FILED

2016 JUN 13 PM 1:27

CLERK U.S. DISTRICT COURT
CENTRAL DIST. OF CALIF.
LOS ANGELES

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IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

[UNDER SEAL],

Plaintiff,

v.

[UNDER SEAL],

Defendants.

CASE NO.: CV 13-5861 GHK(AJWx)

SECOND AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT AND STATE FALSE CLAIMS ACTS

FILED UNDER SEAL (Pursuant to 31 U.S.C. § 3729 False Claims Act)

JURY TRIAL DEMANDED

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IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

UNITED STATES OF AMERICA *ex rel* MARIA GUZMAN,

STATE OF CALIFORNIA *ex rel* MARIA GUZMAN,

STATE OF DELAWARE *ex rel* MARIA GUZMAN,

DISTRICT OF COLUMBIA *ex rel* MARIA GUZMAN

CASE NO.: CV 13-5861 GHK(AJWx)

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JURY TRIAL DEMANDED

STATE OF FLORIDA *ex rel*
MARIA GUZMAN,

STATE OF GEORGIA *ex rel*
MARIA GUZMAN,

STATE OF HAWAII *ex rel*
MARIA GUZMAN,

STATE OF ILLINOIS *ex rel*
MARIA GUZMAN,

STATE OF INDIANA *ex rel*
MARIA GUZMAN,

STATE OF LOUISIANA *ex rel*
MARIA GUZMAN,

COMMONWEALTH OF
MASSACHUSETTS *ex rel*
MARIA GUZMAN,

STATE OF MICHIGAN *ex rel*
MARIA GUZMAN,

STATE OF MINNESOTA *ex rel*
MARIA GUZMAN,

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STATE OF MONTANA *ex rel*
MARIA GUZMAN,

STATE OF NEVADA *ex rel*
MARIA GUZMAN,

STATE OF NEW HAMPSHIRE *ex rel*
MARIA GUZMAN,

STATE OF NEW JERSEY *ex rel*
MARIA GUZMAN,

STATE OF NEW MEXICO *ex rel*
MARIA GUZMAN,

STATE OF NEW YORK *ex rel*
MARIA GUZMAN,

STATE OF NORTH CAROLINA *ex rel*
MARIA GUZMAN,

STATE OF OKLAHOMA *ex rel*
MARIA GUZMAN,

STATE OF RHODE ISLAND *ex rel*
MARIA GUZMAN,

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STATE OF TENNESSEE *ex rel*
MARIA GUZMAN,

STATE OF TEXAS *ex rel*
MARIA GUZMAN,

COMMONWEALTH OF VIRGINIA
ex rel MARIA GUZMAN,

STATE OF WASHINGTON *ex rel*
MARIA GUZMAN,

Plaintiff,

v.

INSYS THERAPEUTIC, INC.;
MICHAEL BABICH, an Individual;
ALEC BURLAKOFF, an Individual;
JOHN N. KAPOOR, an Individual;
and DOES 2 through 15,

Defendants.

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Introduction

1. Qui tam relator Maria Guzman ("Guzman"), by her attorneys, individually and on behalf of the United States of America, files this complaint against INSYS Therapeutics, Inc. ("INSYS") to recover damages, penalties, and attorneys' fees for violations of the federal False Claims Act, 31 U.S.C. §§ 3729 et seq., ("FCA" or "False Claims Act").

2. INSYS instituted a kickback-fueled off-label marketing campaign to induce doctors to prescribe INSYS's drug SUBSYS, a powerful opioid agonist drug that stimulates activity at opioid receptors in the central nervous system normally stimulated by naturally occurring opioids. SUBSYS is a fentanyl product, in the opioid agonist family with such other drugs as morphine, oxycodone, and heroin. As a result of the off-label campaign and egregious financial kickbacks, SUBSYS is being marketed and prescribed far beyond its stated indication, which is limited to breakthrough cancer pain only, at a beginning dosage of 100 micrograms.

3. The FDA has contraindicated SUBSYS for several uses due to the risk of overdose and requires enrollment in a special program in order to prescribe this potent and addictive drug. INSYS's off-label campaign, which includes the kiss of death message, which encourages doctors to quickly titrate patients, has resulted in at least one pharmacist contacting the relator to ask her to return a patient to a lower, safer dosage. INSYS off-label marketing and financial inducements have been

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successful as many doctors write SUBSYS for contraindicated and off-label uses in Medicare and Medicaid patients, including for postoperative pain and back pain, which is counter to FDA warnings of respiratory failure and death. INSYS also utilizes a mail order pharmacy that sends SUBSYS to patients who had not requested the drug and that does not properly instruct patients on the storage of SUBSYS, which can lead to children fatally ingesting the drug.

4. INSYS instituted programs throughout the country to induce doctors to prescribe SUBYS over those of competitors by means of monetary payments, trips to strip clubs and shooting ranges, stock options, hiring physician's significant others, and expensive meals in violation of federal anti-kickback laws. One physician, Dr. Stuart Krost, was promised a $100,000 payment for this "support with SUBSYS" and INSYS spent $58,000 on meal expenses for doctors in just one month. INSYS, focusing on increasing its market share and generating high revenues, disregarded patient well-being, such as sending congratulatory emails to sales representatives that state, "Cha Ching again!" when a patient is prescribed SUBSYS for $40,000. INSYS has increased profits enough to publicly trade SUBSYS, earning $36 million in gross proceeds from the sale of 4.6 million shares in May 2013. Many of the INSYS executives have stock options for hundreds of thousands of dollars.

5. INSYS also maintains a work environment in which the male-dominated executive and management team frequently sexually treat female doctors who fail to

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prescribe "enough" SUBSYS in exchange for their kickbacks from INSYS with blatant disrespect, best summarized in a text message from INSYS Vice President of Sales Alec Burlakoff, in a text message to the Relator regarding a female doctor in her territory: "She fuckn sucks kock mia! What else can I say! XOXOXO…I hate that stupid bitch – dr banchik!!!!!!!! I want to jerk off in her fuckn face! Joe would jerk off in her face, but his dick is too tiny for him to grab." The same attitudes and behavior were used harass female sales representatives.

6. In connection with the filing of this original Complaint, Relator has furnished the United States with substantially all material evidence and information in Relator's possession.

Jurisdiction and Venue

7. This Court has subject matter jurisdiction over this action under 31 U.S.C. §§ 3730 and 3732.

8. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732 (a) because the Defendant transacts business in this judicial district.

9. Venue is proper in this District pursuant to 31 U.S.C. § 3732 (a) and under 28 U.S.C. § 1391(c) because the Defendant transacts business in this judicial district.

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Parties

10. Relator Maria Guzman is a citizen of the United States and a resident of Clayton, North Carolina.

11. Relator resided in Florida until June 2013.

12. Guzman began working for INSYS in January 2012 as a Specialty Sales Professional and was fired in July of 2013.

13. At all times material hereto, John N. Kapoor was the Founder and Executive Chairman of INSYS, and held the majority of its shares. He exercised his authority to direct and control many of the activities described herein. Kapoor was adamant that doctors selected for the speakers program be actively prescribing Subsys. In addition, Kapoor was aware of and supported the sales initiative to push doctors to prescribe 400 mcg only instead of 100 or 200 mcg doses.

14. At all times material hereto, Michael Babich was the Chief Executive Officer of INSYS, and exercised his authority to direct and control many of the activities described herein.

15. Michael Babich has served as President since November 2010 and was appointed Chief Executive Officer in March 2011. From March, 2007 until his appointment as President of INSYS Therapeutics. Babich was Chief Operating Officer and a Director of INSYS Pharma, Inc., a wholly owned subsidiary. He had

previously worked at EJ Financial Enterprises, Inc., a venture capital firm founded by Defendant Kapoor.

16. Alec Burlakoff was originally hired by INSYS as a regional sales manager but in September of 2012, was quickly promoted to national Vice-President of Sales, where he exercised his authority to direct and control many of the activities described herein

17. Before coming to sell INSYS' opioid, Burlakoff had been previously employed selling opioids for Cephalon, which plead guilty to criminal charges for the illegal marketing of the opioid Actiq. To illegally market Actiq, Cephalon had its sales representatives (a) call on physicians who would not normally prescrive the drugs in the course of their practice; (b) prompt the doctors to initiate conversations about off-label uses; (c) tell doctors how to document their off-label uses to get the drugs paid for by Medicare, Medicaid, and private insurers; and (d) send the doctors to lavish "consultant" meetings. Cephalon also underpaid its sales representatives, and then offered them sizeable sales-based bonuses to encourage off-label sales.

18. Burlakoff helped manage Cephalon's sales of Fentora, a fentanyl-based drug that Cephalon sold after the Actiq scandal broke, and adopted Cephalon's criminal marketing strategies when he moved to INSYS.

19. Defendant INSYS Therapeutics, Inc. is a specialty pharmaceutical company headquartered at 444 South Ellis Street, Chandler, Arizona, 85224.

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20. INSYS is incorporated in Delaware at 1209 Orange Street, City of Wilmington, County of New Castle, Delaware, 19801.

21. Relator is informed and believes and based thereon alleges that each of the entities identified as Does 1-15, inclusive, were the employers, agents, contractors, directors, or otherwise responsible for the acts alleged herein. Their identity is unknown at this time and will be set forth later when it is known.

22. INSYS has two marketed products: SUBSYS and Dronabinol SG Capsule, and is awaiting approval for Dronabinol Oral Solution.

23. SUBSYS is a fentanyl sublingual spray: a proprietary, single-use product that delivers fentanyl, and opioid analgesic, in seconds for transmucosal absorption under the tongue.

24. Transmucosal immediate-release fentanyl ("TIRF") products generated $440 million in U.S. sales in 2010 and INSYS believes this market has the potential to expand with its faster-acting fentanyl product, SUBSYS.

25. In March 2011, INSYS submitted a New Drug Application to the Food and Drug Administration ("FDA") for Fentanyl SL Spray for the treatment of breakthrough cancer pain in opioid-tolerant patients.

26. The FDA approved SUBSYS for the limited use of relieving breakthrough cancer pain, which is characterized by sudden, often unpredictable, episodes of intense pain that can peak in severity despite pain medication.

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27. SUBSYS was approved for sale on January 5, 2012 and was made publicly available on March 26, 2012.

28. On May 7, 2013, 5 days after its initial public offering of common stock, INSYS closed the offering as all 4,600,000 shares had been sold, with aggregate gross proceeds of $36.8 million.

29. INSYS's Executive Team is comprised of three men and the INSYS Board of Directors has seven male members; there are no females on the Executive Team or the Board and very few female managers.

30. The absence of women in leadership roles at INSYS contributes to the rampant sexual harassment and the hostile work environment for its female employees, including sales representatives experiencing unwanted flirtatious comments from executives and management sending sexually explicit text messages to female members of their sales team.

31. The INSYS Code Conduct states that, "INSYS values a work environment that is free of any form of harassment…[which] can included unwelcomed sexual conduct, threats or offensive comments."

FACTUAL ALLEGATIONS

Work History and INSYS's Hiring Strategies.

32. In January 2012, Guzman began working for INSYS as a Specialty Sales Professional.

33. Guzman remains on the INSYS South East Region sales team, with her territory in the West Palm Beach area of Florida.

34. Before serving as a sales representative for SUBSYS, Guzman did not possess any pharmaceutical sales experience: Guzman earned her Bachelor's degree in Education and Dance, worked for G&K Services (a company that provides work uniforms), and was a Marketing Associate for Corporate Counseling Associates.

35. INSYS hiring individuals without pharmaceutical experience as sales representatives serves as a standard practice for the company.

36. INSYS Specialty Sales Professionals who lack previous pharmaceutical experience are unfamiliar with compliant marketing standards.

37. In or around late 2012, INSYS hired [redacted], a dental hygienist who lacked pharmaceutical sales experience, as a South East Region sales representative.

38. INSYS apparently hired [redacted] to have sexual relations with doctors in exchange for SUBSYS prescriptions, which has been implied by INSYS management and employees, through statements such as one in which Joe Rowan, the Southeast Regional Sales Manager told Dr. Bart Gatz that she ([redacted]) was as dumb as rocks, but that she was sleeping with another doctor and getting a lot of prescriptions out of him." During the April 2013 National Sales Conference Rowan publicly stated that

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[redacted] had been "out there working it" in regards to forming relationships with her doctors.

39. Aside from recruiting individuals who lack pharmaceutical sales experience, INSYS has also hired many former Cephalon, Inc. employees. One such employee was Karen Hill, who became Insys' national trainer for sales and actively promoted Insys' aggressive off label marketing strategy.

40. On or around September 29, 2008, the Department of Justice ("DOJ") announced a $435 million settlement to resolve off-label marketing claims relating to Actiq, a TIRF product, and two other drugs.

41. On or around September 29, 2008, the DOJ stated that $375 million of the plea agreement was to resolve False Claims Act allegations arising from claims to Medicaid, Medicare, and other federal programs.

42. Like the SUBSYS label, the Actiq label stated that the drug was for opioid tolerant cancer patients with breakthrough cancer pain, to be prescribed by oncologists or pain specialists familiar with opioids.

43. Cephalon utilized the mantra "pain is pain," and instructed Actiq sales representatives to focus on physicians other than oncologists and to promote Actiq for uses other than breakthrough cancer pain.

44. INSYS employees also promote this motto and target doctors other than oncologists.

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45. In December 2011, INSYS hired Matt Napoletano ("Napoletano"), a former Cephalon executive who led the launch for several of its pain products, as its Vice President of Marketing.

46. In or around November or December 2012, INSYS hired former Cephalon employee Dan Tondre ("Tondre") as a Specialty Sales Professional.

47. During a conference call in late 2012 or early 2013 with other Special Sales Professionals and managers, Tondre described how he sold INSYS drugs to doctors, stating that, "Pain is pain. It does not matter whether it is back pain or a migraine. Pain is pain and SUBSYS treats pain."

48. INSYS management frequently has praised Tondre for his success at Cephalon and has instructed other sales representatives to follow his lead in the marketing of SUBSYS.

49. In December 2012, Rowan sent a text message to the South East Region sales team congratulating Tondre for making a 1200 mcg SUBSYS sale and then stating that Tondre was "asking for the business wow…it works…let's get them Southeast."

50. INSYS has hired other former Cephalon employees, many of whom handled marketing for that company, including Vice President of Sales Alec Burlakoff, Specialty Sales Professional and National Trainer Karen Hill, Specialty Sales Professional and Regional Sales Manager for the South East Region Joseph

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Rowan, Specialty Sales Professional and Regional Trainer Nannette Alonzo, Specials Sales Professional Marcus Seiferith, and Medical Marketing Communications Senior Manager Desiree Hollandsworth.

51. INSYS has comprised a team of employees who have either been recruited from a pharmaceutical company that settled a multi-million dollar off-label marketing lawsuit or individuals without any pharmaceutical sales experience or familiarity with compliant marketing standards.

52. Babich has actually praised the hiring strategy, stating "The majority of our sales reps have no prior pharmaceutical experience. We think that is very important from the perspective of "they are out there delivering a message."

53. Burlakoff effected and supported Babich's marketing strategy. INSYS, for example, hired Sunrise Lee, a former dancer at a Florida strip club as a sales executive. Sunrise also managed an escort service and had no academic degree. Burlakoff defended the decision, claiming "Doctors really enjoyed spending time with her and found Sunrise to be a great listener." "She's more of a closer", he added praising her "empathy".

54. Babich also established a compensation system certain to induce misbehavior. Under Babich, INSYS established sales force incentives which completely reverse the pharmaceutical industry compensation manual. Although typical pharmaceutical reps earn salaries in the $80-90,000 range with a potential for

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$30-40,000 in bonuses, Subsys reps earn only $40,000 in salary with a potential $72,000 in bonuses. Babich boasted that Subsys' 38% sales growth between the third quarter and the fourth quarter of 2013 was "strong testimony to the success of this approach."

55. Babich's carrot was paired nicely with Burlakoff's stick. Burlakoff frequently threatened to fire any sales representative who didn't get at least one new prescription written every day.

56. INSYS also established relationships with and speaker programs for former Cephalon prescribers, including Doctor Stuart Krost ("Dr. Krost"), Doctor Bart Gatz ("Dr. Gatz"), and Doctor Lisa Banchik ("Dr. Banchik").

The INSYS Business Model and Kickbacks to Doctors.

57. After Burlakoff arrived, the speaker program became an overt kickback program sometimes with just the doctor and one attendee. Relator is informed and believes and based thereon alleges that Burlakoff told the sales staff that the purpose of the speaker's program was to "put money into the pockets" of doctors

58. Under Burlakoff, the INSYS business model consists of providing doctors with substantial compensation – including, stock options, strip club trips, and hiring physicians' significant others – so that the doctor then returns the "favor" to the sales representative by prescribing SUBSYS. One physician was even offered $100,000 in payments.

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59. In or around March 2013, National Trainer Karen Hill created a PowerPoint presentation ("2013 PowerPoint") for Specialty Sales Professionals which illustrates the centrality of payoffs, such as instructing representatives to target Drs. Lee and Arcila for more lucrative speaking opportunities and stating that Drs. Kornick, Kramarich, and Khanna will be paid through more preceptorships (which usually entail allowing a representative to shadow the doctor but which INSYS is using as another marketing tool).

60. The 2013 PowerPoint contains several pictures of doctors out drinking with INSYS staff.

61. The 2013 PowerPoint outlines what "hot buttons" representatives should utilize with doctors, such as "$" and "hanging out."

62. The 2013 PowerPoint provides "special notes" about the doctors and ways to increase sales with them such as "loves to party."

63. The 2013 PowerPoint highlights "challenges" that representatives will face with some of the doctors such as "very conservative and cautious…continue challenging her thinking" as well as "potential" with some physicians, such as "good with increasing strengths."

64. In July 2012, Vice President for Sales Alec Burlakoff sent a text message to Guzman stating, "I know pedro [Dr. Charles Huang's physician's

assistant] very well also…He's the one who probably writes the most. Let's take pedro out for some fun! I bet you he would LOVE to smoke with us!"

65. INSYS's tactics have resulted in doctors recommending and writing SUBSYS prescriptions for their patients, including those on Medicare and Medicaid, in exchange for kickbacks, and often times switching patients from Actiq, SUBSYS's competitor.

Kickbacks and Speaker Programs.

66. One of the primary ways INSYS provides doctors with kickbacks for prescribing SUBSYS is through its speaker programs.

67. INSYS speaker programs consist of the doctors giving presentations to others regarding their experience with SUBSYS and in return they receive a speaker fee.

68. INSYS officially states that speaker programs are based on clinical experience, and not on the amount of SUBSYS the doctor prescribes. However, John Kapoor, INSYS' founder and executive chairman, instructed Burlakoff that Subsys speakers should support and show belief in the product or they would have to be removed from the speaker program. This support and belief was evidenced by high prescriptions.

69. In July 2012, Burlakoff sent a text message to several sales representatives in which he stated "we have done all these programs and we are flat

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in sales…Are our speakers doing their part…We must hold our speakers accountable, programs are going to begin to get cancelled very quickly…Clearly, we have done a poor [job] setting proper expectations for our speaker."

70. In July 2012, Burlakoff sent Guzman a text message stating, "Don't worry about Dr Banchik or Dr Vendrys's speaking abilities. They do not need to be good speakers, they need to write a lot of Subsys."

71. In December 2012, Burlakoff sent the following text message: "Mia - just wanted to make sure you know that Dr Banchik is taking you for a ride. She doesn't produce shit for units or dollars. She needs to understand you can't keep giving her programs, when gatz has truly earned them! Show her the numbers!"

72. During the April 2013 conference, Rowan explained how he would like the speaker program ran, instructing representatives not to take doctors to Ruth's Chris Steakhouse or other expensive restaurants because he did not want a large amount of money spent on "dipshits that aren't going to write," but would rather keep that money in the budget to spend on other doctors for "better uses."

73. The INSYS Code of Conduct states that the company must "monitor all fees, payments, and compensation paid for advisory, consulting or other services to avoid even the appearance of inappropriate influence."

74. The INSYS Certificate of Compliance states, "INSYS has established an annual spending limit of $1,500 on meals and educational items which may be

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provided to a healthcare professional." Fees from services to such healthcare professionals are excluded from this amount but are always based on fair market value…items of nominal value (less than $10) or financial support for educational programs are also exempt from this amount."

75. In April 2013, Burlakoff sent Dr. Krost a text message in April 2013 which stated, "Dr. Krost…I know it[']s not a lot to you, but I can commit to 100K to you via speaker programs or meals toward your restaurant. We don't need the food, just charge our card and give [a]s an itemized receipt. Just need your support on subsys."

76. In October 2012, Burlakoff sent Guzman a text message and an email stating that Dr. Krost would earn $1,600 per program and that INSYS would hold all of Dr. Krost's programs in the restaurant he owns, to persuade him to switch his Aqtiq patients to SUBSYS.

77. In October 2012, Burlakoff indicated to Guzman in a text message that INSYS would pay Dr. Gatz $750 per hour for trainings conducted via telephone.

78. In December 2012, Burlakoff sent Guzman a text message stating that INSYS paid Dr. Gatz $36,000 in one quarter for speaker programs.

79. The doctors affiliated with INSYS participate in the speaker programs because of the substantial payments and kickbacks they receive, rather than their belief in the benefit of the drug for cancer patients.

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80. In September 2012, Burlakoff sent Guzman a text message indicating that "I think dr krost would want to speak, he loves money."

81. On August 16, 2012, Dr. Banchik sent a text message to Guzman thanking her for a "fun night" and stating "I just wish I had more MD`S that can write it themselves but these people will refer to me to write it for them."

82. In 2012, Dr. Banchik received speaker fees and referrals from participating in the INSYS speaker programs, and because she then obtained more patients through these referrals, she was able to prescribe more SUBSYS and in return earn more speaker programs and fees from INSYS.

83. In September 2012, Dr. Banchik indicated how important these speaker fees to her when she sent a text message to Burlakoff asking why INSYS had failed to pay her for her program, stating, "I am not happy Alec."

84. In September 2012, Dr. Gatz sent Guzman an email inquiring about when he would be paid the $7,200 he was offered for three speaker programs in which he participated, as his honoraria check had been lost.

Strip Clubs, Shooting Ranges, Meals, and Referrals.

85. In addition to the program speaker fees that doctors receive for prescribing SUBSYS, INSYS also provides doctors with other kickbacks.

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86. On or around Friday, January 18, 2013, Burlakoff and Rowan treated Dr. Gatz to a strip club visit, where they purchased him two $500 private champagne room sessions, to ensure he continued prescribing SUBSYS.

87. On or around January 19, 2013, Burlakoff sent Guzman a text message expressing that it "[w]ent fantastic last night. Bart and I got back around 4 am."

88. Shortly after January 18, 2013, Rowan sent Dr. Gatz a text message stating, "Dr. Gatz, we appreciate you more than you could believe….Leaving that meeting Alec and I felt very confident and what was going to happen….And you show loyalty to us like no other…You need anything at all, it is done."

89. Dr. Gatz responded to Rowan's text message in January 2013 with, "Thank you for the best weekend in years!!!"

90. The strip club visit resulted in an increase in prescription volume, as Guzman reported to Burlakoff and Rowan on Wednesday, January 23, 2013, just five days later, that Dr. Gatz had already written 17 SUBSYS prescriptions in three days.

91. Under the its Code of Conduct, the $1,000 INSYS spent for private champagne room sessions would not qualify as payment for an advisory services from Dr. Gatz nor would it qualify as gift of less than $100 designed for the patient or for educational purposes; it would fall under the category of prohibited recreational activity.

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92. INSYS has also provided Dr. Gatz with many expensive dinners, stock options, lunches for his office, and a trip to a shooting range, which serves as part of a company-wide scheme to both encourage doctors to, and reward them for, prescribing SUBSYS.

93. From on or about July 2 to July 10, 2012, Dr. Gatz prescribed 120 units of SUBSYS.

94. On July 18, 2012, Burlakoff instructed Guzman in a text message that she could take Dr. Gatz and "whoever out," and that he would supply his credit card number for the dinner.

95. From on or about July 23 to July 30, 2012, Dr. Gatz prescribed a total of 300 SUBSYS units.

96. On or about October 10, 2012, INSYS provided Dr. Gatz's office with lunch.

97. From on or about October 16 to October 30, Dr. Gatz wrote prescriptions for 720 units of SUBSYS.

98. In or around November 2012, Rowan suggested that INSYS send top prescribing doctors Thanksgiving dinners. Thanksgiving dinners were provided to Dr. Gatz' entire office staff. Insys correspondingly increased spending limits on sales representatives' charge cards to cover this additional expense.

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99. During the April 2013 Arizona conference, Rowan and is South East Region sales team acknowledged how successful these meals were and, in particular, how Dr. Gatz's Office Manager ensured that prior authorizations were completed after the meals were delivered.

100. A January 2013 report sent to INSYS sales representatives indicates that the company spent over $58,000 on meal expenses for doctors, with Rowan and Burlakoff spending a total of approximately $15,000.

101. The INSYS Code of Conduct states that "[m]eals may occasionally be provided to HPCs [health care professionals] so long as they are modest and shared at a reasonable location that is conducive to discussing educational information."

102. The INSYS Certificate of Compliance specifies that "INSYS has established an annual spending limit of $1,500 on meals" per provider.

103. The Compliance Guidance for Pharmaceutical Manufacturers states that "entertainment, recreation, travel, meals and other benefits…potentially implicate the anti-kickback statute if any one purpose of the arrangement is to generate business for the pharmaceutical company."

104. The INSYS Code of Conduct states that the company must "monitor all fees, payments, and compensation paid for advisory, consulting or other services to avoid even the appearance of inappropriate influence."

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105. In the January 2013 email containing the expense report, Burlakoff stated that the representatives with the highest meal expenses should be ranked number one in their region and obtaining a "return on investment."

106. From on or about January 24 to February 5, 2013, Dr. Gatz prescribed a total of 670 SUBSYS units.

107. On or about February 5, 2013, Rowan sent text messages to Dr. Gatz and Guzman asking, "Would you like to get a bite to eat? Somewhere spectacular! Maybe shoot guns before?"

108. On or about February 19, 2013, Rowan took Dr. Gatz to the shooting range.

109. From on or about February 19 to March 7, 2013, Dr. Gatz prescribed a total of 1010 units of SUBSYS.

110. On or about March 11, 2013, Rowan sent Dr. Gatz a text message stating that he would take Dr. Gatz out to dinner anywhere he wanted, so that they could "eat and celebrate life."

111. INSYS also celebrated Dr. Gatz's loyalty in recommending SUBSYS by providing him with stock option.

112. In early 2013, Dr. Gatz had a conversation with Guzman regarding the stock options INSYS had offered her and she ascertained from his excited tone and knowledge of managing this particular stock that he was also receiving such options.

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113. On February 19, 2013, Guzman's belief that Dr. Gatz was receiving stock was confirmed by a conversation that she heard between Rowan and Dr. Gatz while the three were out at the shooting range and dinner, a conversation in which Rowan told Dr. Gatz that "INSYS takes care of its people" and that "I [Rowan] have stock options, [Guzman] has stock options, and you will have stock options."

114. During the conversation regarding the stock options, Dr. Gatz also indicated that he would like a position with INSYS and a home in Arizona, and Rowan reiterated that "INSYS takes care of its people."

Hiring a Doctor's Significant Other Family Member, or Friend.

115. In addition to the monetary and meal kickbacks, INSYS also encourages doctors to subscribe SUBSYS by hiring their significant others or family members.

116. On or around August 18, 2012 Burlakoff sent a text message to Dr. Charles Huang ("Dr. Huang") stating "I need to know if Paula [Dr. Huang's girlfriend] would take a full time job working for me? I also could use a few Subsys prescriptions. We have not seen anything, I want to have some fun!!! Can't do it w/o subsys scripts coming in at least once a day. Have Paula call me next week. Let's make it like the old days, turn the subsys switch on please Dr Huang!!...We mean what we say, just need you too (sic) get it going strong."

117. From on or about August 21, 2012 to August 22, 2012, Dr. Huang prescribed 60 units of SUBSYS.

118. INSYS hired Dr. Huang's girlfriend, Paula, in or around fall 2012.

119. On or about March 28, 2013, Rowan asked Guzman if she could recommend any sales representatives for the Nashville, Tennessee region, and stated that the only qualification that INSYS required was that the individual was eighteen years old and that he did not care if the person did not possess a college degree.

120. During the conversation regarding a Nashville sales representative on or around March 28, 2013, Rowan told Guzman that the individual could be "anyone as long as it was a doctor's girlfriend, son or daughter," and further that if the individual were "banging a doctor, that would be perfect."

121. Relator is informed and believes and based thereon alleges that that Burlakoff had personal knowledge of INSYS hiring other sales representatives at the request of Subsys prescribers.

122. Babich engaged in the same misconduct. Relator is informed and believes and based thereon alleges that Dr. Ruan in Mobile, Alabama promised promised Babich that if Babich hired Joe Rowan as a sales representative, Dr. Ruan would become the top prescriber of Subsys. Rowan was hired and assigned to Dr. Ruan, who did indeed become a top prescriber of Subsys for certain periods. Dr. Ruan's partner, Dr. Couch, was also a top Subsys prescriber and the two doctors had ownership interest in a pharmacy that dispensed Subsys.

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Burlakoff Offered Physicians Lucrative Business Deals and Partnerships

123. Relator is informed and believes and based thereon alleges that Burlakoff personally offered Gawin Awerbuch, M.D., financial incentives, including commissions based on the number of prescriptions and the strength of the dosage. These illegal incentives triggered a prescription-writing spree which did not abate until May of 2014 when Awerbuch was arrested for Medicare fraud and illegal distribution of controlled substances. By then Awerbuch had written 1,283 prescriptions for Subsys for Medicare beneficiaries alone, costing Medicare nearly seven million dollars.

124. Relator is informed and believes and based thereon alleges that Burlakoff gave the manager of a multisite pain management clinic an annual compensation package of $73,000 for the manager's "contacts" while letting the manager keep the INSYS job secret from the pain management clinic.

Instructions for Avoiding Anti-Kickback Standards.

125. Some INSYS managers and sales representatives were aware of the illegality of using kickback schemes to obtain SUBSYS sales, particularly the former Cephalon employees.

126. During the April 2013 INSYS conference in Arizona, management and specialty sales professionals shared methods with one another on how to avoid anti-kickback standards.

127. During the April 2013 conference, former Cephalon employee and INSYS National Trainer Hill stated that she would have a "legit [speaker] program" at an inexpensive restaurant where INSYS would provide her with $100 to spend per person, and she would use that budget to purchase wine and instruct the restaurant staff to box the wine for the doctors to take home, remaining cautious as to how the doctors left with the wine.

128. During a meeting at the April 2013 Arizona conference, Former Cephalon employee and Manager Rowan stated that he is able to order beer, wine, cigars, and expensive meats through his friend who owns a delicatessen, and that him and another employee have been "doing this for years," which is one of the reasons he hired that employee.

129. After informing his sales team about his delicatessen owner friend at the 2013 conference meeting, Rowan then asked his representatives, "do you think he runs it through as a cigar or a filet mignon? No. He runs it across as, you figure the rest out."

130. During the April 2013 meeting, Rowan indicated that the representatives would receive more of a benefit from providing the doctor and his or her family with some filet mignons and bottles of wine than by providing a lunch to the office.

131. During the 2013 conference meeting, Rowan stated that he used his friend to order expensive products and then used them to encourage physicians to

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prescribe SUBSYS, providing the example of how he inconspicuously placed a cooler filled with filet mignons by Dr. Couch's desk and then told the doctor "thank me later."

132. After Rowan described his methods for avoiding kickback standards during the 2013 conference meeting, Hill instructed that the representatives should get everything through a caterer, and that she had heard of other representatives getting televisions for their doctors through a caterer.

133. After Hill's comments regarding obtaining items for doctors through caterers during the April conference meeting, Rowan then told the South East Region team, "I don't want to know what you do," but stated that they should do what they need to, but "it's not on me."

134. During the April conference meeting, Rowan instructed his sales representatives to "think outside of the box," and provided the example of going into a restaurant during lunch, asking the staff to ring up a to-go receipt for ten people, but then asking them to not provide the lunch but rather give the representative credit for when they returned with the doctor and his or her spouse later that night for dinner.

135. After providing the example of how to treat doctors to dinner by appearing to be within kickback standard limits during the April 2013 conference, Rowan then told the representatives, "This is the shit we've done all of our careers.

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But be smart about it, don't be a dipshit. I'm not forcing you to do this, but just telling you this is what we do."

136. After explaining how he encouraged doctors to write SUBSYS prescriptions by offering them filet mignons and dinners during the 2013 conference meeting, Rowan explained "I don't think I did anything wrong because I did it with food;" however, when one sales representative in the meeting began writing notes regarding his methods, Rowan stated, "there is nothing to write down, just thinking outside of the box."

SUBSYS's Indication and Usage, and INSYS's Off-Label Marketing.

137. INSYS developed methods for persuading doctors to prescribe SUBSYS for contraindicated and off-label uses, which the FDA states can be deadly.

138. According to its label, the FDA indicated SUBSYS for the limited use of management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.

139. Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 25 mcg of transdermal fentanyl/hour.

140. The FDA contraindicated SUBSYS for use in opioid non-tolerant patients because life-threatening respiratory depression and death could occur in patients not on a chronic regiment of opioids. For this reason, SUBSYS is

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contraindicated in the management of acute or postoperative pain, including headaches or migraines.

141. According to the label, the FDA intended that SUBSYS be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain.

142. According to the label, the initial dose of SUBSYS to treat episodes of breakthrough cancer pain is always 100 mcg.

143. According to the SUBSYS label, due to the potential for fatal overdose, physicians should not convert patients on a mcg per mcg basis from any other fentanyl product.

144. According to the SUBSYS label, death has been reported in children who have accidently ingested transmucosal immediate-release fentanyl products and therefore SUBSYS must be kept out of the reach of children.

145. Due to the risk of misuse, abuse, addiction, and overdose, SUBSYS is only available through a restricted program created by the FDA: the TIRF Risk Evaluation and Mitigation Strategy (REMS) program.

146. INSYS has systematically violated and continues to violate every one of these FDA indications and warnings

147. INSYS has created the "effective dosage message," which continually encourages sales representatives to push doctors to prescribe doses higher than 100

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mcg and to quickly titrate patients to high levels because low SUBSYS dosages, as Babich states, are known as "the kiss of death."

148. Relator is informed and believes and based thereon alleges that Burlakoff personally trained representatives to use the off-label message that if patients had previously taken another Fentanyl product, the doctors should start patients on dosage levels higher than those indicated by the FDA because the FDA-approved starting dose might be insufficient. Burlakoff insisted that "everyone knows it doesn't work at that level."

149. Relator is informed and believes and based thereon alleges that the field training Burlakoff conducted via "ride alongs" differed markedly from their formal trainings, as Burlakoff recommended that doctors start patients on doses 400% greater than the FDA-approved starting dose, and that they move patients to doses 800% and 1600% greater as quickly as possible.

150. Relator is informed and believes and based thereon alleges that Babich was fully aware of the financial advantage to INSYS of pushing patients to dangerously high dosage levels. For example, at a May, 2014 conference, he stated that "as patients stay on the drug longer, they have a tendency to move up in dose, making prescriptions more valuable as the patient stays on the drug . . ."

151. Relator is informed and believes and based thereon alleges that Kapoor yelled at sales representatives to get doctors to quickly move patients to higher doses,

and that he also pressured sales managers to start their patients on doses higher than the FDA allowed.

152. Relator is informed and believes and based thereon alleges that at the same April, 2014 sales meeting where Burlakoff told his sales staff to disregard his previous instructions to push off-label uses and off-label dosage labels for Subsys, he also warned the staff that anyone who discussed problems with doctors or patients in an email would be fired.

153. INSYS has recently begun to rely on Linden Care Pharmacy, a mail order pharmacy in New York, for its SUBSYS supply.

154. INSYS management promotes sales representatives and doctors to use this pharmacy, as illustrated in a text message that Burlakoff sent to Guzman on or around February 20, 2013, instructing her to, "Just use Linden care, they don't bitch."

155. In March 2013, Guzman became concerned about using this pharmacy because a pharmacist in her territory, Doctor Brad Williams ("Dr. Williams") from Family Care Pharmacy, told her in both a telephone conversation and email letter that it was dangerous for SUBSYS to be distributed to patients through the mail as this illustrated that a pharmacist had not properly educated the patient on storage and disposal of the drug, which could result in children or pets accidently ingesting and overdosing on this powerful drug.

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156. During the March 2013 telephone call with Guzman, Dr. Williams told her that some of his patients had come into the pharmacy complaining that they had not even ordered SUBSYS but that it had arrived through the mail at their homes.

157. During the March 2013 conversation with Guzman, Dr. Williams also expressed his concern that medication crossing state lines from New York, where Linden Care is located, to Florida, where his patients lived, violated state laws.

158. Guzman alerted Burlakoff to Dr. William's concern with the potential risk to patient health and safety by utilizing a mail order pharmacy, but INSYS continues to instruct sales representatives to use Linden Care.

159. During the April 2013 conference in Arizona, Liz Gurrieri ("Gurrieri") from the Internal Reimbursement Center ("IRC") stated that representatives could pre-populate their opt-in forms with Linden Care for the pharmacy section of the form.

160. Relator is informed and believes and based thereon alleges that Babich knew that only about 10% were for patients with a cancer diagnosis. The majority of prescriptions were for patients with low back pain, sciatica, or peripheral neuropathy secondary to diabetes. Babich observed this because he personally saw all of the patients' diagnoses as they were funneled through the PA team, which was given each patient's diagnosis and a list of drugs the patient had previously taken. It was so unusual for the team to actually see a patient with a cancer diagnosis that they would

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get excited. Babich, who remained in close personal contact with the PA team, was aware of this..

161. Relator is informed and believes and based thereon alleges that Burlakoff trained the Subsys sales force to "agree" with doctors that the drug was good for any pain spike, whether or not it was for breakthrough cancer pain.

162. Relator is informed and believes and based thereon alleges that Babich also, at a September, 2012 sales meeting, instructed the sales staff to give physicians the off-label message that "breakthrough pain is the same as breakthrough cancer pain".

163. Relator is informed and believes and based thereon alleges that Burlakoff would do "ride alongs", where he accompanied sales representatives on physician calls so he could teach them his illegal techniques, and that those representatives with pharmaceutical industry experience were alarmed by what they saw and heard Burlakoff do.

164. Relator is informed and believes and based thereon alleges that Burlakoff personally trained representatives to use the off-label message that "pain is pain".

165. Relator and other employees observed and remarked that Babich and Burlakoff were only interested in driving sales and making money by selling Subsys to every kind of patient.

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166. Relator is informed and believes and based thereon alleges that only after law enforcement began scrutinizing INSYS' sales practices and Dr. Awerbuch's Subsys script-writing spree did Burlakoff, at an April, 2014 training session, tell the sales representatives that they could no longer be doing what he had trained them to do, thus admitting that they had been trained to market Subsys illegally.

The IRC and Prior Authorization.

167. INSYS created the IRC in order to help doctors and patients obtain approval for SUBSYS, including for off-label and contraindicated uses.

168. The IRC and physicians enter into agreements, in which the physician provides patient information that the IRC then uses to complete prior authorization forms.

169. INSYS utilizes Specialty Sales Professionals to gather patient information and assist in receiving prior authorization. This includes instructing sale representatives to review private patient information within doctors' offices.

170. The IRC handles appeals when prior authorization requests are denied.

171. The IRC occasionally issues "super vouchers " to patients while their prior authorization and appeals are pending, which allows for free SUBSYS until approval is obtained.

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172. The IRC sometimes uses past and/or later-found instances of patients' cancer diagnoses to obtain the Centers for Medicare and Medicaid Services ("CMS") approval for the treatment of non-cancer pain.

173. On or around April 19, 2013, Gurrieri stated during an INSYS conference presentation to the South East Region team that the IRC needs to know if a patient had cancer in 1992 or if they have cancer – even if that is not what the doctor is treating them for – because that cancer diagnosis is almost an assurance of approval.

174. Gurrieri stated during the April 2013 presentation that patient face sheets are important for the representatives to collect from the doctors because it is through reading those forms that the IRC "finds cancer a lot of the time."

175. During the conference presentation, Gurrieri stated that INSYS is "obviously promoting this on-label," but then went on to instruct the representatives to ask doctors if the patient has a history of cancer and to ensure they include all documentation for SUBSYS approval.

Instructing Sales Representatives to Market for Off-Label Uses.

176. INSYS engages in the off-label marketing of SUBSYS by encouraging doctors to write prescriptions for conditions other than breakthrough cancer pain.

177. INSYS is careful to not include the promotion of off-label marketing in official training material or emails, and recently warned employees during the April 2013 conference to keep questionable communications out of text messages.

178. INSYS nevertheless educates its sales representatives on how to implement off-label marketing strategies during conference calls and in-person meetings.

179. During the April 2013 conference in Arizona, Regional Sales Manager Rowan told the South East Region team, "Don't be afraid of what we are indicated for."

180. During this conference meeting on or around April 18, 2013, Rowan asked his sales team to state the SUBSYS indication and the team responded it was for breakthrough cancer pain. Rowan replied it was for breakthrough pain in cancer patient, and he then stated "let's change that" and then stressed "pain" in his second pronouncement of the indication.

181. Specialty Sales Professional Tondre then instructed the other representatives during the conference meeting on or around April 18, 2013 to ask their doctors if there was any difference in their patients having cancer or back pain, and that if the patient ranks high on the pain scale, that "that's the whole point, pain is pain."

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182. The "pain is pain" mantra Tondre mentioned during the April conference meeting was the same that he had used in an early 2013 conference call where he stated "pain is pain, and SUBSYS treats pain;" this same mantra helped prompt the DOJ to file a False Claims Act suit against Tondre's previous employer, Cephalon, as stated in the DOJ September 29, 2008 press release.

183. Sales Manager Rowan allowed Tondre to share his methods for encouraging doctors to write off-label or contraindicated prescriptions without interruption during the April 2013 conference meeting.

184. Later in the conference meeting on or around April 18, 2013, Rowan instructed the team to call him if there were any issues that should not be put in writing, such as associating speaker programs and fees with how many prescriptions a doctor wrote.

185. During the conference meeting on or around April 18, 2013, Rowan told his team that SUBSYS was great for sickle cell anemia, which is not a type of cancer.

186. In its September 29, 2008 press release regarding the FCA lawsuit against Cephalon, the DOJ stated that promoting fentanyl products for sickle cell anemia constituted off-label marketing.

187. During the conference meeting on or around April 18, 2013, former Cephalon employee Hill instructed other representatives on the methods she utilized

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on "how to throw something out to a doctor without sounding off-label," such as quoting another doctor.

188. After Hill stated that a representative could quote another doctor in order to offer the off-label promotion of SUBSYS during the April 2013 conference meeting, Rowan interjected and stated that this was not allowed because a representative cannot use a third party to achieve off-label marketing.

189. After Rowan mentioned that using a third party to achieve off-label marketing was not allowed during the April conference meeting, Hill then provided an example of the conversation she would have with the doctor to get around this requirement: "I was speaking to some of the other reps and their doctors are writing for this, that, and the other. Do they have cancer? I don't know, but they were talking about sickle cell anemia."

190. After Hill provided an alternative to "not sound off-label" when encouraging doctors writing SUBSYS for conditions other than breakthrough cancer pain during the April 2013 conference meeting, Rowan allowed Hill to instruct the other representatives without interruption and did not indicate this method was inappropriate; instead, Rowan stated shortly after that a doctor who writes SUBSYS is not worried about its indication.

191. Following the conversation regarding how to encourage doctors to write SUBSYS prescriptions for sickle cell anemia in the conference meeting on or around

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April 18, 2013, a member of the South East sales team mentioned that doctors just want to hear the indication first, and then they are ready to listen to other uses, followed by Rowan adding that "If you want to talk science, you're going to suck."

Targeting Doctors who are Not Oncologists or Pain Specialists.

192. INSYS has also pursued relationships with doctors who are not oncologists or pain specialists knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain, as approved by the FDA.

193. In its September 29, 2008 press release regarding the FCA suit against Cephalon, the DOJ stated that Cephalon's focus on physicians other than oncologists constituted off-label marketing.

194. On February 21, 2013, IRC Prior Authorization Assistant Tamara Kalmykova ("Kalmykova") emailed Guzman regarding one of Dr. Banchik's patients, stating that the approval request was denied partly because Medicaid identified Dr. Banchik as a neurologist and required proof that Dr. Banchik specialized in pain management.

195. Dr. Banchik is neurologist at the Neurology Centers of Palm Beach, as stated on her patient forms and on her biography on the Neurology Center's website.

196. The Neurology Centers of Palm Beach's website indicates that Dr. Banchik has experience with and provides lectures on pain management, but that her primary background is in neurology, which includes the specialty area of headaches.

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197. The Neurology Center of Palm Beach's website does not list cancer treatment as a specialty area, although it does list headaches/migraines and various forms of injuries as areas of focus for the Neurology Center's physicians.

198. INSYS is targeting doctors who are not oncologists or pain management physicians specializing in cancer treatment and who likely see far more neurological patients than cancer patients.

199. The FDA contraindicated SUBSYS for acute pain stemming from migraines or headaches, due to the serious consequences that could result from prescribing SUBSYS to patient not on a chronic regiment of opioids for cancer treatment.

200. Dr. Banchik mentioned to Guzman in August 2012 that doctors who were unable to prescribe SUBSYS could refer their patients to her to write the prescription, which indicates that Dr. Banchik was likely unfamiliar with these referred patients' particular histories, which thus increases the chances of SUBSYS causing serious side effects in these new patients who doctors unfamiliar with SUBSYS referred specifically for such a prescription.

201. INSYS's pursuit of relationships with non-FDA approved doctors is not an uncommon practice for the company.

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202. On or around August 16, 2012, National Trainer Hill admitted in a text message to Guzman that none of the attendees at a speaker program she had recently conducted were oncologists or pain specialists.

203. Hill serves as the INSYS National Trainer and was a former Cephalon employee, who should be aware of FDA standards.

204. On or around April 19, 2013 during the Arizona conference, a South East Region sales representative stated that she had a neurologist that was prescribing 1600 mcg for a patient.

INSYS's Off-Label Marketing Results in Doctors Prescribing SUBSYS for Contraindications, Off-Label Use, and Over-Titrating.

205. INSYS's off-label marketing schemes have resulted in doctors writing prescriptions for contraindicated uses, such as postoperative pain, and for off-label uses, such as back pain.

206. INSYS has also crafted the "kiss of death" and "effective dosage" messages, which encourage doctors to start patients at a higher dose than 100 mcg and/or titrate patients quickly, which is counter to the FDA dosage instructions and can be very dangerous with such a potent opioid agonist.

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Prescriptions for Contraindications.

207. SUBSYS is contraindicated for postoperative pain and for headaches/migraines because life-threatening respiratory depression and death could occur in patients.

208. INSYS ignores the FDA contraindications warnings and encourages doctors to recommend SUBSYS for such uses, which has resulted in prescriptions for contraindicated conditions.

209. On or around February 21, 2013, Kalmykova emailed Guzman regarding one of Dr. Banchik's Medicaid patients, stating that his approval request had been denied because the office notes focused on the patient's knee surgery rather than the cancer diagnosis, under which the request was filed.

210. Dr. Banchik's Medicaid patient whom Kalmykova emailed Guzman about on or around February 21, 2013 had previously had cancer but the SUBSYS prescription was to treat the patient's post-operation pain following knee surgery.

211. Kalmykova also indicated in her email to Guzman on or around February 21, 2012 that the IRC needed office notes that supported the correct diagnosis (cancer), thus impliedly asking Guzman and Dr. Banchik to alter office notes that had stated the actual purpose for the Medicaid patient's prescription (post-operative pain) so the request would fit CMS's approval requirements.

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212. On or around March 18, 2013, Kalmykova followed up with Guzman regarding Dr. Banchik's Medaid patient, asking Guzman if INSYS now had all the required documentation from Dr. Banchik, especially because "the patient has actually tried the medication due to the one time approval that we got from his work comp back in February."

213. The February 2012 prior authorization for SUBSYS Dr. Banchik's Medicaid patient received through worker's compensation was not for treatment of the patient's cancer pain, but rather for his knee injury.

214. The Relator believes that the initial prescription for Dr. Banchik's Medicaid patient in February 2012 was 200 mcg, 30 units.

215. According to an email from Burlakoff on May 13, 2012, 30 units of SUBSYS at a 200 mcg dose costs about $900 dollars and 120 units at a 400 mcg dose costs approximately $5,100.

Prescriptions for Off-Label Uses.

216. The treatment of back pain is one of the primary off-label uses for which doctors prescribe SUBSYS.

217. On or around April 18, 2013 during the Arizona INSYS conference, management and sales representatives discussed a method for encouraging doctors to prescribe SUBSYS for the off-label use of treating back pain: instruct the physician

to ask the patient if there was anything they could not do during the day because of their back.

218. During this conference meeting on or around April 18, 2013, Hill and Tondre stated representatives could rephrase this by asking if the patient was restricted from doing anything because of pain or asking about the patient's "functionality."

219. After Tondre provided an alternative method for promoting SUBSYS for the off-label use of back pain, Rowan stated that INSYS was lucky to have Tondre's knowledge and then instructed the representatives to paint a picture and allow the doctor "to go there themselves."

220. INSYS's instructions to representatives on how they can sell SUBSYS for non-FDA approved uses without "sounding off-label" and marketing SUBSYS by utilizing the mantra "pain is pain" has resulted in a substantial number of off-label prescriptions, many for Medicare and Medicaid patients.

221. In order to enroll in the REMS program and be authorized by the FDA to prescribe SUBSYS, physicians must sign a TIRF form stating that he or she understands the SUBSYS indication.

222. On or around March 6, 2013, Dr. Gatz prescribed SUBSYS for a Medicare patient using diagnosis codes 724.2 (lumbago), 722.52, and 721.3 for

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"lumbosacral spondylosis" and "lumbar radiculopathy," which are, respectively, a degenerative condition affecting the lower spine and lower-back nerve root pain.

223. On or around March 11, 2013, Dr. Gatz prescribed 600 mcg of SUBSYS for a Medicare patient with chronic pain; a staff member in Dr. Gatz's office confirmed in a March 18, 2013 text message to Guzman that the patient had chronic pain and not cancer.

224. On or around April 11, 2013, Doctor Daniel Ettedgui ("Dr. Ettedgui") prescribed 800 mcg of SUBSYS for a Medicare patient with the diagnosis codes of "Amputation of Leg Above Knee 897.2; Lumbosacral Plexus Lesions 353.1; Sciatica Neuralgia 724.3; Lumber Radiculopathy 724.4."

225. On or around April 12, 2013 INSYS Director of Managed Markets Mike Grury ("Grury") sent Burlakoff and Guzman text messages stating that Jessica Chavez from the IRC contacted Medicare in order to get the patient approved for a voucher, which INSYS can use to sway the patient's purchasing decision and potentially dissuade them from less expensive alternatives and generic medications.

226. On December 18, 2012, in text messages between Jay Patel ("Patel") from Apex Pharmacy and Guzman, Patel confirmed that the diagnosis provided by Dr. Gatz for a SUBSYS prescription was for patient Joseph Leo's back pain.

227. On February 11, 2013, a staff member from Dr. Gatz's office sent Guzman a text message stating that they had just found out that patient Joseph Leo

had cancer, verifying that Dr. Gatz had previously prescribed SUBSYS for the off-label use of treating his back pain.

Falsification of Documents to CMS.

228. The IRC used Dr. Gatz's new cancer diagnosis for Joseph Leo to continue obtaining approval for the patient's SUBSYS prescription to treat his back pain, particularly because the IRC stated at the April 2013 conference that the department reviews patients' medical information to find cancer to obtain prior authorization.

229. The Relator possess knowledge of at least one instance in which the IRC utilized a previous cancer diagnosis or a cancer diagnosis found after the patient already received SUBSYS to treat a non-cancer condition in order to gain prior authorization from CMS for the non-cancer use through falsification of documents.

230. In or around late April or early May 2013, the IRC filled out a prior authorization form and identified the diagnosis as cancer; however, upon receiving the form, Dr. Gatz's office whited out the cancer diagnosis and wrote "chronic pain," as this was the reason Dr. Gatz had prescribed SUBSYS.

231. In or around late April or early May 2013, after Dr. Gatz modified the prior authorization to reflect "chronic pain" as the diagnosis, the IRC indicated to CMS that the form was incorrect and sent a "corrected" form, with the cancer diagnosis, to CMS.

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232. While Dr. Gatz did not participate in the falsification of the prior authorization form sent to CMS in or around April or May 2013, he and the IRC have worked together in other cases to submit false information to CMS.

233. On or around December 18, 2012, Dr. Gatz filled out an IRC prior authorization form for a patient and identified the diagnosis as "neoplastic pain," which matches code 338.3 (Breakthrough Cancer Pain) that the IRC included in the Medicare form for the same patient on or around December 21, 2012.

234. Dr. Gatz's January 23, 2013 Patient Face Sheet (which provides background information on the client) for the patient with the December 2012 neoplastic pain diagnosis, uses diagnosis codes 719.48 (pain in joint) and 337.00 (nerve damage).

235. The difference in the diagnosis codes used on the forms submitted to CMS by the IRC and Dr. Gatz with the Patient Face Sheet indicates that Dr. Gatz was prescribing SUBSYS for nerve and joint pain, but he and the IRC were using the cancer diagnosis to obtain CMS approval.

Switching Patients from Actiq Indicates the Large Number of Medicare and Medicaid Patients being Prescribed SUBSYS.

236. One of INSYS's primary marketing plans is to encourage doctors to switch patients from Actiq and Fentora to SUBSYS.

237. During a conference call on or around December 12, 2012, Guzman sent a text message to Hill stating that most patients using Actiq are on Medicare or Medicaid, in response to management instructing the sales representatives on the call to switch Actiq patients to SUBSYS while also stating that compliance issues existed when offering Medicare and Medicaid patients SUBSYS.

238. INSYS has been successful in inducing doctors to switch patients from Actiq to SUBSYS, including Dr. Liporace, Dr. Krost, Dr. Banchik, and Dr. Gatz in Guzman's territory alone.

239. On or around February 11, 2013, Dr. Gatz prescribed 100 mcg of SUBSYS for a Medicare patient.

240. On or around March 19, 2013, Dr. Banchik prescribed SUBSYS for a Medicaid cancer patient.

241. Guzman is informed and based thereon alleges that Medicare and Medicaid patients account for a substantial amount of SUBSYS purchasers in her territory and all over the country.

242. INSYS management, such as Burlakoff, are careful to officially state that vouchers and other incentives cannot be given to Medicare or Medicaid patients for compliance reasons but management encourages and/or is aware that vouchers and incentives are provided to persuade Medicare and Medicaid to purchase SUBSYS.

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243. On December 12, 2012, a concerned Guzman sent Burlakoff a text message stating that Dr. Banchik had "put a bunch [of] Medicare patients" on free SUBSYS product, to which Burlakoff responded that he spoke with Babich and that it was fine.

Titration and Over-Prescribing.

244. INSYS disregards the FDA's titration warning and encourages doctors to prescribe strong doses of SUBSYS.

245. The FDA states on the SUBSYS label that the initial dose to treat episodes of breakthrough cancer pain is always 100 mcg.

246. The SUBSYS label instructs doctors to prescribe the initial titration supply of 100 mcg SUBSYS units, which limits the number of units in the home during titration, and to avoid prescribing a higher does until patients have used up all units to prevent confusion and possible overdose.

247. The FDA states that patients should take a maximum of two doses of SUBSYS for any breakthrough pain episode.

248. In or around August 2012, INSYS created a new marketing tactic referred to as the "effective dosage" or "the kiss of death" message.

249. The effective dosage message and the kiss of death consists of telling doctors that 100 mcg is not effective for pain relief and continually pushing them to

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titrate to higher dosages, with the "magic number" referred to in the April 2013 Arizona conference as 800 mcg.

250. As part of the effective dosage message or kiss of death campaign, INSYS sends a "Daily Rep Report for Low Strength Use" via email every day for dosages at or below 400 mcg to sales representatives.

251. While INSYS refrains from referencing the kiss of death or the effective dosage message in official emails and statements, INSYS management encourages this marketing scheme in person, over the telephone, and through some text messages.

252. On or around August 24, 2012, Burlakoff sent a text message to Guzman and other representatives stating, "We will do the Matt Napolitano/Marketing/effective dose message."

253. Napoletano is a former Cephalon marketing executive.

254. On or around September 6, 2012, Burlakoff sent a text message to Guzman and other sales professionals stating that INSYS would "get together as a whole company, and review 'effective dose message;'" indicating that this message is used throughout INSYS.

255. INSYS's off-label marketing titration campaign has resulted in doctors starting patients on SUBSYS dosages that are higher than the FDA-approved 100 mcg.

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256. On or around May 13, 2013, Burlakoff sent an email containing a chart of twelve new patients for the week of May 11, all of which were trying SUBSYS for the first time. Only one individual had 100 mcg listed under the "strength" column, with the other eleven patients receiving strengths between 200 mcg and 1600 mcg, with the average dosage level at approximately 600 mcg.

257. On or around March 1, 2013, Guzman received a voicemail from Patel of Apex Pharmacy stating that the 1200 mcg dosage of SUBSYS for a patient was too high, and that if the prior authorization had not been completed, that INSYS should hold off and return the patient to 800 mcg.

258. In or around March 2013, Burlakoff sent an email congratulating one individual who had encouraged a doctor to switch a patient from 1600 mcg of Actiq to a SUBSYS prescription that would be titrated to 1200 mcg, and then stated "Cha Ching again!" for the $40,320 that INSYS would make from the sale to this patient.

259. On or around April 12, 2013, Hill told Guzman during a conversation that the 10-pack of SUBSYS was only to discourage a patient from staying on 100 mcg and was to force them to go up in strength.

260. During the conversation on or around April 12, 2013, Hill told Guzman that Linden Care, upon which INSYS is increasingly relying =to supply SUBSYS, will only dispense a 10-pack of 100 mcg or 200 mcg and up.

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261. On or around April 18, 2013, Rowan instructed representatives during the INSYS conference to "increase the strength as much as possible – that will give you the most bang for your buck."

262. On or around April 18, 2013, one sales representative stated during a conference meeting that a doctor had prescribed a 1200 mcg and a 600 mcg dose to a patient, with one being covered by insurance and the other being covered out-of-pocket.

263. On the SUBSYS label, the FDA states that, "To reduce the risk of overdose during titration, patients should have only one strength of SUBSYS available at any time."

264. After the representative mentioned the dual doses for one patient during the April 2013 conference meeting, Rowan and Gurrieri offered a way around the FDA and CMS standards by stating that one prescription could be filled one day and the second could be filled the next.

265. On or around April 18, the sales representative stated during the conference meeting that the doctor had switched the patient with two prescriptions doses from another fentanyl product, but prescribed the same amount of mcg for SUBSYS.

266. The SUBSYS label states that, "When prescribing, do not switch patients on a mcg per mcg basis from any other oral transmucosal fentanyl product to

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SUBSYS;" the FDA warns against this under the "Medication Errors" portion of the label, stating in bold that this can result in a fatal overdose.

COUNT I: FALSE CLAIMS ACT VIOLATIONS

31 U.S.C. § 3729(a)(1) Against

Defendants

267. Guzman realleges and incorporates the allegations set forth above as though fully set forth therein.

268. Defendants knowingly caused to be presented to the United States Government false or fraudulent claims for payment or approval under the federally-funded Medicaid and Medicare programs in violation of 31 U.S.C. § 3729(a)(1) when INSYS violated 42 U.S.C. § 1320a-7b with its structured kickback system to induce doctors to recommend SUBSYS because 42 U.S.C. § 1320a-7b(g) provides that a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of the federal False Claims Act.

269. Defendants knowingly offered kickbacks to doctors when its managers instructed representatives to offer incentives to doctors in exchange for SUBSYS prescriptions, even though INSYS management knew this violated FCA laws, including during the April 2013 conference when Rowan told representatives not to "put in black and white" that speaker programs and fees are based on the amount of SUBSYS a doctor prescribes.

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270. INSYS management and sales representatives shared methods in which to maneuver around anti-kickback standards and compliance laws, such as ordering meals during lunch as to-go orders but instructing the restaurant to credit the representative when they later brought in just the doctor and his or her spouse, or by ordering televisions through caterers for speaker programs.

271. INSYS management was aware of FCA laws and compliance standards but justified its instructions to sales representatives to violate such laws a standards, such as when Regional Sales Manager Rowan stated during the April 2013 conference that he did not believe he was doing anything wrong because he was inducing doctors with food, and then stated that he was not asking the sales representatives to do anything wrong, just to be aware of how they can be a top sales person.

272. Defendants knowingly caused to be presented to the Government false or fraudulent claims for payment or approval under the federally-funded Medicaid program when in or around February 21, 2013, it submitted to CMS forms indicating that a previous cancer diagnosis was the reason for Dr. Banchik prescribing SUBSYS for a Medicaid patient when the prescription was being used to treat postoperative knee pain, a contraindicated use; this practice is widespread throughout INSYS, particularly because the IRC obtains approval from Medicaid and Medicare for the entire company.

273. Defendants knowingly caused to be presented to the Government false or fraudulent claims for payment or approval when in late April or early May 2013, the IRC filled out a prior authorization form and identified the diagnosis as cancer on the form but Dr. Gatz later whited out the cancer diagnosis and wrote "chronic pain" (the reason for the SUBSYS prescription); the IRC told CMS that the form was incorrect with the chronic pain diagnosis and sent a "corrected" form. This practice is widespread throughout INSYS, particularly because the IRC obtains approval from Medicaid and Medicare for the entire company.

274. Defendants knowingly caused to be presented to the Government false or fraudulent claims for payment or approval when in or around December 18, 2012, the IRC, working with Dr. Gatz, submitted to CMS prior authorization and Medicare forms indicating that the patient's diagnosis was neoplastic pain when Dr. Gatz's Patient Face Sheet noted that the patient had joint and nerve pain, a Sheet to which the IRC had access; this practice is widespread throughout INSYS, particularly because the IRC obtains approval from Medicaid and Medicare for the entire company.

275. Defendants knowingly caused to be presented to the Government false or fraudulent claims for payment or approval when it engaged in off-label marketing, such as failing to meet the off-label dissemination requirements of 21 U.S.C. §360aaa, distributing misbranded drugs in violation of 21 U.S.C. §331(a), and

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encouraged doctors to prescribe SUBSYS for uses it knew were not approved by the FDA and assisted through the IRC in obtaining and approval and payment from Medicaid and Medicare for SUBSYS prescriptions for non-approved uses in violation of 42 U.S.C §1396r-8(k)(3) and 42 U.S.C. §§ 1395w-102 – §1395w-104.

276. The United States, unaware of the falsity of the claims and/or statements made by Defendants and in reliance on the accuracy thereof, paid Defendants for such false or fraudulent claims.

277. By reasons of the acts and conduct of Defendants in violation of 31 U.S.C. § 3729(a)(1), the United States has suffered actual damages, including the total amounts paid in response to all such false or fraudulent claims for payment. In addition, the United States is entitled to recover civil money penalties, and other monetary relief as deemed appropriate.

COUNT II: OFF-LABEL DISSEMINATION VIOLATIONS

21 U.S.C. §360aaa Against Defendants

278. Guzman realleges and incorporates the allegations from Paragraphs 1 through 266, inclusive, as though fully set forth therein

279. A manufacturer may disseminate information concerning the safety, effectiveness, or benefit of a use not described in the approved labeling only if: (1) there is an application filed pursuant to 21 U.S.C. § 355; (2) the information meets the requirements of 21 U.S.C. § 360aaa-1; (3) the information is not derived from

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clinical research conducted by another manufacturer or permission has been given to use such information; (4) the manufacturer has, within 60 days before dissemination submitted to the Secretary (A) a copy of the information to be disseminated and (B) any clinical trial information relating to the safety or effectiveness of the new use; (5) the manufacturer has complied with section 360aaa-3; (6) along with the information on the new use to be disseminated, the manufacturer includes a statement disclosing (A)(i) that the use in not approved, (ii) that the information is being disseminated at the manufacturer's expense, (iii) the names of the authors who have received compensation from the manufacturer, (iv) the official labeling for the drug, (v) a statement that there are products or treatments that have been approved for the use, (vi) identification of any person that provided funding for the research, and (B) a bibliography of other articles that have been published about the use of the drug.

280. Defendants did not satisfy these requirements before encouraging doctors to prescribe SUBSYS for contraindicated and off-label uses, such as for postoperative pain and back pain, and before it pursued doctor who were neither oncologist nor pain management specialists knowledgeable in opioids to prescribe SUBSYS for patients, including those insured by Medicare and Medicaid, and therefore violated 21 U.S.C. § 360aaa.

281. Because Defendants did not meet the 21 U.S.C. § 360aaa dissemination requirements and thus engaged in off-label marketing of SUBSYS, they violated 31

U.S.C. § 3729(a)(1) by knowingly presenting or causing to be presented to the United States Government false or fraudulent claims for payment or approval under the federally-funded Medicaid and Medicare programs.

COUNT III: MEDICAID NON-APPROVED USE VIOLATIONS
42 U.S.C. § 1396r-8(k)(3) Against Defendants

282. Guzman realleges and incorporates the allegations from Paragraphs 1 through 266, inclusive, as though fully set forth therein

283. Reimbursement by Medicaid is, with only one rare exception (an anticancer chemotherapeutic regimen), prohibited if the drug is not being used for a medically accepted indication. 42 U.S.C. §1396r-8(k)(3).

284. 42 U.S.C. §1396r-8 (k)(6) defines a medically accepted indication as one which is approved under the Food, Drug, and Cosmetic Act.

285. The FDA approved SUBSYS for the limited use of treatment for breakthrough pain in cancer patients.

286. INSYS management instructed sales representatives on and allowed former Cephalon employees to share methods for promoting SUBSYS to doctors for off-label and contraindicated uses without sounding "off-label," including at the April 2013 INSYS conference in Arizona and during an early 2013 conference call in which former Cephalon employee Dan Tondre explained his sales motto "pain is pain."

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287. During the April 2013 INSYS conference in Arizona, Defendants instructed sales representatives on methods for promoting SUBSYS for treating sickle cell anemia and back pain, neither of which were conditions approved or indicated by the FDA for SUBSYS use.

288. During the April 2013 INSYS conference in Arizona, Manager Joe Rowan told sales representatives, "I don't want to know what you do," but stated that they should do what they need to, but "it's not on me."

289. Defendants are aware that doctors are prescribing SUBSYS for off-label and contraindicated uses for Medicaid patients, which is prohibited by 42 U.S.C. §1396r-8(k)(3), encourages doctors to write and continue writing these prescriptions, and assists them in gaining authorizations for the off-label and contraindicated prescriptions through the IRC.

290. In February 2013, the IRC worked to obtain CMS approval for a Medicaid patient of Dr. Banchik's to treat the pain he experienced following knee surgery by using the patient's past history of cancer.

291. The FDA contraindicates SUBSYS for the use in treating postoperative pain.

292. The FDA states that SUBSYS is to be prescribed by oncologist or pain specialists familiar with opioids.

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293. Defendants pursued relationships with non-oncologists, such as neurologists, for the purpose of encouraging those doctors to prescribe SUBSYS.

294. Medicaid patients account for a significant portion of SUBSYS users.

295. Defendants violated 42 U.S.C. § 1396r-8(k)(3) when they encouraged doctors to prescribe SUBSYS for uses they knew were not approved by the FDA and assisted through the IRC in obtaining approval and payment from Medicaid for SUBSYS prescriptions for non-approved uses.

296. Because Defendants violated 42 U.S.C. § 1396r-8(k)(3) by encouraging doctors to prescribed SUSYS for non-approved uses and assisted doctors in obtaining approval and payment for non-approved uses, they also violated 31 U.S.C. § 3729(a)(1) by knowingly presenting or causing to be presented to the United States Government false or fraudulent claims for payment or approval under the federally-funded Medicaid program.

COUNT IV: MEDICARE NON-APPROVED USE VIOLATIONS 42 U.S.C. §§ 1395w-102 – §1395w-104 Against Defendants

297. Guzman realleges and incorporates the allegations from Paragraphs 1 through 266, inclusive, as though fully set forth therein

298. Medicare Part D, 42 U.S.C. §§1395w-102 – §1395w-104, states that a plan sponsor is required to provide coverage of qualified prescription drugs.

299. The definition for a covered Medicare drug is outlined in 1395w-102(e), which includes the term "medically accepted indication."

300. 42 U.S.C. §1396r-8 (k)(6) defines a medically accepted indication as one which is approved under the Food, Drug, and Cosmetic Act.

301. The FDA approved SUBSYS for the limited use of treatment for breakthrough pain in cancer patients.

302. INSYS management instructed sales representatives on and allowed former Cephalon employees to share methods for promoting SUBSYS to doctors for off-label and contraindicated uses without sounding "off-label," including at the April 2013 INSYS conference in Arizona and during an early 2013 conference call in which former Cephalon employee Dan Tondre explained his sales motto "pain is pain."

303. During the April 2013 INSYS conference in Arizona, Defendants instructed sales representatives on methods for promoting SUBSYS for treating sickle cell anemia and back pain, neither of which were conditions approved or indicated by the FDA for SUBSYS use.

304. During the April 2013 INSYS conference in Arizona, Manager Joe Rowan told sales representatives, "I don't want to know what you do," but stated that they should do what they need to, but "it's not on me."

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305. Defendants' off-label marketing has resulted in doctors prescribing SUBSYS for off-label uses, such as Dr. Gatz writing SUBSYS prescriptions for Medicare patients to treat their back and chronic pain and Dr. Ettedgui prescribing SUBSYS for a Medicare patient to treat his post-amputation and lower-back pain.

306. Defendants are aware that doctors are prescribing SUBSYS for off-label and contraindicated for Medicare patients, which is prohibited by 42 U.S.C. §§1395w-102 – §1395w-104, and encourages them to write and continue writing these prescriptions, and assists them in gaining authorizations for these off-label and contraindicated prescriptions through the IRC.

307. In or around December 18, 2012, the IRC and Dr. Gatz submitted forms to Medicare indicating that the patient's diagnosis was neoplastic pain in order to gain approval for the SUBSYS prescriptions; however, Dr. Gatz's Patient Face Sheet indicated that the patient had joint and nerve pain, which are off-label uses.

308. The FDA states that SUBSYS is to be prescribed by oncologist or pain specialists familiar with opioids.

309. Defendants pursued relationships with non-oncologists, such as neurologists, for the purpose of encouraging those doctors to prescribe SUBSYS.

310. Medicare patients account for a significant portion of SUBSYS users.

311. Defendants violated 42 U.S.C. § 1395w-102 when they encouraged doctors to prescribe SUBSYS for uses it knew were not approved by the FDA and

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assisted through the IRC in obtaining approval and payment from Medicare for SUBSYS prescriptions for non-approved uses.

312. Because Defendants violated 42 U.S.C. § 1395w-102 by encouraging doctors to prescribed SUSYS for non-approved uses and assisted doctors in obtaining approval and payment for non-approved uses, they also violated 31 U.S.C. § 3729(a)(1) by knowingly presenting or causing to be presented to the United States Government false or fraudulent claims for payment or approval under the federally-funded Medicare program.

COUNT V:
VIOLATION OF THE CALIFORNIA FALSE CLAIMS ACT
(Cal. Gov't. Code § 12651(a)(1))

313. The allegations of paragraphs 1 through 266 are realleged as if fully set forth herein. The California False Claims Act provides, in pertinent part, that:

> (a) Any person who commits any of the following acts shall be liable to the state or to the political subdivision for three times the amount of damages which the state or the political subdivision sustains because of the act of that person. A person who commits any of the following acts shall also be liable to the state or to the political subdivision for the costs of a civil action brought to recover any of those penalties or damages, and may be liable to the state or political subdivision for a civil penalty of up to ten thousand dollars ($10,000) for each false claim:
>
> > (1) Knowingly presents or causes to be presented to an officer or employee of the state or of any political

> subdivision thereof, a false 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 claim paid or approved by the state or by any political subdivision.
>
> (3) Conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state or by any political subdivision.
>
> . . .
>
> (7) Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state or to any political subdivision.

Cal. Gov't. Code § 12651.

314. By virtue of the conduct alleged herein, Defendants, and each of them knowingly caused to be presented to California false claims for payment or approval, in violation of Cal. Gov't. Code § 12651(a)(1).

315. Additionally, Defendants, and each of them gave or caused to be given 'kickbacks' to physicians and other licensed health care professionals to induce them to prescribe Subsys in violation of state law, including Cal. Welfare & Inst. Code s 14107.2.

316. California paid the false claims because of the conduct of Defendants, and each of them. As a result of these payments and the conduct California has been damaged in an amount to be determined at trial.

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317. For each violation of the California False Claims Act, California is entitled to recover treble damages from Defendants, and each of them. *See* Cal. Gov't. Code § 12651(a).

318. In addition, for each violation of the California False Claims Act, California is entitled to recover from Defendants, and each of them costs of this action, as well as a civil penalty of up to $10,000.00 per false claim. Id.

COUNT VI
VIOLATION OF THE CALIFORNIA FALSE CLAIMS ACT
(Cal. Gov't. Code § 12651(a)(2))

319. The allegations of paragraphs 1 through 266 are realleged as if fully set forth herein. By virtue of the conduct alleged herein, Defendants, and each of them knowingly made or used, or knowingly caused to be made or used, false records or statements to get false claims paid or approved by California, in violation of Cal. Gov't. Code § 12651(a)(2).

320. California paid the false claims because of the conduct of Defendants, and each of them. As a result of these payments and the illegal conduct California has been damaged in an amount to be determined at trial.

321. For each violation of the California False Claims Act, California is entitled to recover treble damages from Defendants, and each of them. See Cal. Gov't. Code § 12651(a).

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322. In addition, for each violation of the California False Claims Act, California is entitled to recover from Defendants, and each of them costs of this action, as well as a civil penalty of up to $10,000.00 per false claim. Id.

COUNT VII
VIOLATION OF THE CALIFORNIA FALSE CLAIMS ACT
(Cal. Gov't. Code § 12651(a)(3))

323. The allegations of paragraphs 1 through 266 are realleged as if fully set forth herein.

324. By virtue of the conduct alleged herein, Defendants, and each of them conspired to defraud California by getting false claims allowed or paid by California, in violation of Cal. Gov't. Code § 12651(a)(3).

California paid the false claims because of the conduct of Defendants, and each of them.

325. As a result of these payments and the conduct of Defendants, and each of them, California has been damaged in an amount to be determined at trial.

326. For each violation of the California False Claims Act, California is entitled to recover treble damages from Defendants, and each of them. See Cal. Gov't. Code § 12651(a).

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327. In addition, for each violation of the California False Claims Act,California is entitled to recover from Defendants, and each of them costs of this action, as well as a civil penalty of up to $10,000.00 per false claim. Id.

COUNT VIII

VIOLATION OF THE CALIFORNIA FALSE CLAIMS ACT

(Cal. Gov't. Code § 12651(a)(7))

328. The allegations of paragraphs 1 through 266are realleged as if fully set forth herein.

329. By virtue of the conduct alleged herein, Defendants, and each of them knowingly made, used, or caused to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to California, in violation of Cal. Gov't. Code § 12651(a)(7).

330. California paid the false claims because of the conduct of Defendants, and each of them.

331. As a result of these payments California has been damaged in an amount to be determined at trial.

332. For each violation of the California False Claims Act, California is entitled to recover treble damages from Defendants, and each of them. See Cal. Gov't. Code § 12651(a).

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333. In addition, for each violation of the California False Claims Act, California is entitled to recover from Defendants, and each of them costs of this action, as well as a civil penalty of up to $10,000.00 per false claim. Id.

334. **WHEREFORE**, Relator respectfully requests this Court to enter judgment for California and against Defendants, and each of them on each of Counts VI through IX of this Complaint, and impose damages and penalties in an amount equal to three times the loss sustained by the California Medicaid Program ("Medi-Cal"), plus penalties of $10,000 for each false claim or statement.

COUNT IX

DELAWARE FALSE CLAIMS AND REPORTING ACT ("DFCA")

(Del. C. 1201 et seq.)

335. The allegations of paragraphs 1 through 266are re-alleged as if fully set forth herein.

The DFCA provides, in pertinent part, that:

> (a) Any person who (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; (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 Government; (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid; . . . or (7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government, 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. . . .

Del. C. § 1201-1202

336. Defendants, and each of them knowingly (1) knowingly caused false claims to be presented for payment; (2) knowingly caused false statements or records to be used to get false or fraudulent claims paid by the Medicaid program; (3) conspired to defraud the Government by getting a false or fraudulent claim paid; and/or (4) knowingly caused to be made or used false records or statements to avoid or reduce the obligation to repay claims to the Delaware Medicaid Program. Since this program is jointly funded by Delaware and the United States, Defendants, and each of them, engaged in conduct which conduct directly resulted in significant financial loss to the State of Delaware and the United States.

337. Additionally, Defendants, and each of them gave or caused to be given 'kickbacks' to physicians and other licensed health professionals to induce them to prescribe Subsys, in violation of state law, including 31 Del. C. § 1001 *et seq*.

338. For each violation of the DFCA, Delaware is entitled to recover treble damages from Defendants, and each of them and a civil penalty of not less than $5,500 and not more than $11,000 for each violation. 6 Del. C. 1201.

339. **WHEREFORE,** Relator respectfully requests this Court to enter judgment for the State of Delaware and against Defendants, and each of them and

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impose damages and penalties as follows: an amount equal to three times the loss sustained by the Medicaid Program, plus penalties of $11,000 for each violation.

COUNT X

DISTRICT of COLUMBIA FALSE CLAIMS ACT

(D.C. OFFICIAL CODE §§ 2-308.13 et seq.)

340. The allegations of paragraphs 1 through 266 are realleged as if full set forth herein.

The DCFCA provides, in pertinent part, that:

> (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 o f the following acts shall also be liable 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; (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 District; (3) Conspires to defraud the District by getting a false claim allowed or paid by the District; . . . or (7) Knowingly makes or uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government, shall be liable to the District.

D. C. Code § 2.308-14(a).

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341. Defendants, and each of them knowingly (1) knowingly caused false claims to be presented for payment; (2) knowingly caused false statements or records to be used to get false or fraudulent claims paid by the Medicaid program; (3) conspired to defraud the District by getting a false or fraudulent claim paid; and/or (4) knowingly caused to be made or used false records or statements to avoid or reduce the obligation to repay claims to the District's Medicaid Program. Since this program is jointly funded by the District and the United States, Defendants, and each of them, engaged in conduct which conduct directly resulted in significant financial loss to the District of Columbia and the United States.

342. Additionally, Defendants, and each of them gave or caused to be given 'kickbacks' to physicians and hospitals to induce the physicians to purchase and/or prescribe Defendants, and each of them drugs, in violation of state law, including D.C. Code § 3-702

343. **WHEREFORE**, Relator respectfully requests this Court to enter judgment for the District of Columbia and against Defendants, and each of them on each of the Counts of this Complaint, and impose damages and penalties in an amount equal to three times the loss sustained by the District of Columbia Medicaid program, plus penalties of $10,000 for each false claim or statement.

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COUNT XI

VIOLATION OF THE FLORIDA FALSE CLAIMS ACT

§§ 68.081-.092, FLORIDA STATUTES

344. The allegations of paragraphs 1 through 266 are realleged as if fully set forth herein.

> Fla. Stat. 68.082(2) provides liability for any person who (a) knowingly presents, or causes to be presented, to an officer or employee of an agency a false or fraudulent claim for payment or approval; (b) knowingly makes, uses, or causes to be made or sued, a false record or statement to get a false or fraudulent claim paid or approved by an agency; (c) conspires to submit a false or fraudulent claim to an agency or to deceive an agency for the purpose of getting a false or fraudulent claim allowed or paid...is liable to the state for a civil penalty of not less than $5,500 and not more than $11,000 and for treble the amount of damages the agency sustains because of the act or omission of that person.

345. Defendants, and each of them knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Florida.

346. Defendants, and each of them knowingly presented or caused to be presented false claims for payment to the Florida Medicaid Program creating liability for a false claims action pursuant to §68.081, Fla. Stat., et. seq.

347. As a result of the conduct of Defendants, and each of them, set forth in this count, the State of Florida paid the improper Medicaid claims and has suffered actual damages.

348. Additionally, Defendants, and each of them gave or caused to be given 'kickbacks' to physicians and other licensed health professionals to induce them to prescribe Subsys in violation of state law, including Fla. Stat. §§ 409.920.

349. Pursuant to §§ 68.082(2) and 68.086, Fla. Stat., the Defendants, and each of them, are liable for treble the actual damages sustained, not less than $5,500 and not more than $11,000 penalty per claim, all other relief set forth in said statutes, prejudgment interest, attorneys' fees and court costs.

350. **WHEREFORE**, Relator respectfully requests that judgment be entered in favor of the State of Florida against Defendants, and each of them, as follows:

351. For treble the amount of the State of Florida's actual damages plus civil penalties of $11,000.00 for each false claim submitted; for reasonable attorney's fees and costs of this civil action; and for such other and further relief as the Court deems just and equitable.

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COUNT XII

VIOLATION OF THE GEORGIA FALSE MEDICAID CLAIMS ACT

(GEORGIA CODE 49-4-168 et seq.)

352. The allegations of paragraphs 1 through 266are realleged as if fully set forth herein. This is a claim for treble damages and civil penalties under the Georgia State False Medicaid Claims Act.

353. Section 49-4-168.1.(a) of the Georgia State False Medicaid Claims Act provides in pertinent part as follows:

> 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;
>
> (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;
>
> (3) Conspires to defraud the Georgia Medicaid program by getting a false or fraudulent claim allowed or paid;
> ...
> (7) Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay, repay or transmit money or property to the State of Georgia,
>
> 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.

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Defendants, and each of them violated the provisions set forth hereinabove.

354. For each violation of the statute, the Commonwealth of Georgia is entitled to recover treble damages from Defendants, and each of them. See §49-4-168.1.(a) of the Georgia State False Medicaid Claims Act.

355. **WHEREFORE**, the Relator respectfully requests this Court to enter judgment for the Commonwealth of Georgia and against Defendants, and each of them for an amount of three times the amount of damages sustained by the Commonwealth of Georgia and a civil penalty of $10,000 for each act of submitting false statements by INSYS, Kapoor, Babich, and Burlakoff.

COUNT XIII
HAWAII FALSE CLAIMS ACT,
Haw. Rev. Stat. § 661-21, et seq.

356. The allegations of paragraphs 1 through 266are realleged as if fully set forth herein. This is a claim for treble damages and civil penalties under the Hawaii False Claims Act. Haw. Rev. Stat. § 661-21, et seq.

357. Defendants, and each of them knowingly presented or caused to be presented to an officer or employee of the state a false or fraudulent claim for payment or approval.

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358. Defendants, and each of them knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state.

359. Defendants, and each of them conspired to defraud the state by getting a false or fraudulent claim allowed or paid.

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

361. By reason of these payments, the Hawaii Medicaid Program has been damaged in a substantial amount.

362. **WHEREFORE**, the Relator respectfully requests this Court to enter judgment for the State of Hawaii and against defendants Defendants, and each of them for an amount of three times the amount of damages sustained by the State of Hawaii and a civil penalty of $11,000 for each act of submitting false statements.

COUNT XIV

ILLINOIS WHISTLE BLOWER REWARD AND PROTECTION ACT

363. The allegations of paragraphs 1 through 266are realleged as if fully set forth herein.

364. Section 3 of the Illinois WHISTLE BLOWER Reward and Protection Act, 740 ILCS § 175/3, provides in pertinent part:

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> (a) Any person who: ... (7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the State;... is liable to the State for a civil penalty of not less than $5,500 and not more than $11,000, plus 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
>
> (b) Knowing and knowingly defined. As used in this Section, the terms "knowing" and "knowingly" mean that a person, with respect to information: (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 of specific intent to defraud is required.

365. Defendants, and each of them knowingly made, or used or caused to be made or used, false records or statements, submitted or caused the submission of false claims, and also did these things to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Illinois Medicaid Program. Said program is jointly funded by the United States and the State of Illinois. By engaging in the conduct outlined above, Defendants, and each of them caused significant financial loss to the United States and the State of Illinois.

366. Additionally, Defendants, and each of them gave or caused to be given 'kickbacks' to physicians and other health care professionals to induce them to prescribe Subsys in violation of state law, including Ill. Stat., Ch. 305, § 5/8A-3.

367. **WHEREFORE**, the Relator respectfully requests this Court to enter judgment for the State of Illinois and against Defendants, and each of them for an amount of three times the amount of damages sustained by the State of Illinois and a civil penalty of $11,000 for each act of submitting false statements by Defendants, and each of them.

COUNT XV
VIOLATION OF THE INDIANA FALSE CLAIMS ACT
(INDIANA CODE 5-11-5.5)

368. The allegations of paragraphs 1 through 266 are realleged as if fully set forth herein.

369. Pursuant to the Indiana False Claims Act (IC 5-11-5.5(b)):

> (b) A person who knowingly or intentionally:
>
> > (1) presents a false claim to the state for payment or approval;
> >
> > (2) makes or uses a false record or statement to obtain payment or approval of a false claim from the state;
> >
> > ****
> >
> > is, except as provided in subsection ©, liable to the state for a civil penalty of at least five thousand dollars ($5,000) and for up to three (3) times the amount of damages sustained by the state. In addition, a person who violates this section is liable to the state for the costs of a civil action brought to recover a penalty or damages.

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370. Defendants, and each of them knowingly presented, or caused to presented, false claims and/or false records or statements regarding Subsys, to get false claims paid.

371. Additionally, Defendants, and each of them, gave or caused to be given 'kickbacks' to physicians and other health professionals to induce them to prescribe Subsys, in violation of state law, including I.C. 12-15-24-2.

372. Defendants, and each of them knowingly presented or caused to be presented false claims for payment to the Indiana Medicaid Program creating liability for a false claims action pursuant to I.C. 5-11-5.5.

373. As a result of conduct set forth in this count, the State of Indiana paid the improper Medicaid claims and has suffered actual damages.

374. Pursuant to I.C. 5-11-5.5(b), a civil penalty of at least five thousand dollars ($5,000) and up to three (3) times the amount of damages sustained by the state, and for the costs of this civil action.

375. **WHEREFORE**, Relator respectfully requests that judgment be entered in favor of the State of Indiana against Defendants, and each of them, as follows:

376. For a civil penalty of at least five thousand dollars ($5,000) and for up to three (3) times the amount of damages sustained by the state, and for the costs of this civil action.

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COUNT XVI

VIOLATION OF THE LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW

(LA. REV. STATE. ANN § 46:439.1 et seq.)

377. The allegations of paragraphs 1 through 266 are realleged as though fully set forth herein.

378. Pursuant to §437.2 of the Louisiana Medical Assistance Programs Integrity Law:

> "This Part is enacted to combat and prevent fraud and abuse committed by some health care providers participating in the medical assistance programs and by other persons and to negate the adverse effects such activities have on fiscal and programmatic integrity."

379. Section 438.3 of the Louisiana Medical Assistance Programs Integrity Law provides in pertinent part:

> A. No person shall knowingly present or cause to be presented a false or fraudulent claim.
>
> B. No person shall knowingly engage in misrepresentation to obtain, or attempt to obtain, payment from medical assistance programs funds.
>
> C. No person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim.
>
> ****

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This Law defines a "false or fraudulent claim" to be:

> "... a claim which the health care provider or his billing agent submits knowing the claim to be false, fictitious, untrue, or misleading in regard to any material information. "False or fraudulent claim" shall include a claim which is part of a pattern of incorrect submissions in regard to material information or which is otherwise part of a pattern in violation of applicable federal or state law or rule. (Section 437.3(8))

380. Defendants, and each of them knowingly presented, or caused to presented, false claims for payment and/or false records or statements regarding Subsys in order to get claims paid or in order to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Louisiana Medicaid Program.

381. Additionally, Defendants, and each of them gave or caused to be given 'kickbacks' to physicians and other health professionals to induce them to prescribe Subsys, in violation of state law, including La. Rev. Stat. § 14:70.5.

382. Defendants, and each of them knowingly presented or caused to be presented false claims for payment to the Louisiana Medicaid Program creating liability for a false claims action pursuant to the Louisiana Medical Assistance Programs Integrity Law.

383. As a result of the conduct of Defendants, and each of them, as set forth in this count, the State of Louisiana paid the improper Medicaid claims and has suffered actual damages.

384. Pursuant to Section 438.6 of the Louisiana Medical Assistance Programs Integrity Law:

> (1) Actual damages incurred as a result of a violation of the provisions of this Part shall be recovered only once by the medical assistance programs and shall not be waived by the court.
>
> (2) Except as provided by Paragraph (3) of this Subsection, actual damages shall equal the difference between what the medical assistance programs paid, or would have paid, and the amount that should have been paid had not a violation of this Part occurred plus interest at the maximum rate of legal interest provided by Civil Code Article 2924 from the date the damage occurred to the date of repayment.
>
> (3) If the violator is a managed care health care provider or a health care provider under a voucher program, actual damages shall be determined in accordance with the violator's provider agreement.
>
> B. Civil fine.
>
> (1) Any person who is found to have violated R.S. 46:438.2 shall be subject to a civil fine in an amount not to exceed ten thousand dollars per violation, or an amount equal to three times the value of the illegal remuneration, whichever is greater.
>
> (2) Except as limited by this Section, any person who is found to have violated R.S. 46:438.3 shall be subject to a civil fine in an amount not to exceed three times the amount of actual damages sustained by the medical assistance programs as a result of the violation.

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C. Civil monetary penalty.

(1) In addition to the actual damages provided in Subsection A of this Section and the civil fine imposed pursuant to Subsection B of this Section, one or more of the following civil monetary penalties may be imposed on the violator:

> (a) Up to ten thousand dollars for each false or fraudulent claim, misrepresentation, illegal remuneration, or other prohibited act as contained in R.S. 46:438.2, R.S. 46:438.3, or R.S. 46:438.4.
>
> (b) Payment of interest on the amount of the civil fine imposed pursuant to Subsection B of this Section at the maximum rate of legal interest provided by Civil Code Article 2924 from the date the damage occurred to the date of repayment.

(2) Prior to the imposition of a civil monetary penalty, the court shall consider if there are extenuating circumstances as provided in R.S. 46:438.7.

D. Costs, expenses, fees, and attorney fees.

(1) Any person who is found to have violated this Subpart shall be liable for all costs, expenses, and fees related to investigations and proceedings associated with the violation, including attorney fees.

(2) All awards of costs, expenses, fees, and attorney fees are subject to review by the court using a reasonable, necessary, and proper standard of review.

• • •

E.

(1) If recovery is due from a health care provider under the provisions of Subsections A and B of this Section, such recovery shall constitute civil liquidated damages for breach of the conditions and requirements of participation in the medical assistance programs which are and shall be construed by the courts to be remedial, but not retroactive, in nature.

(2) Any award of civil liquidated damages, costs, expenses, and attorneys' fees shall be in addition to criminal penalties and to the civil monetary penalty provided in Subsection C of this Section.

385. **WHEREFORE**, Relator respectfully requests that judgment be entered in favor of the State of Louisiana and against Defendants, and each of them, as follows:

386. Actual damages plus interest at the maximum rate of legal interest provided by Civil Code Article 2924 from the date the damage occurred to the date of repayment; a civil fine in an amount not to exceed ten thousand dollars per violation, or an amount equal to three times the value of the illegal remuneration, whichever is greater; and/or for violation of R.S. 46:438.3 a civil fine in an amount not to exceed three times the amount of actual damages sustained by the medical assistance programs as a result of the violation; and civil money penalties up to ten thousand dollars for each false or fraudulent claim, misrepresentation, illegal remuneration, or other prohibited act as contained in R.S. 46:438.2, R.S. 46:438.3, or R.S. 46:438.4,

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and payment of interest on the amount of the civil fine imposed pursuant to Subsection B of the above-referenced Louisiana law at the maximum rate of legal interest provided by Civil Code Article 2924 from the date the damage occurred to the date of repayment; plus all costs, expenses, and fees related to investigations and proceedings associated with the violation, including attorney fees; and such other and further relief as this Honorable Court deems fit and proper.

COUNT XVII
FOR VIOLATION OF THE MASSACHUSETTS FALSE CLAIMS ACT
(M.G.L. c. 12 § 5A, et seq.)

387. The allegations of paragraphs 1 through 266 are realleged as if fully set forth herein.

388. Defendants, and each of them knowingly made, or used or caused to be made or used, false claims for payment and/or false records or statements regarding Subsys in order to get false claims paid and/or to decrease an obligation to pay or transmit money or property to the Massachusetts Medicaid Program. Said program is jointly funded by the United States and the Commonwealth of Massachusetts. By engaging in the conduct outlined above, Defendants, and each of them caused significant financial loss to the United States and the Commonwealth of Massachusetts.

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389. Additionally, Defendants, and each of them gave or caused to be given 'kickbacks' to physicians and other licensed health professionals to induce them to prescribe Subsys in violation of state law, including Mass. Gen. Law 118E § 41.

390. **WHEREFORE**, the Relator respectfully requests this Court to enter judgment for the Commonwealth of Massachusetts and against Defendants, and each of them for an amount of three times the amount of damages sustained by the Commonwealth of Massachusetts and a civil penalty of $10,000 for each act of submitting false statements by Defendants, and each of them.

COUNT XVIII
VIOLATION OF THE MICHIGAN MEDICAID FALSE CLAIMS ACT

391. The allegations of paragraphs 1 through 266 are realleged as though fully set forth herein

392. Section 400.603 of the State of Michigan's Medicaid False Claims Act provides in part:

> (1) 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.
>
> (2) A person shall not knowingly make or cause to be made a false statement or false representation of a material fact for use in determining rights to a medicaid benefit.
>
> (3) A person, who having knowledge of the occurrence of an event affecting his initial or continued right to receive a medicaid benefit or the initial or continued right of any

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> other person on whose behalf he has applied for or is receiving a benefit, 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.
>
> ***

M.C.L. §400.602(f) provides:

393. Defendants, and each of them knowingly presented, or caused to presented, false claims for payment and/or false records or statements regarding Subsys in order to get false claims paid and/or in order to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Michigan Medicaid Program.

394. Additionally, Defendants, and each of them gave or caused to be given 'kickbacks' to physicians and other health care professionals to induce them to prescribe Subsys, in violation of state law, including § 400.604.

395. Defendants, and each of them knowingly presented or caused to be presented false claims for payment to the Michigan Medicaid Program creating liability for a false claims action pursuant to Michigan's Medicaid False Claims Act.

396. As a result of the conduct set forth in this count, the State of Michigan paid the improper Medicaid claims and has suffered actual damages.

397. Pursuant to M.C.L. §400.612(1):

> 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.

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398. M.C.L. §400.610a also provides for an award against Defendants for reasonable attorneys' fees, costs and expenses.

399. **WHEREFORE,** Relator respectfully requests that judgment be entered in favor of the State of Michigan and against Defendants as follows:

400. A civil penalty equal to the full amount received plus triple the amount of damages suffered by the state, plus attorneys' fees, costs and expenses, and any other and further relief that this Honorable Court deems fit and proper.

COUNT XIX
VIOLATION OF THE MINNESOTA FALSE CLAIMS ACT
Minn. Stats. 15C.01 – .13

401. The allegations of paragraphs 1 through 266 are realleged as though fully set forth herein.

402. Section 15C.02 of the Minnesota False Claims Act provides in part:

> (a) A person who commits any act described in clauses (1) to (7) is liable to the state . . . for a civil penalty of not less than $5,500 and not more than $11,000 per false or fraudulent claim, plus three times the amount of damages that the state . . . sustains because of the act of that person,,,
>
> (1) knowingly presents or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (2) knowingly makes or uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

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> (3) knowingly conspires to commit a violation of clause (1), (2), (4), (5), (6), or (7);
>
> . . .
>
> (7) knowingly makes or 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 state . . . or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay money or transmit property to the state . . ."

403. Defendants, and each of them knowingly presented, or caused to presented, false or fraudulent claims for payment or approval; knowingly made or used or caused the submission or use of false records or statements regarding Subsys material to these claims; and/or false records or statements in order to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Minnesota. Defendants, and each of them, conspired among themselves and with others to do these things.

404. Additionally, Defendants, and each of them gave or caused to be given 'kickbacks' to physicians and other health care professionals to induce them to prescribe Subsys, in violation of state law, including Minn.Stat. 69J.23 et. seq.

405. Defendants, and each of them knowingly presented or caused to be presented false claims for payment to the Minnesota Medicaid Program creating liability for a false claims action pursuant to Minnesota's False Claims Act.

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406. As a result of the conduct set forth in this count, the State of Minnesota paid the improper Medicaid claims and has otherwise suffered actual damages.

407. §15C.12 also provides for an award against Defendants for reasonable attorneys' fees, costs and expenses.

408. **WHEREFORE,** Relator respectfully requests that judgment be entered in favor of the State of Minnesota and against Defendants and each of them as follows:

409. A civil penalty equal to the full amount received plus triple the amount of damages suffered by the state, plus attorneys' fees, costs and expenses, and any other and further relief that this Honorable Court deems fit and proper.

COUNT XX
VIOLATION OF THE MONTANA FALSE CLAIMS ACT
(MONT. CODE, CH. 465, HB 146 (2005))

410. The allegations of paragraphs 1 through 266 are realleged as though fully set forth herein

411. Section 3 of the Montana False Claims Act (Mont. Code, CH. 465, HB 146 (2005)) provides in pertinent part as follows:

> Section 3. False claims -- procedures -- penalties. (1) A person causing damages in excess of $500 to a governmental entity is liable, as provided in [sections 10 and 11], for any of the following acts:

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(a) knowingly presenting or causing to be presented to an officer or employee of the governmental entity a false claim for payment or approval;

(b) knowingly making, using, or causing to be made or used a false record or statement to get a false claim paid or approved by the governmental entity;

(c) conspiring to defraud the governmental entity by getting a false claim allowed or paid by the governmental entity;

****

(g) knowingly making, using, or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the governmental entity or its contractors; or
(h) as a beneficiary of an inadvertent submission of a false claim to the governmental entity, subsequently discovering the falsity of the claim and failing to disclose the false claim to the governmental entity within a reasonable time after discovery of the false claim.

412. Defendants, and each of them, knowingly presented, or caused to presented, false claims for payment and/or false records or statements regarding Subsys in order to get false claims paid, and/or to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Montana Medicaid Program.

413. Additionally, Defendants, and each of them gave or caused to be given 'kickbacks' to physicians and other health professionals to induce them to prescribe Subsys, in violation of state law, including Mon. 45-6-313.

414. As a result of the conduct set forth in this count, the State of Montana paid the improper Medicaid claims and has suffered actual damages.

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415. Section 3 of the Montana False Claims Act provides in pertinent part:

> (2) In a civil action brought under [section 5 or 6], a court shall assess not less than two times and not more than three times the amount of damages that a governmental entity sustains because of the person's act, along with costs and attorney fees, and may impose a civil penalty of up to $10,000 for each act.

416. Section 11 of the Montana False Claims Act also provides for an award of attorneys's fees and costs against Defendants.

417. **WHEREFORE,** Relator respectfully requests that judgment be entered in favor of the State of Montana and against Defendants and each of them as follows:

418. Three times the amount of damages that a governmental entity sustains because of the Defendants's acts, along with costs and attorney fees, and a civil

419. penalty of up to $10,000 for each act, and any other and further relief that this Honorable Court deems fit and proper.

COUNT XXI
VIOLATION OF THE NEVADA FALSE CLAIMS ACT
(NRS 357.010 et seq.)

420. The allegations of paragraphs 1 through 266, inclusive, are realleged as though fully set forth herein.

421. Defendants, and each of them knowingly submitted or caused the submission of false claims for payment and/or made, or used or caused to be made or used, false records or statements regarding Subsys in order to get false claims paid

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and/or to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Nevada Medicaid Program.

422. Additionally, Defendants, and each of them gave or caused to be given 'kickbacks' to physicians and other health professionals to induce them to prescribe Subsys, in violation of state law, including Nev. Rev. Stats. § 422.560.

423. **WHEREFORE,** Relator respectfully requests this Court to enter judgment for the State of Nevada and against Defendants and each of them, and to award damages to the State of Nevada as authorized by the provisions of NRS 357.040.

COUNT XXII

CLAIMS OF THE STATE OF NEW HAMPSHIRE

VIOLATION OF THE NEW HAMPSHIRE FALSE CLAIMS ACT

(NEW HAMPSHIRE CODE §167:61-b)

424. The allegations of paragraphs 1 through 266are realleged as though fully set forth herein

425. The New Hampshire False Claims Act (167:61-b) provides in pertinent part:

> I. Any person shall be 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 that the state sustains because of the act of that person, who:

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> (a) Knowingly presents, or causes to be presented, to an officer or employee of the department, a false or fraudulent claim for payment or approval.
>
> (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 department.
>
> (c) Conspires to defraud the department by getting a false or fraudulent claim allowed or paid.
>
> . . .
>
> (f) Is a beneficiary of an inadvertent submission of a false claim to the department, who subsequently discovers the falsity of the claim, and fails to disclose the false claim to the department within a reasonable time after discovery of the false claim.

426. Defendants, and each of them knowingly presented, or caused to presented, false claims for payment and/or false records or statements regarding Subsys in order to get false claims paid and/or to conceal, avoid, or decrease an obligation to pay or transmit money to the State of New Hampshire Medicaid Program.

427. Additionally, Defendants, and each of them gave or caused to be given 'kickbacks' to physicians and other health care professionals to induce them to prescribe Subsys, in violation of state law, including N.H. Rev. Stat. §§ 167:61-a, I(I) & (j).

428. As a result of the conduct set forth in this count, the State of New Hampshire paid the improper Medicaid claims and has suffered actual damages in excess of $5,000.00.

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429. Section 167:61-e of the New Hampshire False Claims Act also provides for an award of attorneys fees and costs against Defendants.

430. **WHEREFORE**, Relator respectfully requests that judgment be entered in favor of the State of New Hampshire and against Defendants, and each of them, as follows:

431. A civil penalty of $10,000, plus 3 times the amount of damages that the state of New Hampshire has sustained because of the acts of Defendants, plus attorneys' fees and costs, and any other and further relief that this Honorable Court deems fit and proper.

COUNT XXIII

VIOLATION OF THE NEW JERSEY FALSE CLAIMS ACT

(2A:32C et. seq.)

432. The allegations of paragraphs 1 through 266are realleged as though fully set forth herein

433. §2A:32C-3 of the New Jersey False Claims Act provides in pertinent part:

> Any person who commits any of the following acts 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 37 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,

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for each false claim, plus three times the amount of damages which the State sustains because of the act of that person:

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 claim for payment or approval;

b. Knowingly makes, 1 uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the State;

c. Conspires to defraud the State by getting a false claim allowed or paid by the State;

. . .

g. Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State.

434. Defendants, and each of them knowingly presented, or caused to presented, false or fraudulent claims for payment and/or false records or statements regarding Subsys in order to get false or fraudulent claims paid; and/or to conceal, avoid, or decrease an obligation to pay or transmit money to the State of New Jersey Medicaid Program.

435. Additionally, Defendants, and each of them gave or caused to be give 'kickbacks' to physicians and other health professionals to induce them to prescribe Subsys, in violation of state law, including N.J. Stat. §§ 30:4D-17©.

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436. Defendants, and each of them knowingly presented or caused to be presented false claims for payment to the New Jersey Medicaid Program creating liability for a false claims action pursuant to New Jersey's False Claims Act.

437. As a result of the conduct set forth in this count, the State of New Jersey paid the improper Medicaid claims and has suffered actual damages.

438. Pursuant to Section 8 of the New Jersey False Claims Act, the court may also award reasonable attorneys' fees, costs and expenses against the Defendants.

439. **WHEREFORE**, Relator respectfully requests that judgment be entered in favor of the State of New Jersey and against Defendants, and each of them, as follows:

440. 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 37 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 claim, plus three times the amount of damages, plus attorneys fees, costs and expenses, and any and all other relief that this court deems fit and proper.

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COUNT XXIV

VIOLATION OF THE NEW MEXICO MEDICAID FALSE CLAIMS ACT and the NEW MEXICO FRAUD AGAINST TAXPAYERS ACT"

441. The allegations of paragraphs 1 through 266are realleged as though fully set forth herein.

442. §27-14-4 of The New Mexico Fraud Against Taxpayers Act \provides in pertinent part that:

> "[A] person commits an unlawful act and shall be liable to the state for three times the amount of damages that the state sustains as a result of the act if the 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; . . . (C) 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; (D) conspires to defraud the state by getting a claim allowed or paid under the medicaid program knowing that such claim is false or fraudulent; (E) makes, uses, or causes to be made or used a record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state, relative to the medicaid program, knowing that such record or statement is false . . ."

443. Defendants, and each of them knowingly presented, or caused to presented, false or fraudulent claims for payment and/or false records or statements to get claims paid; and or to conceal, avoid, or decrease an obligation to pay or transmit money to the State of New Mexico Medicaid Program.

444. Additionally, Defendants, and each of them gave or caused to be given 'kickbacks' to physicians and other health care professionals to induce them to prescribe Subsys, in violation of state law, including N.M. Stat. § 30-44-1–8.

445. Defendants, and each of them knowingly presented or caused to be presented false claims for payment to the New Mexico Medicaid Program creating liability for a false claims action pursuant to New Mexico's Fraud Against Taxpayers Act.

446. As a result the conduct set forth in this count, the State of New Mexico paid the improper Medicaid claims and has suffered actual damages.

447. §44-9-3 of the New Mexico Fraud Against Taxpayers Act provides in pertinent part that:

> C. A person who violates Subsection A of this section shall be liable for:
>
> (1) three times the amount of damages sustained by a state agency because of the violation;
>
> (2) a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand dollars ($10,000) for each violation;
>
> (3) the costs of a civil action brought to recover damages or penalties; and
>
> (4) reasonable attorney fees, including fees for state agency counsel.

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448. **WHEREFORE**, Relator respectfully requests that judgment be entered in favor of the State of New Mexico and against Defendants, and each of them, as follows:

449. Three times the amount of damages sustained by the State of New Mexico's Medicaid Program; a civil penalty of $10,000.00 for each violation; the costs of this Action; reasonable attorneys fees; and all other relief that this Honorable Court deems fit and proper.

COUNT XXV
VIOLATION OF THE NEW YORK FALSE CLAIMS ACT
(NEW YORK CODE §39 - ARTICLE XIII §§ 187 *et seq.*)

450. The allegations of paragraphs 1 through 266 are realleged as though fully set forth herein.

451. The New York False Claims Act (NYC §39 - Article XIII §§187 *et seq.*) provides in pertinent part as follows:

> §189. Liability for certain acts.
>
> 1. Subject to the provisions of subdivision two of this section, any person who:
>
> (a) 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;

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> (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;
>
> (c) conspires to defraud the state or a local government by getting a false or fraudulent claim allowed or paid;
>
> . . .
>
> (g) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to 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; and (ii) to any local government for three times the amount of damages sustained by such local government because of the act of that person.

452. Pursuant Section 188(3) of the New York False Claims Act, proof of specific intent to defraud is not required.

453. Defendants, and each of them knowingly presented, or caused to presented, false or fraudulent claims for payment or approval; false records or statements to get a false or fraudulent claim paid; and/or to conceal, avoid, or decrease an obligation to pay or transmit money to the State of New York Medicaid Program.

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454. Additionally, Defendants, and each of them gave or caused to be given 'kickbacks' to physicians and other health professionals to induce them to prescribe Subsys, in violation of state law, including N.Y. Soc. Serv. Law s 366-d, 366-f.

455. As a result of the conduct set forth in this count, the State of New York paid the improper Medicaid claims and has suffered actual damages.

456. Pursuant to §190(7) of the New York False Claims Act, the court may award reasonable attorneys' fees, reasonable expenses, and costs, against Defendants, and each of them..

457. **WHEREFORE**, Relator respectfully requests that judgment be entered in favor of the State of New York and against Defendants, and each of them, as follows:

458. A civil penalty of twelve thousand dollars, plus three times the amount of damages which the state sustained because of the acts of Defendants; plus costs, reasonable attorneys' fees, reasonable expenses, and any and all further relief that this Honorable Court deems fit and proper.

COUNT XXVI

VIOLATION OF THE NORTH CAROLINA FALSE CLAIMS ACT

(NORTH CAROLINA STATUTES – §§1-605 –18)

459. The allegations of paragraphs 1 through 266 are realleged as though fully set forth herein.

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460. § 1-607 provides in pertinent part as follows:

> (a) Any person who commits any of the following acts shall be liable to the State for three times the amount of damages that the State sustains because of the act of that person. A person who commits any of the following acts also shall be liable to the State for the costs of a civil action brought to recover any of those penalties or damages and shall be liable to the State for a civil penalty of not less than five thousand, five hundred dollars ($5,500) and not more than eleven thousand dollars ($11,000) for each violation:
>
> (1) Knowingly presents or causes to be presented, 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 material to a false or fraudulent claim;
>
> (3) knowingly conspires to commit a violation of clause (1), (2), (4), (5), (6), or (7) of this section;
>
> . . .
>
> (7) 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 State or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay money or transmit property to the state . . ."

461. Defendants, and each of them knowingly presented, or caused to presented, false or fraudulent claims for payment or approval; knowingly made or used or caused the submission or use of false records or statements regarding Subsys material to these claims; and/or false records or statements in order to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Minnesota.

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Defendants, and each of them, conspired among themselves and with others to do these things.

462. Additionally, Defendants, and each of them gave or caused to be given 'kickbacks' to physicians and other health care professionals to induce them to prescribe Subsys, in violation of state law, including North Carolina Stat. 69J.23 et. seq. Defendants, and each of them knowingly presented or caused to be presented false claims for payment to the North Carolina Medicaid Program creating liability for a false claims action pursuant to North Carolina's False Claims Act.

463. As a result of the conduct set forth in this count, the State of North Carolina paid the improper Medicaid claims and has otherwise suffered actual damages.

464. §§1-610 (d) and (e) also provide for an award against Defendants for reasonable attorneys' fees, costs and expenses.

COUNT XXVII
VIOLATION OF THE OKLAHOMA FALSE CLAIMS ACT
(OKLAHOMA STATUTES – TITLE 63, SECTION 5053)

465. The allegations of paragraphs 1 through 266 are realleged as though fully set forth herein.

466. Section 5053.1(B) provides in pertinent part as follows:

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B. 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;

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;

3. Conspires to defraud the state by getting a false or fraudulent claim allowed or paid;

. . .

7. Knowingly makes, uses, or causes to be made or used, a false record to conceal, avoid, or decrease an obligation to pay or transmit money or property to 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 ($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 time the amount of damages which the state sustains because of the act of that person.

467. Defendants, and each of them knowingly presented or caused to be presented false claims for payment to the Oklahoma Medicaid Program creating liability for a false claims action pursuant to Oklahoma's False Claims Act.

468. Defendants, and each of them knowingly presented, or caused to presented, false records or statements regarding Subsys in order to get false or

fraudulent claims paid; and/or to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Oklahoma Medicaid Program.

469. As a result of the conduct set forth in this count, the State of Oklahoma paid the improper Medicaid claims and has suffered actual damages.

470. Pursuant to Section 5053.4 of the Oklahoma False Claims Act, an award of reasonable attorneys' fees, costs and expenses is also to be awarded against Defendants.

471. **WHEREFORE**, Relator respectfully requests that judgment be entered against Defendants, and each of them, and in favor of the State of Oklahoma as follows:

472. A civil penalty of Ten Thousand ($10,000.00), (unless a penalty is imposed for the act of that Defendants in violation of this subsection under the Federal False Claims Act for the same or a prior action), plus three time the amount of damages which the State of Oklahoma sustained because of the act of that person; plus costs, reasonable attorneys' fees, expenses, and any and all further relief that this Honorable Court deems fit and proper.

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COUNT XXVIII

VIOLATION OF THE STATE FALSE CLAIMS ACT

(RHODE ISLAND CODE - CHAPTER 9-1.1)

473. The allegations of paragraphs 1 through 266are realleged as though fully set forth herein

474. Pursuant to Chapter 9-1.1, of the State False Claims Act of the State of Rhode Island:

> (a) 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;
>
> (3) Conspires to defraud the state by getting a false or fraudulent claim allowed or paid;
>
> . . .
>
> (7) Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to 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.

475. Defendants, and each of them knowingly presented, or caused to presented, false claims for payment; and/or false records or statements Subsys in order get false claims paid; and/or to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Rhode Island Medicaid Program.

476. Additionally, Defendants, and each of them gave or caused to be given 'kickbacks' to physicians and other health professionals to induce them to prescribe Subsys, in violation of state law, including 40-8.2-1, *et seq*.

477. Defendants, and each of them knowingly presented or caused to be presented false claims for payment to the Rhode Island Medicaid Program creating liability for a false claims action pursuant to Rhode Island's State False Claims Act.

478. As a result of the conduct set forth in this count, the State of Rhode Island paid the improper Medicaid claims and has suffered actual damages.

479. Pursuant to Section 9-1.1-4 of the State False Claims Act, Defendants, and each of them are also liable for attorneys' fees, costs and expenses.

480. **WHEREFORE**, Relator respectfully requests that judgment be entered against Defendants, and each of them, and in favor of the State of Rhode Island as follows:

481. A civil penalty of ten thousand dollars ($10,000), plus three (3) times the amount of damages which the state sustained because of the act of Defendants; plus an award to the state for the costs of this civil; reasonable attorneys fees, costs and

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expenses; and any and all other and further relief as this Honorable Court deems fit and proper.

COUNT XXIX

VIOLATION OF THE TENNESSEE MEDICAID FALSE CLAIMS ACT

(TENNESSEE 71-5-182 et seq.)

482. The allegations of paragraphs 1 through 266are realleged as though fully set forth herein.

483. Section 71-5-182 of the Tennessee Medicaid False Claims Act provides in pertinent part:

> (a)(1) 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;
>
> (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;
>
> (C) Conspires to defraud the state by getting a claim allowed or paid under the Medicaid program knowing such claim is false or fraudulent; or
>
> (D) Makes, uses, or causes to be made or used, a record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state, relative to the Medicaid program, 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

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of damages which the state sustains because of the act of that person.

484. Defendants, and each of them, knowingly presented or caused to be presented false claims for payment to the Tennessee Medicaid Program creating liability for a false claims action pursuant to Tennessee's Medicaid False Claims Act.

485. Defendants, and each of them, knowingly used or caused the use of false or fraudulent records or statements in order to either get false claims paid.

486. As a result of the conduct set forth in this count, the State of Tennessee paid the improper Medicaid claims and has suffered actual damages.

487. Pursuant to Section 71-5-183 of the Tennessee Medicaid False Claims Act, Defendants, and each of them arev also liable for attorneys' fees, costs and expenses.

488. **WHEREFORE**, Relator respectfully requests that judgment be entered against Defendants, and each of them, and in favor of the State of Tennessee as follows:

489. A civil penalty of ten thousand dollars ($10,000), plus three (3) times the amount of damages which the state sustains because of the act of that person; plus an award of attorneys' fees, costs and expenses; and all further relief that this Honorable Court deems fit and proper.

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COUNT XXX

VIOLATION OF THE TEXAS MEDICAID FRAUD PREVENTION ACT

(TEXAS HUMAN RESOURCE CODE 36.001 - 36.117)

490. The allegations of paragraphs 1 through 266are realleged as though fully set forth herein.

491. Section 36.002 of the Texas Medicaid Fraud Prevention Act provides in pertinent part as follows:

> A person commits an unlawful act if the person:
>
> (1) knowingly makes or causes to be made a false statement or misrepresentation of a material fact to permit a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized;
>
> (2) knowingly conceals or fails to disclose information that permits a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized;
>
> ****
>
> (4) knowingly makes, causes to be made, induces, or seeks to induce the making of a false statement or misrepresentation of material fact concerning:
>
> > (A) the conditions or operation of a facility in order that the facility may qualify for certification or recertification required by the Medicaid program, including certification or recertification as: (I) a hospital; (ii) a nursing facility or skilled nursing facility; (iii) a hospice; (iv) an intermediate care facility for the mentally retarded; (v) an assisted living facility; or (vi) a home health agency; or

> (B) information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program;
>
> (5) except as authorized under the Medicaid program, knowingly pays, charges, solicits, accepts, or receives, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or product or the continued provision of a service or product if the cost of the service or product is paid for, in whole or in part, under the Medicaid program;
>
> ****
>
> (9) knowingly enters into an agreement, combination, or conspiracy to defraud the state by obtaining or aiding another person in obtaining an unauthorized payment or benefit from the Medicaid program or a fiscal agent;
>
> ****
>
> (12) knowingly makes, uses, or causes the making or use of a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to this state under the Medicaid program.

492. Defendants, and each of them knowingly presented, or caused to presented, false records or statements regarding Subsys in order to get false claims paid and or in order conceal, avoid, or decrease an obligation to pay or transmit money to the State of Texas Medicaid Program.

493. Additionally, Defendants, and each of them gave or caused to be given 'kickbacks' to physicians and other health care professionals to induce them to

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prescribe Subsys, in violation of state law, including Tex. Hum. Res. Code §§ 32.039, 32.0391, and 36.002(a)(5).

494. Defendants, and each of them knowingly presented or caused to be presented false claims for payment to the Texas Medicaid Program creating liability for a false claims action pursuant to Texas's Medicaid Fraud Prevention Act.

495. As a result of the conduct set forth in this count, the State of Texas paid the improper Medicaid claims and has suffered actual damages.

496. Section 36.052 of the Texas Medicaid Fraud Prevention Act provides in pertinent part as follows:

> (a) ..., a person who commits an unlawful act is liable to the state for: (1) the amount of any payment or the value of any monetary or in-kind benefit provided under the Medicaid program, directly or indirectly, as a result of the unlawful act, including any payment made to a third party; (2) interest on the amount of the payment or the value of the benefit described by Subdivision (1) at the prejudgment interest rate in effect on the day the payment or benefit was received or paid, for the period from the date the benefit was received or paid to the date that the state recovers the amount of the payment or value of the benefit; (3) a civil penalty of . . . (B) not less than $1,000 or more than $10,000 for each unlawful act committed by the person that does not result in injury to a person described by Paragraph (A); and (4) two times the amount of the payment or the value of the benefit described by Subdivision (1).

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497. Pursuant to §36.110 and §36.117 of the Texas Medicaid Fraud Prevention Act, Defendants, and each of them arev also liable for attorneys' fees, costs and expenses.

498. **WHEREFORE**, Relator respectfully requests that judgment be entered against Defendants, and each of them, and in favor of the State of Texas as follows:

499. The amount of all payments or the value of the monetary or in-kind benefit provided under the Medicaid program, directly or indirectly, as a result of the unlawful acts of Defendants, and each of them, including any payments made to a third parties; interest on the amount of said payment or the value of said benefit at the prejudgment interest rate in effect on the day the payment or benefit was received or paid, for the period from the date the benefit was received or paid to the date that the state recovers the amount of the payment or value of the benefit; a civil penalty of . . . $10,000 for each unlawful act committed by the person that did not result in injury to a person described by Paragraph 36.052(a)(3)(A); and two times the amount of the payment or the value of the benefit described by Subdivision 36.052(a)(1); plus attorneys' fees, costs and expenses, and any further relief that this Honorable Court deems fit and proper.

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COUNT XXXI

VIOLATION OF VIRGINIA FRAUD AGAINST TAXPAYERS ACT

(VIRGINIA CODE 8.01-216.1 et seq.)

500. The allegations of paragraphs 1 through 266are realleged as though fully set forth herein.

501. Section 8.01-216.3 of the Virginia Fraud Against Taxpayers Act provides in pertinent part as follows:

> A. 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;
>
> 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;
>
> 3. Conspires to defraud the Commonwealth by getting a false or fraudulent claim allowed or paid;
>
> . . .
>
> 7. Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to 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.

502. Defendants, and each of them obtained or attempted to obtain benefits or payments pursuant to the Virginia Fraud Against Taxpayers Act and any amendments thereto as provided for in Va. Code § 8.01-216.3 in a greater amount than that to which it was entitled by means of willful false statements and misrepresentations regarding Subsys, which caused a loss to the Commonwealth of Virginia.

503. Additionally, Defendants, and each of them gave or caused to be given 'kickbacks' to physicians and other health professionals to induce them to prescribe Subsys, in violation of state law, including Virginia Code § 32.1-315.

504. For each violation of the statute, the Commonwealth of Virginia is entitled to recover treble damages from Defendants, and each of them. *See* Va. Code § 8.01-216.3.

505. **WHEREFORE**, the Relator respectfully requests this Court to enter judgment for the Commonwealth of Virginia and against Defendants, and each of them, for an amount of three times the amount of damages sustained by the Commonwealth of Virginia and a civil penalty of $10,000 for each act of submitting false statements by INSYS, Kapoor, Babich, and Burlakoff.

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COUNT XXXII
VIOLATION OF THE WASHINGTON STATE MEDICAID FRAUD FALSE CLAIMS ACT
RCE 74.66.005 et. Seq

506. The allegations of paragraphs 1 through 266 are realleged as though fully set forth herein.

507. A person is "liable to the government entity for a civil penalty of not less than five thousand five hundred dollars and not more than eleven thousand dollars, plus three times the amount of damages which the government entity sustains because of the act of that person if the person: (a) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval; (b) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; c) conspires to commit one or more of the violations of this subsection (1); (d) has possession, custody, or control of property or money used, or to be used by the government entity and, knowingly delivers, or causes to be delivered, less than all of that money or property . . . (g) 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 entity."

508. Pursuant Section 188(3) of the New York False Claims Act, proof of specific intent to defraud is not required.

509. Defendants, and each of them knowingly presented, or caused to presented, false or fraudulent claims for payment or approval; false records or statements to get a false or fraudulent claim paid; and/or to conceal, avoid, or decrease an obligation to pay or transmit money to the Washington State Medicaid Program.

510. Additionally, Defendants, and each of them gave or caused to be given 'kickbacks' to physicians and other health professionals to induce them to prescribe Subsys, in violation of state law, including RCW 74.09.240.

511. Additionally, Defendants, and each of them had possession, custody, or control over money which should have been delivered to the Washington State Medicaid Program, and caused less than all of that money to be delivered.

512. As a result of the conduct set forth in this count, the State of Washington paid the improper Medicaid claims and has suffered additional actual damages.

513. Pursuant to RCW 74.66.070(1)© of the Washington State Medicaid Fraud False Claims Act, the court may award reasonable attorneys' fees, reasonable expenses, and costs, against Defendants, and each of them..

514. **WHEREFORE**, Relator respectfully requests that judgment be entered in favor of the State of Washington and against Defendants, and each of them, as follows:

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515. A civil penalty of eleven thousand dollars, plus three times the amount of damages which the state sustained because of the acts of Defendants; plus costs, reasonable attorneys' fees, reasonable expenses, and any and all further relief that this Honorable Court deems fit and proper.

COUNT XXXIII
ILLEGAL RETALIATION IN VIOLATION OF FEDERAL FALSE CLAIMS ACT; 31 U.S.C. §3730(h), AGAINST INSYS THERAPEUTICS, ONLY

516. Guzman realleges and incorporates the allegations from Paragraphs 1 through 266, inclusive, as though fully set forth therein

517. Through reporting about and attempting to stop some of the fraudulent conduct of Defendants, Relator was threatened, discriminated against, and ultimately fired by INSYS Therapeutics because of lawful acts done by her in furtherance of conduct protected by 31 U.S.C. §3729, et. seq.

518. Relator is entitled to all relief necessary to make her whole, including reinstatement with the same seniority to the position she had before she was illegally fired, 2 times the amount of back pay lost, interest on the back pay, and compensation for any special damages sustained as a result of this illegal retaliation.

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COUNT XXXIV

ILLEGAL RETALIATION IN VIOLATION OF FLORIDA FALSE CLAIMS ACT; §68.088 FLORIDA STATUTES, AGAINST INSYS THERAPEUTICS, ONLY

519. Guzman realleges and incorporates the allegations from Paragraphs 1 through 266, inclusive, as though fully set forth therein

520. Through reporting about and attempting to stop some of the fraudulent conduct of Defendants, Relator was threatened, discriminated against, and ultimately fired by INSYS Therapeutics because of lawful acts done by her in furtherance of conduct protected under this Act.

521. By its terms, §68.088 protects **"[A]ny employee"** who engages in protected conduct, thus broadening, for purposes of the Florida FCA, the more limited set of employees protected under the more general statute, the "Whistle-Blower Act", §§ 112.3187 – 112.31895.

522. Moreover, because of the seal requirements peculiar to the Florida False Claims Act, Relator is, by definition, excused from strict compliance with the requirement that she report the fraud to the Florida Commission on Human Relations and follow the administrative process for required reporting while this Action remains under seal.

523. Relator is entitled to all relief necessary to make her whole, including reinstatement with the same seniority to the position she had before she was illegally

fired, back pay lost, interest on the back pay, and compensation for any special damages sustained as a result of this illegal retaliation.

COUNT XXXV

ILLEGAL RETALIATION IN VIOLATION OF PUBLIC POLICY; §§448.102 – 104, FLORIDA STATUTES, AGAINST INSYS THERAPEUTICS, ONLY

524. Guzman realleges and incorporates the allegations from Paragraphs 1 through 266, inclusive, as though fully set forth therein

525. Guzman objected to INSYS' illegal practices which were endangering patients and resisted those practices. This was known to her supervisors to whom she complained. She was fired in retaliation for this..

526. Relator is entitled to all relief necessary to make her whole, including reinstatement with the same seniority to the position she had before she was illegally fired, back pay lost, interest on the back pay, and compensation for any special damages sustained as a result of this illegal retaliation.

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PRAYER FOR RELIEF

WHEREFORE, the Relator Maria Guzman, acting on behalf of and in the name of the United States of America, and the various States and on her own behalf, prays that judgment be entered against Defendant, and each of them, for violation of the False Claims Acts as follows:

1. In favor of the United States against the Defendants and each of them for treble damages to the Federal Government from the submission of false claims, and the maximum civil penalties for each violation of the False Claims Act;
2. In favor of the Relator for the maximum amount pursuant to 31 U.S.C. § 3739(d) to include reasonable expenses, attorney fees, and costs incurred by the Relator;
3. In favor of each State identified hereinabove against the Defendants and each of them for treble damages to the Federal Government from the submission of false claims, and the maximum civil penalties for each violation of the False Claims Act;
4. In favor of Relator for the maximum amount allowed pursuant to each State False Claims Act;
5. For all costs of the False Claims Act civil action;

6. For the Relator on her retaliation causes of action under 31 U.S.C. §3730(h), against Defendant INSYS Therapeutics, only, reinstatement with the same seniority to the position she had before she was illegally fired, 2 times the amount of back pay lost, interest on the back pay, and compensation for any special damages sustained as a result of this illegal retaliation.

7. For the Relator on her causes of action under §68.088 Florida Statutes and §§448.102 – 104, Florida statutes, against Defendant INSYS Therapeutics, only, all relief necessary to make her whole, including reinstatement with the same seniority to the position she had before she was illegally fired, back pay lost, interest on the back pay, and compensation for any special damages sustained as a result of this illegal retaliation; and

8. In favor of the Relator, the United States, and each State set forth hereinabove for further relief as this court deems just and equitable.

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Respectfully submitted,

Dated: June 13, 2016

THE EMPLOYMENT LAW GROUP

LAW OFFICE OF MARK KLEIMAN

By: _____

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DEMAND FOR A JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure and pursuant to the local rules of this Court, the Relator demands a jury trial as to all issues so triable.

Respectfully submitted,

Dated: June 13, 2016

THE EMPLOYMENT LAW GROUP

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing **SECOND AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT AND STATE FALSE CLAIMS ACTS** was served via USPS Certified Mail / Return Receipt Requested, on this 13th day of June, 2016, upon the addressees listed on the attached Service List.

Mark Kleiman

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