. At the Branded Launch, sales representatives from around the country are presented with marketing visual aid materials. These materials are supposed to be what is used to promote the drug use to healthcare providers.

63. During breakfast, dinners and while socializing, Relator and sales representatives from around the country discuss illegal marketing and promotions that help increase their market share and sales.

64. During the Branded Launch, Relator participated in specific discussions regarding Savella and Bystolic with sales representatives from the following states: (1) Arkansas; (2) California; (3) Florida; (4) Georgia; (5) Illinois; (6) Iowa; (7) Minnesota; (8) New Jersey; (9) New Mexico; (10) New York; and (11) Virginia.

65. On or around September 27, 2011, Relator had a field ride with Edwards. During this sales ride Edwards instructed Relator to promote Savella as a non-narcotic pain reliever with improved energy and mood. In addition, Edwards instructed Relator to market Savella as a prescription for pain patients and to avoid mentioning fibromyalgia, the indication for which the FDA approved Savella. Relator was specifically told to not say anything about fibromyalgia when marketing Savella. Jessie Edwards referred to fibromyalgia as the "f-word" and instructed Relator not to use the "f-word." These instructions were in direct contradictions to federal rules and his May 2011 meeting.

66. On November 9, 2011, Relator scanned and emailed the document that Relator created during his September 27, 2011 ride along with Edwards to FLI Director of Compliance Matti that specifically included instructions for the off-label marketing of Savella.

67. On March 5, 2012 through March 8, 2012, Defendants conducted a National Sales Meeting with Areas 3 and 5 in Dallas, Texas. At the National Sales Meetings, Defendants create plans of action ("POA") that instruct sales representatives on the marketing and messaging of new drugs. Sales representatives refer to these plans of action as "plans of attack."

68. During breakfast, dinners and while socializing, Relator and sales representatives from around the country discuss illegal marketing and promotion that help increase their market share and sales.

69. During the National Sales Meeting in Dallas, Texas, Relator participated in specific discussions regarding illegal marketing of Savella, Bystolic, and Viibryd with sales representatives from the following states: (1) Louisiana; (2) Indiana; (3) Texas; and (4) Michigan.

70. On March 23, 2012, Relator met with Edwards and Cox and received a "Letter of Concern." The letter is the first written warning Relator has received. During the meeting, Cox informed Relator that this letter was not based on his performance, rather that it was about his attitude although the letter has no reference to issues with his attitude.

71. Relator is paid a small base salary plus commission based on the total number of prescriptions that are sold, ordered, and prescribed by physicians regarding the drugs that he markets.

72. Sales representatives are compensated through "Incentive Compensation Programs." The Quarter 4, FY 2012 states, in part, "All representatives can earn compensation dollars based on their promoted products. In order for us to achieve our corporate goals, all representatives must maximize growth with Viibryd, Bystolic and Savella. **Those**

representatives who exceed their goals and contribute large market share or TRx growth within segments, can receive the largest program awards." (emphasis in original).

C. Defendants' Practice of Promoting and Selling Savella for Non FDA-Approved Usages

73. FPI's management openly encourage and direct their entire Savella sales force to promote Savella as a non-narcotic pain reliever and anti-depressant even though the FDA has not approved the drug for the treatment of these specific conditions.

74. FPI's management trains its sales representatives to avoid referring to Savella as a prescription drug used to treat fibromyalgia. FPI's purpose is to promote Savella as a drug prescribed by doctors for the treatment of diagnosis outside FDA approval.

75. Relator was instructed by Edwards to promote Savella by informing doctors of milnacipran's, (the generic form of Savella) use in the European market as an anti-depressant in direct violation of federal regulations.

76. Relator has confirmed that similar sales tactics are taught and used throughout the country by the aforementioned conversations with sales representatives working in different states.

77. Savella has sample titration kits that last two weeks. The number one side effect of Savella during the start of treatment is nausea and gastrointestinal issues (diarrhea/constipation); Edwards instructed Relator to market two sample kits instead of one in order for patients to overcome the initial negative side effects associated with Savella in contradiction to the FDA approved package insert.

78. Relator has confirmed that similar sales tactics are taught and used throughout the country by the aforementioned conversations with sales representatives working in different states.

79. Edwards instructed Relator to market Savella as a non-narcotic pain reducer that enhanced energy in comparison to other non-narcotic pain reducers which decrease energy. Relator was instructed to market Savella for use in combination with Lyrica. Lyrica is a drug that has a side effect of drowsiness. No FDA approved study or literature allows for this combination to be marketed.

80. Edwards instructed Relator to market Savella as a preferred state Medicaid drug. As a preferred state Medicaid drug, Savella cost $3.00 per thirty (30) day prescription. This was to induce doctors to prescribe Savella for their low-income Medicaid patients

81. Edwards instructed Relator to promote Savella to doctors as a way to get rid of patients who are only seeking narcotic pain relievers such as oxycotin. At Edwards' instruction, Relator informed doctors that the non-narcotic nature of Savella meant that it had no "street value" and therefore, doctors prescribing Savella for patients seeking medication for pain management on a fraudulent basis (in order to sell it) would no longer have to deal with drug seeking patients.

82. Relator has confirmed that similar sales tactics are taught and used throughout the country by the aforementioned conversations with sales representatives working in different states.

D. Defendants' Practice of Promoting and Selling Bystolic for Non FDA-Approved Usages

83. FPI's management openly encouraged and directed their entire Bystolic sales force to promote Bystolic for migraine headache relief and for use in patients with congestive heart failure even though the FDA had not approved the drug for the treatment of these specific conditions.

84. Relator has confirmed that similar sales tactics are taught and used throughout the country by the aforementioned conversations with sales representatives working in different states.

85. FPI's management trained its sales representatives to avoid referring to Bystolic strictly as a prescription drug used to treat hypertension. FPI's purpose was to promote Bystolic as a drug that would be prescribed by doctors for the treatment of diagnosis outside FDA approval.

86. Relator has confirmed that similar sales tactics are taught and used throughout the country by the aforementioned conversations with sales representatives working in different states.

87. Upon information and belief, Defendants have not returned any sums of money to the United States government or the various State governments listed in this complaint as a result of false claims made relating to Savella, Bystolic and Viibryd described herein.

E. Defendants' Knowing Violation of Federal and State Anti-Kickback Statutes

88. As part of his position as sales representative, it is Relator's duty to arrange luncheons and dinners with physicians/specialists to promote/speak/educate physicians attending these luncheons/dinners about the benefits of Savella, Bystolic, and Viibryd.

89. Instead of recruiting speakers and consultants based on their experience or credentials, Defendants target physicians based on their potential prescription writing volume.

90. In 2010, Relator arranged a luncheon and dinner that was scheduled to feature Dr. Wells as a speaker at both events. Upon information and belief Dr. Wells is the number one prescriber of Savella in Wisconsin. Dr. Wells was to be paid $2,500 for the events, $1250 for lunch and $1250 for dinner. Dr. Wells requested car service for transportation. The event was

held at Black Wolf Run in Kohler, Wisconsin, a luxurious resort. Dr. Wells did not perform a speech or presentation at the luncheon session but was still paid for it. Edwards specifically told Relator to pay Wells for both speeches even though Edwards knew that Dr. Wells did not perform a speech or presentation at the luncheon session.

91. On February 28, 2012, at a presentation by Dr. Turbett, Relator heard Turbett state the following to a physician attending the dinner: "I love Bystolic, but I really love my paycheck from Forest."

92. Defendants' sales representatives would hold these alleged continuing medical educations at upscale restaurants, such as Mr. B's and Lake Park Bistro in Milwaukee, WI, and provide the attending doctors with lavish meals in order to market the featured drug and secure more prescriptions from those doctors rather than to educate.

93. Relator holds these dinners at the following upscale restaurants: (1) Cucina (Kohler, WI); (2) Courthouse Pub (Manitowoc, WI); (3) Beckett's (Oshkosh, WI); (4) Sebastian's (Fond du Lac, WI); (5) Black Wolf Run (Kohler, WI); and (6) Steffano's (Sheboygan, WI).

94. Sales representatives are usually given $12,000 quarterly budget; Relator was regularly approved of quarterly budge in excess of $12,000 and up to $26,000 to bring speakers in. He was required to submit his requests for approval and was never denied.

95. Defendants produce and provide to sales representatives reports that show what doctors were prescribing on a weekly basis. These reports are known as "Quick Qlik reports." Defendants used these reports to see whether they were receiving a return on their investment. They would compare the amount of prescriptions a doctor made before and after being paid for a

speaking engagement to see whether the money paid resulted in the doctor prescribing additional Savella prescriptions.

96. Defendants produced reports showing the type of patients that doctors were seeing. These reports include the practice areas of doctors and the name and number of prescriptions written without any corresponding indication for which indication the prescription is being indicated. For example, the report will show how many prescriptions of Cymbalta, a competing drug, are being written by a particular physician. However, the report does not include whether the doctor is prescribing Cymbalta for its on-label or off-label use. Defendants' sales representatives use this report to target specific physicians.

97. Defendants would produce reports that ranked doctors by the likelihood of them prescribing Savella. The doctors would be ranked on a scale of 1-10, a ranking of 10 would indicate that the doctor was a high volume prescriber of fibromyalgia patients.

98. Defendants produce internal Plan Track reports that lists what type of patients doctors were seeing, what percentage of patients were Medicare, Medicaid, or private insurance patients, and what percentage of patients were being prescribed specific drugs. This report is used by sales representatives to target specific physicians.

99. Upon information and belief, Defendants have not returned any sums of money to the United States government or the various State governments listed in this complaint as a result of false claims made relating to Savella, Bystolic and Viibryd described herein.

COUNT ONE

False Claims Act, 31 U.S.C. § 3729(a)(1)(A)

89. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

90. This is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

91. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented false or fraudulent claims for the improper payment or approval of prescriptions of Savella, Bystolic and Viibryd by virtue of its corporate-wide conduct throughout the United States.

92. The United States, unaware of the falsity or fraudulent nature of the claims that Defendants caused, paid for claims that otherwise would not have been allowed.

93. By reason of these payments, the United States has been damaged, and continues to be damaged in a substantial amount.

COUNT TWO

False Claims Act, 31 U.S.C. § 3729(a)(1)(B)

94. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

95. This is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C. § 3729(a)(1)(B).

96. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly made, used, or caused to be made or used false records or statements material to a false or fraudulent claim for the improper payment or approval of prescriptions of Savella, Bystolic and Viibryd by virtue of its corporate-wide conduct throughout the United States.

97. The United States, unaware of the falsity or fraudulent nature of the claims that Defendants caused, paid for claims that otherwise would not have been allowed.

98. By reason of these payments, the United States has been damaged, and continues to be damaged in a substantial amount.

COUNT THREE

False Claims Act, 31 U.S.C. § 3729(a)(1)(c)

99. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

100. This is a claim for treble damages and civil penalties under the False Claims Act, 31 U.S.C. § 3729(a)(1)(C).

101. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly conspired to commit violations of the False Claims Act for the improper payment or approval of prescriptions of Savella, Bystolic and Viibryd by virtue of its corporate-wide conduct throughout the United States.

102. The United States, unaware of the falsity or fraudulent nature of the claims that Defendants caused, paid for claims that otherwise would not have been allowed.

103. By reason of these payments, the United States has been damaged, and continues to be damaged in a substantial amount.

COUNT FOUR

Arkansas Medicaid Fraud False Claims Act, Ark. Code Ann. § 20-77-901

104. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

105. This is a claim for treble damages and civil penalties under the Arkansas Medicaid Fraud False Claims Act, Ark. Code Ann. § 20-77-901.

106. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Arkansas Medicaid Program false or fraudulent claims for payment or approval; and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement; and or conspired to present false or fraudulent claims for payment or approval.

107. The Arkansas Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

108. By reason of these payments, the Arkansas Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT FIVE

California False Claims Act, Cal. Gov't Code § 12651 et seq.

109. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

110. This is a claim for treble damages and civil penalties under the California False Claims Act, Cal. Gov't Code § 12651 *et seq.*

111. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the California Medicaid Program (*i.e.*, Medi-Cal) false or fraudulent claims for payment or approval; and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement; and/or conspired to present false or fraudulent claims for payment or approval.

112. The California Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

113. By reason of these payments, the California Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT SIX

Colorado Medicaid False Claims Act, Colo. Rev. Stat. § 25.5-4-303.5 et seq.

114. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

115. This is a claim for treble damages and civil penalties under the Colorado Medicaid False Claims Act, Colo. Rev. Stat. § 25.5-4-303.5 *et seq.*

116. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Colorado Medicaid Program false or fraudulent claims for payment or approval; and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement; and or conspired to present false or fraudulent claims for payment or approval.

117. The Colorado Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

118. By reason of these payments, the Colorado Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT SEVEN

Connecticut False Claims Act, Conn. Gen. Stat. § 176-301a et seq.

119. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

120. This is a claim for treble damages and civil penalties under the Connecticut False Claims Act, Conn. Gen. Stat. §176-301a *et seq*

121. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Connecticut Medicaid Program false or fraudulent claims for payment or approval; and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement; and/or conspired to present false or fraudulent claims for payment or approval.

122. The Connecticut Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

123. By reason of these payments, the Connecticut Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT EIGHT

Delaware False Claims Act, Del. Code Ann. tit. 6, § 1201 et seq.

124. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

125. This is a claim for treble damages and civil penalties under the Delaware False Claims Act, Del Code Ann. tit. 6, § 1201 *et seq.*

126. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Delaware Medicaid Program false or fraudulent claims for payment or approval; and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement; and/or conspired to present false or fraudulent claims for payment or approval.

127. The Delaware Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

128. By reason of these payments, the Delaware Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT NINE

District of Columbia False Claims Act, D.C. Code § 2-308.14 et seq.

129. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully set forth herein.

130. This is a claim for treble damages and civil penalties under the District of Columbia False Claims Act, D.C. Code § 2-308.14 *et seq.*

131. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the District of Columbia Medicaid Program false or fraudulent claims for payment or approval; and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement; and/or conspired to present false or fraudulent claims for payment or approval.

132. The District of Columbia Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

133. By reason of these payments, the District of Columbia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TEN

Florida False Claims Act, Fla. Stat. Ann. § 68.081 et seq.

134. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

135. This is a claim for treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. Ann. § 68.081 *et seq.*

136. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Florida Medicaid Program false or fraudulent claims for payment or approval; and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement; and/or conspired to present false or fraudulent claims for payment or approval.

137. The Florida Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

138. By reason of these payments, the Florida Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT ELEVEN

Georgia False Medicaid Claims Act; GA. Code Ann. § 49-4-168 et seq.

139. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

140. This is a claim for treble damages and civil penalties under the Georgia False Medicaid Claims Act, GA. Code Ann. § 49-4-168 *et seq.*

141. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Georgia Medicaid Program false or fraudulent claims for payment or approval; and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement; and/or conspired to present false or fraudulent claims for payment or approval.

142. The Georgia Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

143. By reason of these payments, the Georgia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWELVE

Hawaii False Claims Act, Haw. Rev. Stat. § 661-22 et seq.

144. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

145. This is a claim for treble damages and civil penalties under the Hawaii False Claims Act, Haw. Rev. Stat. § 661-22 *et seq.*

146. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Hawaii Medicaid Program false or fraudulent claims for payment or approval; and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement; and/or conspired to present false or fraudulent claims for payment or approval.

147. The Hawaii Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

148. By reason of these payments, the Hawaii Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT THIRTEEN

Illinois False Claims Act, 740 Ill. Comp. Stat. 175/1 et seq.

149. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

150. This is a claim for treble damages and civil penalties under the Illinois False Claims Act, 740 Ill. Comp. Stat. 175/1 *et seq.*

151. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Illinois Medicaid Program false or fraudulent claims for payment or approval; and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement; and/or conspired to present false or fraudulent claims for payment or approval.

152. The Illinois Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

153. By reason of these payments, the Illinois Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT FOURTEEN

Indiana False Claims and Whistleblower Protection Act, Indiana Code § 5-11-5.5

154. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

155. This is a claim for treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Act, Indiana Code § 5-11-5.5.

156. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Indiana Medicaid Program false or fraudulent claims for payment or approval; and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement; and/or conspired to present false or fraudulent claims for payment or approval.

157. The Indiana Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

158. By reason of these payments, the Indiana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT FIFTEEN

Iowa Medicaid False Claims Act, Iowa Code § 685.1 et seq.

159. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

160. This is a claim for treble damages and civil penalties under the Iowa Medicaid False Claims Act, Iowa Code § 685.1 *et seq.*

161. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Iowa Medicaid Program false or fraudulent claims for payment or approval; and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement; and/or conspired to present false or fraudulent claims for payment or approval.

162. The Iowa Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

163. By reason of these payments, the Iowa Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT SIXTEEN

Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. § 46:439.1 et seq.

164. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

165. This is a claim for treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:439.1 *et seq.*

166. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Louisiana Medicaid Program false or fraudulent claims for payment or approval; and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement; and/or conspired to present false or fraudulent claims for payment or approval.

167. The Louisiana Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

168. By reason of these payments, the Louisiana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT SEVENTEEN

Maine False Claims Act, Me. Rev. Stats. Ann. tit. 5 § 215 et seq.

169. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

170. This is a claim for treble damages and civil penalties under the Maine False Claims Act, Me. Rev. Stats. Ann. tit. 5§ 215 *et seq.*

171. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Maine Medicaid Program false or fraudulent claims for payment or approval; and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement; and/or conspired to present false or fraudulent claims for payment or approval.

172. The Maine Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

173. By reason of these payments, the Maine Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT EIGHTEEN

Maryland False Claims Act Md. Code Ann. Health-Gen § 2-601et seq.

174. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

175. This is a claim for treble damages and civil penalties under the Maryland False Claims Act Md. Code Ann. Health-Gen § 2-601 *et seq.*

176. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Maryland Medicaid Program false or fraudulent claims for payment or approval; and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement; and/or conspired to present false or fraudulent claims for payment or approval.

177. The Maryland Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

178. By reason of these payments, the Maryland Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT NINETEEN

Massachusetts False Claims Act, Mass. Ann. Laws ch. 12, § 5(A)-(O)

179. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully set forth herein.

180. This is a claim for treble damages and civil penalties under the Massachusetts False Claims Act, Mass. Ann. Laws ch. 12, § 5(A)-(O).

181. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Massachusetts Medicaid Program false or fraudulent claims for payment or approval; and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement; and/or conspired to present false or fraudulent claims for payment or approval.

182. The Massachusetts Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

183. By reason of these payments, the Massachusetts Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWENTY

Michigan Medicaid False Claim Act, MCLA § 400.601 et seq.

184. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully set forth herein.

185. This is a claim for treble damages and civil penalties under the Michigan Medicaid False Claims Act, MCLA § 400.601 *et seq.*

186. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Michigan Medicaid Program false or fraudulent claims for payment or approval; and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement; and/or conspired to present false or fraudulent claims for payment or approval.

187. The Michigan Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

188. By reason of these payments, the Michigan Medicaid Program has been damaged, and continues to be damaged in a substantial amount

COUNT TWENTY-ONE

Minnesota False Claims Act Minn. Stat. § 15c.01 et seq.

189. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

190. This is a claim for treble damages and civil penalties under the Minnesota False Claims Act Minn. Stat. § 15c.01 *et seq.*

191. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Minnesota Medicaid Program false or fraudulent claims for payment or approval; and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement; and/or conspired to present false or fraudulent claims for payment or approval.

192. The Minnesota Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

193. By reason of these payments, the Minnesota Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWENTY-TWO

Montana False Claims Act, Mont. Code Ann. § 17-8-401 et seq.

194. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully set forth herein.

195. This is a claim for treble damages and civil penalties under the Montana False Claims Act, Mont. Code Ann. § 17-8-401 *et seq.*

196. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Montana Medicaid Program false or fraudulent claims for payment or approval; and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement; and/or conspired to present false or fraudulent claims for payment or approval.

197. The Montana Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

198. By reason of these payments, the Montana Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWENTY-THREE

Nevada False Claims Act, Nev. Rev. Stat. §357.010 et seq.

199. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

200. This is a claim for treble damages and civil penalties under the Nevada False Claims Act, Nev. Rev. Stat. §357.010 *et seq.*

201. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Nevada Medicaid Program false or fraudulent claims for payment or approval; and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement; and/or conspired to present false or fraudulent claims for payment or approval.

202. The Nevada Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

203. By reason of these payments, the Nevada Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWENTY-FOUR

New Hampshire Medicaid Fraud and False Claims, N.H. Rev. Stat. Ann. § 167:61-b, et seq.

204. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully set forth herein.

205. This is a claim for treble damages and civil penalties under the New Hampshire Medicaid Fraud and False Claims Law, N.H. Rev. Stat. Ann. § 167:61-b, *et seq.*

206. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the New Hampshire Medicaid Program false or fraudulent claims for payment or approval; and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement; and/or conspired to present false or fraudulent claims for payment or approval.

207. The New Hampshire Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

208. By reason of these payments, the New Hampshire Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWEWNTY-FIVE

New Jersey False Claims Act, N.J. Rev. Stat. Ann. § 2A:32c-1, et seq.

209. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully set forth herein.

210. This is a claim for treble damages and civil penalties under the New Jersey Medicaid Fraud and False Claims Law, N.J. Rev. Stat. Ann. § 2A:32c-1, *et seq.*

211. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the New Jersey Medicaid Program false or fraudulent claims for payment or approval; and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement; and/or conspired to present false or fraudulent claims for payment or approval.

212. The New Jersey Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

213. By reason of these payments, the New Jersey Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWENTY-SIX

New Mexico Medicaid False Claims Act, N.M. Stat. Ann. 1978, § 27-14-1 et seq.

214. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully set forth herein.

215. This is a claim for treble damages and civil penalties under the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. 1978 § 27-14-1 *et seq.*

216. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the New Mexico Medicaid Program false or fraudulent claims for payment or approval; and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement; and/or conspired to present false or fraudulent claims for payment or approval.

217. The New Mexico Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

218. By reason of these payments, the New Mexico Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWENTY-SEVEN

New York False Claims Act, N.Y. State Fin. Law § 187 et seq.

219. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully set forth herein.

220. This is a claim for treble damages and civil penalties under the New York False Claims Act, N.Y. State Fin. Law § 187 *et seq.*

221. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the New York Medicaid Program false or fraudulent claims for payment or approval; and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement; and/or conspired to present false or fraudulent claims for payment or approval.

222. The New York Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

223. By reason of these payments, the New York Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWEWNTY-EIGHT

North Carolina False Claims Act, N.C. Gen. Stat. § 1-605, et seq.

224. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully set forth herein.

225. This is a claim for treble damages and civil penalties under the North Carolina False Claims Act, N.C. Gen. Stat. § 1-605, *et seq.*

226. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the North Carolina Medicaid Program false or fraudulent claims for payment or approval; and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement; and/or conspired to present false or fraudulent claims for payment or approval.

227. The North Carolina Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

228. By reason of these payments, the North Carolina Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT TWENTY-NINE

Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, § 5053 et seq.

229. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully set forth herein.

230. This is a claim for treble damages and civil penalties under the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63§ 5053 *et seq.*

231. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Oklahoma Medicaid Program false or fraudulent claims for payment or approval; and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement; and/or conspired to present false or fraudulent claims for payment or approval.

232. The Oklahoma Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

233. By reason of these payments, the Oklahoma Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT THIRTY

Rhode Island State False Claims Act, R.I. Gen. Law § 9-1.1-1 et seq.

234. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully set forth herein.

235. This is a claim for treble damages and civil penalties under the Rhode Island State False Claims Act, R.I. Gen. Law § 9-1.1-1 *et seq.*

236. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Rhode Island Medicaid Program false or fraudulent claims for payment or approval; and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement; and/or conspired to present false or fraudulent claims for payment or approval.

237. The Rhode Island Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

238. By reason of these payments, the Rhode Island Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT THIRTY-ONE

Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 et seq.

239. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully set forth herein.

240. This is a claim for treble damages and civil penalties under the Tennessee Medicaid False Claims Act§ 71-5-181 *et seq.*

241. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Tennessee Medicaid Program false or fraudulent claims for payment or approval; and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement; and/or conspired to present false or fraudulent claims for payment or approval.

242. The Tennessee Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

243. By reason of these payments, the Tennessee Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT THIRTY-TWO

Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. § 36.001 et seq.

244. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully set forth herein.

245. . This is a claim for treble damages and civil penalties under the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. § 36.001 *et seq.*

246. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Texas Medicaid Program false or fraudulent claims for payment or approval; and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement; and/or conspired to present false or fraudulent claims for payment or approval.

247. The Texas Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

248. By reason of these payments, the Texas Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT THIRTY-THREE

Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 et seq.

249. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

250. This is a claim for treble damages and civil penalties under the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §8.01-216.1 *et seq.*

251. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Virginia Medicaid Program false or fraudulent claims for payment or approval; and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement; and/or conspired to present false or fraudulent claims for payment or approval.

252. The Virginia Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

253. By reason of these payments, the Virginia Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

COUNT THIRTY-FOUR

Wisconsin False Claims for Medical Assistance Act, Wis. Stat. §20.931

254. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

255. This is a claim for treble damages and civil penalties under the Wisconsin False Claims for Medical Assistance Act, Wis. Stat. §20.931

256. By virtue of the kickbacks, misrepresentations and submissions of non-reimbursable claims described above, Defendants knowingly presented or caused to be presented to the Wisconsin Medicaid Program false or fraudulent claims for payment or approval; and/or knowingly accomplished these unlawful acts by making, or causing to be made or used, a false record or statement; and/or conspired to present false or fraudulent claims for payment or approval.

257. The Wisconsin Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by Defendants, paid for claims that otherwise would not have been allowed.

258. By reason of these payments, the Wisconsin Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

WHEREFORE, Relator requests that judgment be entered against Defendants, ordering that:

(i) Defendants cease and desist from violating the False Claims Act, 31 U.S.C. § 3729, *et seq.*, and the State False Claims Acts;

(ii) Defendants pay not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. § 3729, plus three times the amount of damages the United States has sustained because of Defendants' actions, plus the appropriate amount to the States under similar provisions of the State False Claims Acts;

(iii) Relator be awarded the maximum "relator's share" allowed pursuant to 31 U.S.C. § 3730(d) and similar provisions of the State False Claims Acts;

(iv) Relator be awarded all costs of this action, including attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d) and similar provisions of the State False Claims Acts;

(v) Defendants be enjoined from concealing, removing, encumbering or disposing of assets which may be required to pay the civil monetary penalties imposed by the Court;

(vi) Defendants disgorge all sums by which they have been enriched unjustly by their wrongful conduct; and

(vii) The United States, the States, and Relators recover such other relief as the Court deems just and proper.

Dated at Milwaukee, Wisconsin this 18th day of April, 2012.

By: 

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