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LA CV16 07937-TJH-MRWx

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

UNITED STATES OF AMERICA, *ex rel.* JANE DOE and the States of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUSIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, VIRGINIA, WASHINGTON, the CITY OF CHICAGO, and the DISTRICT OF COLUMBIA,

Relator- Plaintiffs,

v.

INSYS THERAPEUTICS, INC. and LINDEN CARE LLC,

Defendants.

CASE NO. _____

FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)

COMPLAINT

BY FAX

DEMAND FOR JURY TRIAL

FALSE CLAIMS ACT COMPLAINT

The facts alleged in this *qui tam* Complaint establish that INSYS Therapeutics, Inc., ("INSYS") committed a massive fraud at the expense of taxpayers and unwitting patients with respect to its sales of Subsys, and that LINDEN CARE LLC ("LINDEN CARE") enabled that fraud while also profiting from it. Through a widespread off-label marketing campaign, INSYS took a dangerous opioid, approved only for breakthrough pain experienced by opioid-tolerant cancer patients, and pushed it to the pain management field as the ultimate answer for chronic, intractable pain, a use for which it is neither approved nor safe. Industry analysts estimate that more than 90% of Subsys is prescribed for this sort of off-label use. This is no coincidence.

INSYS' management pressures its sales staff to use sex appeal, bribery, and blatant and aggressive off-label promotion to sell as much Subsys as possible despite it being a dangerous controlled substance which has reportedly resulted in numerous overdose-related deaths. Relator Jane Doe ("Relator") experienced INSYS' unlawful misconduct first hand, as detailed herein. She faced the death of a patient who overdosed on opioids while taking Subsys for an off-label and unapproved use.

I. INTRODUCTION

1. On behalf of the United States of America ("United States"), the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada,

New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Virginia, Washington, (collectively, the "States"), the District of Columbia ("D.C."), and the City of Chicago ("Chicago"), and pursuant to the *qui tam* provisions of the Federal False Claims Act, 31 U.S.C. §§ 3729-3733 and the False Claims Acts of the States, D.C., and Chicago, Relator-Plaintiff Jane Doe ("Relator") files this *qui tam* Complaint against INSYS Therapeutics, Inc. ("INSYS") and LINDEN CARE LLC ("LINDEN CARE") (hereinafter referred to collectively as "Defendants").

2. Relator Jane Doe brings this action on behalf of the United States and the Plaintiff States against INSYS and LINDEN CARE for damages and civil penalties arising from violations of the False Claims Act, 31 U.S.C. § 3729, et seq. ("FCA") and state-law counterparts in California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Virginia, Washington, D.C. and Chicago. The States, Chicago, D.C., and the UNITED STATES are hereafter collectively referred to as the Government.

3. The complained of violations arise out of requests for payment from Medicare, Medicaid, TRICARE, and possibly other federally-funded government

healthcare programs (hereinafter referred to as "Government Healthcare Programs"). The state-law violations arise out of requests for payment under the Medicaid programs.

4. This action concerns INSYS' illegal marketing of the patented fentanyl spray Subsys, from 2012, when the Food and Drug Administration ("FDA") approved Subsys, to the present, as well as LINDEN CARE's unlawful distribution of the drug during the same time period.

5. Through their intentional and reckless acts, which included false statements and claims for payment to the Government Healthcare Programs, INSYS and LINDEN CARE have put patients at risk and received millions of dollars in improper government payments.

6. Relator filed anonymously to protect her identity from disclosure due to the fact that she remains employed in the pharmaceutical industry and seeks to avoid the retaliation that would most certainly result if her name were to be released.

7. Relator worked as a sales representative for INSYS for approximately two years, after more than a decade of experience in the pharmaceutical industry.

8. INSYS, a Delaware corporation, is a developer and marketer of pharmaceutical products in the United States and throughout the world.

9. INSYS was founded in 1990 (as Oncomed Inc.) and is headquartered in Phoenix, Arizona. One of its primary business activities involves the company's

manufacture and sale of Subsys, the patented fentanyl spray which is the subject of this action.

10. As detailed herein, INSYS engaged in a variety of illegal marketing practices as part of this fraud, including, but not limited to:

a. Off-label marketing;

b. Misbranding;

c. Coopting physicians by circumventing educational assessments required by TIRF-REMS;

d. Paying kickbacks and other unlawful remuneration to physicians;

e. Focusing the majority of INSYS' sales force on promoting Subsys for non-cancer uses, including contraindicated uses;

f. Advising physicians to begin Subsys patients at dosages twice the FDA-approved entry dose;

g. Advising patients to "titrate up," finding their optimal effective dose, without discussing dosage changes with their physicians;

h. Training and supervising Relator and her sales colleagues in the use of illegal promotion and kickbacks before and during their promotion of Subsys; and

i. Supervising fraudulent practices by the INSYS Reimbursement Center which, upon information and belief, encouraged INSYS' employees to lie

to Medicare Part D insurers to assure prior authorization for Subsys prescriptions.

11. These practices were widespread, egregious and orchestrated from the highest levels of INSYS.

12. LINDEN CARE, a limited liability company based in Woodbury, New York, is a provider of specialty pharmacy services to the pain management industry.

13. LINDEN CARE was founded in 2006, and is licensed in all fifty U.S. states and the District of Columbia.

14. As detailed herein, LINDEN CARE engaged in a variety of illegal practices as part of this fraud, including, but not limited to:

a. Dispensing prescriptions based on faxed prescriptions for Schedule II narcotics in violation of federal regulations;

b. Mislabeling prescription medicines;

c. Dispensing prescriptions in contravention of the terms of the TIRF-REMS program; and

d. Dispensing prescriptions in amounts, dosages, and for indications forbidden by law.

15. Relator has complied with all procedural requirements of the laws under which this case is brought.

16. Relator is informed and believes that the pervasive off-label marketing and kickback schemes herein described began in 2012 and continue to date throughout the United States.

II. JURISDICTION AND VENUE

17. This Court has federal subject matter jurisdiction of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3742(a). This Court has supplemental jurisdiction over the counts relating to the state False Claims Acts pursuant to 28 U.S.C. § 1367.

18. This Court has personal jurisdiction over Defendants INSYS and LINDEN CARE because they can be found in, reside in, or transact business in this District. Additionally, this Court has personal jurisdiction over both Defendants because acts prohibited by 31 U.S.C. § 3729 occurred in this District. 31 U.S.C. §3732(a).

19. Venue is proper in this District pursuant to 28 U.S.C. § 1391 and 31 U.S.C.§ 3732(d), because INSYS and LINDEN CARE transact business in this District. (Or, 31 U.S.C. § 3732(a) by way of acts proscribed by 31 U.S.C. § 3729?)

20. Relator's claims and this Complaint are not based upon allegations or transactions which are the subject of a civil suit or an administrative proceeding in which the Government is already a party, as enumerated in 31 U.S.C. § 3730(e)(3).

21. Relator brings this action based on her direct knowledge and, where indicated, on information and belief. None of the actionable allegations set forth in this Complaint are based on a public disclosure as set forth in 31 U.S.C. §3730(e)(4)(A), and

Relator is the original source of the information upon which this Complaint is based, as that phrase is used in the False Claims Act and other laws at issue herein.

22. At all times relevant hereto, INSYS and LINDEN CARE acted through their agents and employees, and the acts of their agents and employees were within the scope of their agency and employment. The policies and practices alleged in this Complaint were, on information and belief, established and/or ratified at the highest corporate levels of INSYS and LINDEN CARE.

III. THE REGULATORY ENVIRONMENT

A. FDCA and FDA Regulations

23. The Federal Food Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 321 *et seq.*, provides a regulatory regime for the approval of new drugs and new drug formulations intended to be marketed for use in interstate commerce. Under the FDCA, a new drug product cannot be marketed unless the FDA approves the product and determines that it is safe and effective for its intended use. *See* 21 U.S.C. § 355(a).

24. When the FDA approves a drug, it approves the drug only for the particular use for which it was tested, the intended use. 21 C.F.R. § 201.128. An intended use, once approved, is called an "indication." Uses other than the approved indication are called "off-label."

25. In approving uses for a drug, the FDA specifies particular dosages determined to be safe and effective for each indication. The indication and dosages

approved by the FDA are set forth in the drug's labeling, the content of which is also reviewed and approved by the FDA. 21 U.S.C. §§ 352, 355(d). An example of the drug's labeling is the printed insert in the drug's packaging. The FDA will only approve the New Drug Application if the labeling conforms to the uses and dosages that the FDA has approved. 21 U.S.C. §355(d).

26. Under the Food and Drug Administration Modernization Act of 1997 ("FDAMA"), the manufacturer who wishes to market or promote an approved drug for alternative uses, i.e., uses not listed on the approved label, must re-submit the drug for another series of clinical trials similar to those for the initial approval. 21 U.S.C. § 360(a)(b) & (c). Until subsequent approval of the new use has been granted, the unapproved use is considered to be "off-label". The term "off-label" refers to the use of an approved drug for any purpose, or in any manner, other than what is described in the drug's labeling. "Off-label" use includes treating a condition not indicated on the label; treating the indicated condition with a different dose or frequency than specified in the label; or treating a different patient population (e.g. treating a child when the drug is approved to treat adults).

27. While a physician may prescribe a drug for a use other than one for which it is approved, the FDCA prohibits a drug manufacturer from marketing or promoting a drug for non-approved uses. 21 U.S.C. § 331(d), 355(a). It therefore is illegal for a drug

manufacturer and its sales representatives to initiate discussions with medical professionals regarding any off-label use of the drug.

28. The FDA prohibits "misbranding," the labelling of a pharmaceutical without "adequate directions for use." 21 U.S.C. §352(f). "Adequate directions" are those which will allow a lay patient to use the drug safely for its "intended use." 21 C.F.R. §201.5. When a pharmaceutical manufacturer markets a drug, the actions of those who label and attempt to sell the drug form its intended use, whether or not that accords with the indication approved by the FDA. 21 C.F.R. §201.6.

29. In addition to prohibiting manufacturers from directly marketing and promoting a product's unapproved use, Congress and the FDA have acted to prevent manufacturers from employing indirect methods to accomplish the same end. The FDA regulates manufacturer support for Continuing Medical Education ("CME") programs and "speaker" programs that focus on off-label uses.

30. With regard to manufacturer involvement in CME programs, the FDA published an Agency Enforcement Policy Guidance which states that CME programs must be truly independent of the drug companies and sets forth a number of factors that the FDA will consider in determining whether a program is "free from the supporting company's influence and bias". 62 Fed. Reg. 64074, 64093. These factors include, among others, an examination of the relationship between the program provider and supporting company; the company's control of content and selection of presenters;

whether there is a meaningful disclosure of the company's funding and its role in the program; whether multiple presentations of the same program are held; whether the audience is selected by the sales or marketing department of the company; and whether information about the supporting company's product is disseminated after the initial program other than in response to an unsolicited request. The promotion of off-label drug uses at a CME program fails this test of "independence" and violates Congress' off-label marketing restrictions.

31. Pursuant to the Anti-Kickback Act, 42 U.S.C. Section 1320a-7b(b), it is unlawful to knowingly offer or pay any remuneration in cash or in kind in exchange for the referral of any product (including a prescription drug product) for which payment is sought from any federally-funded health care program, including Medicare, Medicaid, and TRICARE.

32. The Anti-Kickback Act is designed to, inter alia, ensure that patient care will not be improperly influenced by inappropriate compensation from the pharmaceutical industry.

33. Every federally-funded health care program requires every provider or supplier to ensure compliance with the provisions of the Anti-Kickback Act and other federal laws governing the provision of health care services in the United States.

34. The Anti-Kickback Act prohibits suppliers such as pharmaceutical manufacturers from compensating, in cash or in kind, a health care provider when a

purpose of the payment is to influence the provider's prescribing habits or to gain favor for its product over the product of any competitor.

35. A violation of the Anti-Kickback Act is a violation of the False Claims Act.

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

36. Congress adopted the FCA and amended it in 1986 to fight fraud in government payments.

37. The United States Civil FCA provides, in pertinent part, that:

> (a)(1) … [A]ny person who (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 records or statement material to a false or fraudulent claim;
> ***
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000… plus 3 times the amount of damages which the Government sustains because of the act of that person.

See 31 U.S.C. § 3729.

38. The FCA imposes liability on false claims and/or false statements material to a false or fraudulent claim.

39. The submission of claims that are induced and written because of the off-label marketing of a pharmaceutical company is a violation of the False Claims Act.

40. The States, D.C., and the Cities that are party to this Complaint have enacted False Claims Act statutes that apply to, inter alia, Medicare and Medicaid fraud and/or fraudulent health care claims submitted for payment by municipal funds.

41. The Medicare Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), which also applies to the state Medicaid programs and/or municipal programs, provides penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration to induce the referral of business reimbursable under a federal health benefits program. The offense is a felony punishable by fines of up to $25,000 and imprisonment for up to 5 years.

42. The Medicare Anti-Kickback statute arose out of Congressional concern that payoffs to those who can influence health care decisions will result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of the federal health care programs from these difficult to detect harms, Congress enacted a prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to overutilization or poor quality of care.

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

44. In accordance with the Anti-Kickback Statute, Medicare regulations directly prohibit providers from receiving remuneration paid with the intent to induce referrals or

business orders, including the prescription of pharmaceuticals paid as a result of the volume or value of any referrals or business generated. *See* 42 C.F.R. § 1001.952(f). Under this statute, drug companies may not offer or pay any remuneration, in cash or kind, directly or indirectly, to induce physicians or others to recommend drugs that may be paid for by a federal health care program. The law not only prohibits outright bribes and rebate schemes, but also prohibits any payment by a drug company that has as one of its purposes inducement of a physician to write additional prescriptions for the company's pharmaceutical products.

45. Such remunerations are kickbacks when paid to induce or reward physicians' prescriptions. Kickbacks increase Government-funded health benefit program expenses by inducing medically unnecessary overutilization of prescription drugs and excessive reimbursements. Kickbacks also reduce a patient's healthcare choices, as physicians may prescribe drug products based on the physician's own financial interests rather than according to the patient's medical needs.

46. The Medicare Anti-Kickback Statute contains statutory exceptions and certain regulatory "safe harbors" that exclude certain types of conduct from the reach of the statute. See 42 U.S.C. § 1320a-7b(b)(3). None of the statutory exceptions or regulatory safe harbors protects INSYS or LINDEN CARE's conduct in this case.

47. Recently, the Patient Protection and Affordable Care Act ("PPACA"), Public Law No. 111-148, Sec. 6402(g), amended the Medicare Anti-Kickback Statute or

"Social Security Act," 42 U.S.C. § 1320a-7b(b), to specifically allow violations of its "anti-kickback" provisions to be enforced under the False Claims Act. The PPACA also amended the Social Security Act's "intent requirement" to make clear that violations of the Social Security Act's anti-kickback provisions, like violations of the False Claims Act, may occur even if an individual does "not have actual knowledge" or "specific intent to commit a violation." *Id.* at Sec. 6402(h).

48. As detailed herein, INSYS devised a scheme whereby the company paid kickbacks to physician-speakers in the form of cash and cash-equivalents with the specific aim of artificially increasing the prescription and sale of Subsys for off-label uses.

49. Knowingly paying kickbacks to physicians to induce them to prescribe a prescription drug on-label or off-label (or to influence physician prescriptions) for individuals who seek reimbursement for the drug from a federal Government health program or causing others to do so, while certifying compliance with the Medicare Anti-Kickback Statute (or while causing another to so certify), or billing the Government as if in compliance with these laws, violates state and federal False Claims Acts.

C. Government Healthcare Programs

50. The federal government enacted the Medicaid program in 1965 as a cooperative undertaking between the federal and state governments to help the states provide health care to low-income individuals. The Medicaid program pays for services

pursuant to plans developed by the states and approved by the U.S. Department of Health and Human Services ("HHS") Secretary through the Centers for Medicare and Medicaid Services ("CMS"). *See* 42 U.S.C. §§ 1396a(a)-(b). States pay doctors, hospitals, pharmacies, and other providers and suppliers of medical items and services according to established rates. *See* 42 U.S.C. §§ 1396b(a)(1), 1903(a)(1). The federal government then pays each state a statutorily established share of "the total amount expended ... as medical assistance under the State plan[.]" *See* 42 U.S.C. § 1396b(a)(1). This federal-to-state payment is known as Federal Financial Participation.

51. Medicare Part A is funded primarily by a federal payroll tax, premiums paid by Medicare beneficiaries, and appropriations from Congress. Medicare Part A generally pays for inpatient services for eligible beneficiaries in hospital, hospice and skilled nursing facilities, as well as some home healthcare services. 42 U.S.C. §§1395e- 42 U.S.C. §§1395i-5. Prescription drugs are covered under Medicare Part A only if they are administered on an inpatient basis in a hospital or similar setting.

52. Medicare Part B is optional to beneficiaries and covers some healthcare benefits not provided by Medicare Part A. Medicare Part B is funded by appropriations from Congress and premiums paid by Medicare beneficiaries who choose to participate in the program. 42 U.S.C, §§ 1395j to 42 U.S.C. §§ 1395w-4. Medicare Part B pays for some types of prescription drugs that are not administered in a hospital setting. 42 U.S.C. § 1395k(a); 42 U.S.C. § 1395x(s)(2); 42 C.F.R. § 405.517. These typically include

drugs administered by a physician or other provider in an outpatient setting, some orally administered anti-cancer drugs and antiemetics (drugs which control the side effects caused by chemotherapy), and drugs administered through durable medical equipment such as a nebulizer. 42 U.S.C. § 1395k(a); 42 U.S.C. § 1395x(s)(2); 42 C.F.R. § 405.517i.

53. Medicare Part D, administered by CMS, went into effect on January 1, 2006. For "dual eligibles," defined as individuals who received prescription drug coverage under Medicaid in addition to Medicare coverage for other health care in 2005, enrollment in Medicare Part D was compulsory. Such beneficiaries were automatically switched to Part D plans for 2006 and commenced receiving comprehensive prescription drug coverage under Medicare Part D.

54. Coverage of prescription drugs under Medicare Part D is subject to the same regulations as coverage under the Medicaid Program described above.

55. TRICARE is the component agency of the U.S. Department of Defense that administers and supervises the health care program for certain military personnel and their dependents. TRICARE contracts with a fiscal intermediary that receives, adjudicates, processes and pays health care claims submitted to it by TRICARE beneficiaries or providers. The funds used to pay the TRICARE claims are government funds.

56. The Railroad Retirement Medicare program is authorized by the Railroad Retirement Act of 1974, at U.S.C.A. §231 et seq. It is administered through the United States Railroad Retirement Board, ("RRB") and furnishes Medicare coverage to retired railroad employees.

57. The Federal Employees Health Benefits Program ("FEHBP") is administered by the United States Office of Personnel Management ("OPM") pursuant to 5 U.S.C.A. § 8901 et seq. and provides health care coverage to federal employees, retirees and their dependents and survivors.

58. The Civilian Health and Medical Program of the Department of Veterans Affairs ("CHAMPVA") is a comprehensive health care program in which the VA shares the cost of covered health care services and supplies with eligible beneficiaries. The program is administered by Health Administration Center and their offices are located in Denver, Colorado. In general, the CHAMPVA program covers most health care services and supplies that are medically and psychologically necessary.

59. Due to the similarity between CHAMPVA and the Department of Defense TRICARE program, the two are often mistaken for each other. CHAMPVA is a Department of Veterans Affairs program whereas TRICARE is a regionally managed health care program for active duty and retired members of the uniformed services, their families and survivors. In some cases, a veteran may appear to be eligible for both/either

program on paper. However, military retirees, or the spouse of a veteran who was killed in action, are and will always be TRICARE beneficiaries.

60. Pursuant to 38 U.S.C.A. § 8126, and the regulations based thereon, and contracts the Veterans Administration had with manufacturers, drugs furnished to the Veterans' Administration by drug manufacturers must be furnished at the best price.

61. The VA and CHAMPUS/TRICARE operate in substantially similar ways to the Medicare and Medicaid programs, but primarily for the benefit of military veterans, their spouses (or widowed spouses) and other beneficiaries.

62. The Indian Health Service is responsible for providing comprehensive health services to more than 1,400,000 Americans. It is administered by the department of health and human services pursuant to 42 U.S.C.A. § 2002 et seq. The statute authorizes the Secretary to enter into contracts with independent providers to furnish health services to Native Americans whenever the Secretary determines that independent providers can better meet the population's need.

63. At all times material to this Complaint, off-label uses of Subsys promoted by INSYS are not eligible for reimbursement under the Government Healthcare Programs because such off-label uses are neither listed in the labeling approved by the FDA nor, on information and belief, otherwise deemed safe and effective by any of the applicable drug compendia.

64. As a direct result of INSYS' improper off-label and misleading marketing practices involving Subsys, in addition to the payment of illegal kickbacks, the Government Healthcare Programs paid false or fraudulent Subsys reimbursement claims for off-label, non-medically accepted indications. The United States would not have paid such false claims but for INSYS' illegal and fraudulent conduct.

D. The Food, Drug, and Cosmetics Act ("FDCA") And FDA Regulations

65. The Food and Drug Administration ("FDA") regulates drugs based on the "intended uses" for such products. Before marketing and selling a prescription drug, a manufacturer must demonstrate to the FDA that the product is safe and effective for each intended use. 21 U.S.C. § 331(d); 21 U.S.C. §§ 355(a).

66. The FDA reviews pharmaceutical manufacturers' applications for new drugs to determine whether the drug's intended uses are safe and effective. *See* 21 U.S.C. § 355. Once a drug is approved for a particular use, doctors are free to prescribe the drug for "non-indicated" or off-label purposes. While doctors may independently request information from drug manufacturers about such off-label uses, with very few exceptions, the FDA prohibits drug manufacturers from marketing or promoting drugs for uses, *i.e.* "indications," not approved by the FDA. As described herein, "off-label" refers to the marketing of an FDA-approved drug for uses that have not undergone FDA review and approval, *i.e.*, for purposes not approved by the FDA.

67. While purely scientific or educational programs are permissible, sales and marketing presentations, promotions, or marketing to physicians for uses other than those approved by the FDA are considered off-label marketing or "misbranding" proscribed by the FDA. *See* 21 U.S.C. §§ 331(a) – (b), 352(a), (f). Additional proscribed marketing activity includes any attempts by a pharmaceutical sales representative to solicit discussions with physicians concerning off-label use.

68. Strong policy reasons exist for strict regulation of off-label marketing. Off-label promotion bypasses the FDA's strict review and approval process and removes the incentive to obtain definitive clinical study data showing the efficacy and safety of a product and, accordingly, the medical necessity for its use.

69. Pursuant to the Food, Drug and Cosmetics Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, the FDA strictly regulates the content of direct-to-physician product promotion and drug labeling information used by pharmaceutical companies to market and sell FDA-approved prescription drugs.

70. The FDA interprets "labeling" in its regulations broadly to include items that are "1) descriptive of a drug; 2) supplied by the manufacturer or its agents; and 3) intended for use by medical personnel." 21 C.F.R. § 202.1. The FDCA defines both misleading statements and the failure to reveal material facts in a label or product labeling as "misbranding." 21 U.S.C. § 321(n). Labeling includes, among other things,

brochures, booklets, detailing pieces, literature, reprints, sound recordings, exhibits and audio visual material. 21 C.F.R. § 202.1(1)(2).

71. FDA regulations deem "advertising" to include advertisements in published journals, magazines, newspapers and other periodicals, and broadcast through media such as television, radio, and telephone communications systems. *See* 21 C.F.R. § 202.1(I)(1). Courts have consistently held that oral statements made by a company's sales representative relating to a pharmaceutical product constitute commercial advertising or promotion. *See Abbott Labs. v. Mead Johnson &Co.*, 971 F.2d 6, 7 (7th Cir. 1992) (interpreting Lanham Act).

72. Pharmaceutical promotional and marketing materials and presentations lacking in fair balance or that are otherwise false or misleading "misbrand" a drug in violation of the FDCA, 21 U.S.C. §§301, 321, 331, 352, 360b, 371; C.F.R. § 202.1(e)(6), (e)(7); 21 C.F.R. § 1.21.

73. Such violations occur where promotional marketing materials and presentations (*i.e.* advertisements) for an FDA approved drug, among other things:

a. Minimize, understate, or misrepresent the side effects, contraindications and/or effectiveness of the drug;

b. Overstate or misrepresent the side effects, contraindications, and/or effectiveness of competing drugs;

c. Expressly or implicitly promote uses, dosages or combination usage of the drug that are not contained in the FDA approved labeling (*i.e.*, off-label uses);

d. Fail to reveal material facts with respect to consequences that may result from the use of the drug as recommended or suggested in the advertisement;

e. Contain representations or suggestions, not approved or permitted in the labeling, that the drug is better, more effective, useful in a broader range of conditions or patients, safer, or has fewer, or less incidence of, or less serious side effects or contraindications than demonstrated by substantial evidence or substantial clinical experience; Present information from a study in a way that implies that the study represents larger or more general experience with the drug than it actually does;

f. Use a quote or paraphrase out of context to convey a false or misleading idea; and/or

g. Are otherwise false, misleading or lacking in fair balance in the presentation of information about the drug being marketed or any competing drug.

See 21 C.F.R. § 202.1(e)(4)(5)(6), and (7).

74. Oral statements and written materials presented at industry-supported activities, including lectures and teleconferences, provide evidence of a product's intended use. If these statements or materials promote a use inconsistent with the product's FDA-approved labeling, the drug is misbranded, as the statements and materials fail to provide adequate directions for all intended uses.

75. Whether the promotion of off-label uses occurs directly or indirectly, the facts related to this promotion may establish the existence of misbranding. "A drug is misbranded if, inter alia, its labelling fails to bear 'adequate direction for use,' 21 U.S.C. §352(f), which FDA regulations define as 'directions under which the lay[person] can use a drug safely and for the purposes for which it is intended.'" *U.S. ex rel. Polansky v. Pfizer, Inc.*, 822 F.3d 613, 615 (2d Cir. 2016) (Citing 21 C.F.R. §201.5). The "intended use" of a drug is determined by the expressions of those legally responsible for labelling them, as well as "the circumstances surrounding the distribution of the [drug]." *Id.* Where accumulated circumstances and impressions lead a factfinder to determine that a drug is intended for an off-label use, the drug is misbranded, with civil and criminal consequences outlined by 21 U.S.C. § 333.

76. In sum, the FDA's regulatory regime protects patients and consumers by ensuring the drug companies do not promote drugs for uses other than those found to be safe and effective by an independent, scientific, governmental body—the FDA.

IV. THE DRUG

77. INSYS manufactures and markets Subsys throughout the United States, and has done so since January 2012, when the FDA approved Subsys for sale.

78. The FDA approved Subsys, a Schedule II opioid medication, for its only indication: the management of breakthrough cancer pain ("BTcP") in opioid-tolerant adults.

79. The ideal treatment for BTcP is a "strong, short-acting opioid medication that works quickly and lasts about as long as a breakthrough pain episode."[1] Fentanyl, an opioid roughly 100 times as potent as morphine, provides the strength needed to treat BTcP, and Subsys' spray delivery allows the patient to absorb the drug much more quickly than would be possible with a pill or lozenge.

80. Subsys has a high potential for abuse and addiction, and its misuse can cause death from respiratory depression.

81. Due to its status as a dangerous "TIRF" (Transmucosal Immediate Release Fentanyl) drug, the FDA approved Subsys for a specific indication, explained by its labeling information, and mandated that patients, prescribing physicians, and distributing pharmacies comply with a "REMS" (Risk Evaluation and Mitigation Strategy).

[1] Farrar J Et al. Oral transmucosal fentanyl citrate: randomized, double-blinded, placebo-controlled trial for treatment of breakthrough pain in cancer patients. J Natl Cancer Inst. 1998;90:611-616. Available at: https://www.oncolink.org/support/side-effects/pain-management/overview-of-pain/fact-sheet-breakthrough-pain (Last Visited: October 4, 2016).

82. Despite these restrictions, its limited indication for cancer patients, and stagnant growth in other TIRF sales, Subsys revenue jumped to $462 million in 2015. Prescriptions for Subsys grew to 49,063 and, since late 2014, Subsys has been the most prescribed TIRF drug (with approximately 48% market share). The majority of prescriptions written by doctors during this period were for off-label uses rather than the FDA-approved BTcP indication. These off-label uses included, but were not limited to, the use of Subsys for non-cancer chronic pain, post-operative pain, and headaches.

A. FDA-Approved Indication

83. The FDA approved the promotion of Subsys "for management of breakthrough pain in cancer patients 18 years of age or older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."[2] (See page 1 of Subsys label)

[2] Subsys label. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/202788s000lbl.pdf

a.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use SUBSYS safely and effectively. See full prescribing information for SUBSYS.
SUBSYS™ (fentanyl sublingual spray), CII
Initial U.S. Approval: 1968

WARNING: RISK OF RESPIRATORY DEPRESSION, MEDICATION ERRORS, ABUSE POTENTIAL
See full prescribing information for complete boxed warning.

- Due to the risk of fatal respiratory depression, SUBSYS is contraindicated in opioid non-tolerant patients (1) and in management of acute or postoperative pain, including headache/migraines. (4)
- Keep out of reach of children. (5.3)
- Use with CYP3A4 inhibitors may cause fatal respiratory depression. (7)
- When prescribing, do not convert patients on a mcg per mcg basis from any other oral transmucosal fentanyl product to SUBSYS. (5.1)
- When dispensing, do not substitute with any other fentanyl products. (5.1)
- Contains fentanyl, a Schedule II controlled substance with abuse liability similar to other opioid analgesics. (9.1)
- SUBSYS is available only through a restricted program called the TIRF REMS Access program. Outpatients, healthcare professionals who prescribe to outpatients, pharmacies, and distributors are required to enroll in the program. (5.10)

----------INDICATIONS AND USAGE----------
SUBSYS is an opioid agonist indicated for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. Patients must remain on around-the-clock opioids when taking SUBSYS. (1)
Limitations of Use:
SUBSYS may be dispensed only to patients enrolled in the TIRF REMS ACCESS program.

----------DOSAGE AND ADMINISTRATION----------
- Patients must require and use around-the-clock opioids when taking SUBSYS. (1)
- Initial dose of SUBSYS: 100 mcg.
- Individually titrate to a tolerable dose that provides adequate analgesia using a single SUBSYS dose per breakthrough cancer pain episode. (2)
- No more than two doses can be taken per breakthrough pain episode. (2.2)
- Wait at least 4 hours before treating another episode of breakthrough pain with SUBSYS. (2.3)
- Limit consumption to four or fewer doses per day once successful dose is found. (2.3)

----------DOSAGE FORMS AND STRENGTHS----------
- Sublingual spray in 100 mcg, 200 mcg, 400 mcg, 600 mcg, 800 mcg dosage strengths. (3)

----------CONTRAINDICATIONS----------
- Opioid non-tolerant patients. (4)
- Management of acute or postoperative pain including headache/migraine and dental pain (4)
- Intolerance or hypersensitivity to fentanyl, SUBSYS, or its components. (4)

----------WARNINGS AND PRECAUTIONS----------
- Clinically significant respiratory and CNS depression can occur. Monitor patients accordingly. (5.1)
- Full and consumed SUBSYS units contain medicine that can be fatal to a child. Ensure proper storage and disposal. (5.3, 16.2)
- Use with other CNS depressants and moderate or strong CYP450 3A4 inhibitors may increase depressant effects including respiratory depression, hypotension, and profound sedation. Consider dosage adjustments if warranted. (5.4)
- Titrate SUBSYS cautiously in patients with chronic obstructive pulmonary disease or preexisting medical conditions predisposing them to respiratory depression and in patients susceptible to intracranial effects of CO_2 retention. (5.6, 5.7)

----------ADVERSE REACTIONS----------
Most common adverse reactions during treatment (frequency ≥5%): vomiting, nausea, constipation, dyspnea, and somnolence. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Insys Therapeutics, Inc., at 1-855-978-2797 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

----------DRUG INTERACTIONS----------
- Boxed Warning and Warnings and Precautions (5.4, 7)

----------USE IN SPECIFIC POPULATIONS----------
- Safety and effectiveness in pediatric patients below 18 years of age have not been established. (8.4)
- Administer SUBSYS with caution to patients with liver or kidney dysfunction. (8.6)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 1/2012

84. Thus, the approval specifies a population of patients – adult cancer sufferers who have become opioid-tolerant from managing persistent pain – and an indication – breakthrough cancer pain. Any other use of the drug, because of a difference in population or indication, is off-label.

85. The FDA also determined that Subsys should only be prescribed by "pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain." (See page 4 of Subsys Label)

1 INDICATIONS AND USAGE
SUBSYS is indicated for the 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. Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid daily for a week or longer. Patients must remain on around-the-clock opioids when taking SUBSYS.

This product must not be used in opioid non-tolerant patients because life-threatening respiratory depression and death could occur at any dose in patients not on a chronic regimen of opioids. For this reason, SUBSYS is contraindicated in the management of acute or postoperative pain.

SUBSYS is intended to 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.

Limitations of Use:
As part of the Transmucosal Immediate-Release Fentanyl (TIRF) REMS ACCESS Program, SUBSYS may be dispensed only to outpatients enrolled in the program. [see *Warnings and Precautions* (5.10)]. For inpatient administration (e.g. hospitals, hospices, and long-term care facilities that prescribe for inpatient use) of SUBSYS, patient enrollment is not required.

2 DOSAGE AND ADMINISTRATION
Healthcare professionals who prescribe SUBSYS on an outpatient basis must enroll in the TIRF REMS ACCESS program and comply with the requirements of the REMS to ensure safe use of SUBSYS. [see Warnings and Precautions (5.10)]

As with all opioids, the safety of patients using such products is dependent on health care professionals prescribing them in strict conformity with their approved labeling with respect to patient selection, dosing, and proper conditions for use.

2.1 Initial Dose
Individually titrate SUBSYS to a dose that provides adequate analgesia and minimizes side effects. The initial dose of SUBSYS to treat episodes of breakthrough cancer pain is always 100 mcg. . When prescribing, do not switch patients on a mcg per mcg basis from any other oral transmucosal fentanyl product to SUBSYS as SUBSYS is not equivalent on a mcg per mcg basis with any other fentanyl product *[see Warnings and Precautions (5.2) and Clinical Pharmacology (12.3)]*.

Prescribe an initial titration supply of 100 mcg SUBSYS units, which limits the number of units in the home during titration.

Avoid prescribing a higher dose until patients have used up all units to prevent confusion and possible overdose.

2.2 Dose Titration

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a.

86. The FDA-approved label expressly provides that Subsys is contraindicated to post-surgical pain, migraine headaches, and dental pain. The label states: "Do not use SUBSYS: […] for short-term pain that you would expect to go away in a few days, such as: pain after surgery; headache or migraine; dental pain." (Subsys Label) (emphasis original).

87. In order to prevent potentially fatal side effects, and to reduce the risk of misuse and abuse, the FDA demanded that prescribing physicians limit patients to the lowest effective dose of the drug. This was to be achieved through "titration," a process by which patients begin taking the drug at 100 Mcg, and may step up the dosage in hundred microgram increments (maximum of two doses in any breakthrough pain episode or four-hour period, whichever is longer). While the highest dose of Subsys is 1600 Mcg, according to studies included in the FDA-approved label, BTcP is well managed in approximately 25% of patients at 400 Mcg or less.

B. TIRF-REMS Distribution Protocol

88. Due to the dangers associated with this class of drugs, the FDA required that Subsys and the other five FDA-approved "Transmucosal Immediate Release Fentanyl" (TIRF) products be accessed only through a Risk Evaluation and Mitigation Strategy (REMS) program. The FDA refers to this protocol as TIRF-REMS.

89. TIRF-REMS is intended to educate "prescribers, pharmacists, and patients on the potential for misuse, abuse, addition, and overdose" of TIRF drugs.

90. In order to comply with TIRF-REMS, prescribers and pharmacists must first enroll in the program.

91. The REMS program requires that prescribers and pharmacists review educational materials on the class of drugs and pass an online "Knowledge Assessment" exam.

92. The prescriber and pharmacist must then read and sign a "Prescriber [or Pharmacist] Enrollment Form," which lists the risks associated with TIRF drugs and requires the parties to acknowledge their responsibilities associated with prescribing and dispensing such a drug. The forms require the signing party to certify, in multiple ways, that they will comply with the labelling and TIRF-REMS protocol in prescribing and dispensing Subsys other TIRFs.

The TIRF REMS Access Program: Prescriber Enrollment Form

The Transmucosal Immediate Release Fentanyl (TIRF) REMS Access Program
Prescriber Enrollment Form

For real-time processing of enrollment, please go to www.TIRFREMSaccess.com.

To submit this form via fax, please complete all required fields below and fax pages 1, 2 and 3 to 1-866-822-1487. Please note, you must review the TIRF REMS Access Education Program and successfully complete the Knowledge Assessment to complete enrollment. If you have not completed the Knowledge Assessment online, please include it with this enrollment form. You will receive enrollment confirmation via email or fax.

I understand that TIRF medicines are only available through the TIRF REMS (Risk Evaluation and Mitigation Strategy) Access program and that I must comply with the program requirements. In addition, I acknowledge that:

1. I have reviewed the TIRF REMS Access Education Program, including the Full Prescribing Information for each TIRF medicine, and I have completed the Knowledge Assessment. I understand the responsible use conditions for TIRF medicines and the risks and benefits of chronic opioid therapy.
2. I understand that TIRF medicines can be abused and that this risk should be considered when prescribing or dispensing TIRF medicines in situations where I am concerned about an increased risk of misuse, abuse, or overdose, whether accidental or intentional.
3. I understand that TIRF medicines are indicated only for the management of breakthrough pain in patients with cancer, who are already receiving, and who are tolerant to, around-the-clock opioid therapy for their underlying persistent pain.
4. I understand that TIRF medicines are contraindicated for use in opioid non-tolerant patients, and know that fatal overdose can occur at any dose.
5. I understand that TIRF medicines must not be used to treat any contraindicated conditions described in the full Prescribing Information, such as acute or postoperative pain, including headache/migraine.
6. I understand that converting patients from one TIRF medicine to a different TIRF medicine must not be done on a microgram-per-microgram basis. I understand that TIRF medicines are not interchangeable with each other, regardless of route of administration, and that conversion may result in fatal overdose, unless conversion is done in accordance with labeled product-specific conversion recommendations (refer to the list of currently approved TIRF products located on the TIRF REMS Access website at www.TIRFREMSaccess.com/TirfUI/ProductList). Note, a branded TIRF medicine and its specific generic product(s) are interchangeable.
7. I understand that the initial starting dose for TIRF medicines for all patients is the lowest dose, unless individual product labels provide product-specific conversion recommendations, and I understand that patients must be titrated individually.
8. I will provide a Medication Guide for the TIRF medicine I intend to prescribe to my patient or their caregiver and review it with them. If I convert my patient to a different TIRF medicine, the Medication Guide for the new TIRF medicine will be provided to, and reviewed with my patient or their caregiver.
9. I will complete and sign a TIRF REMS Access Patient-Prescriber Agreement (PPAF) with each new patient, before writing the patient's first prescription for a TIRF medicine, and renew the agreement every two (2) years.
10. I will provide a completed, signed copy of the Patient-Prescriber Agreement (PPAF) to the patient and retain a copy for my records. I will also provide a completed, signed copy to the TIRF REMS Access program (through the TIRF REMS Access website or by fax) within ten (10) working days.
11. At all follow-up visits, I agree to assess the patient for appropriateness of the dose of the TIRF medicine, and for signs of misuse and abuse.

Prescriber Name* (please print):

For more information about TIRF medicines, please see Full Prescribing Information, including BOXED WARNINGS

93.

94.

The TIRF REMS Access Program: Independent Outpatient Pharmacy Enrollment Form

The Transmucosal Immediate Release Fentanyl (TIRF) REMS Access Program
Independent Outpatient Pharmacy Enrollment Form

For real-time processing of enrollment, please go to www.TIRFREMSaccess.com.

To submit this form via fax, please complete all required fields below and fax pages 1, 2, 3 and 4 to 1-866-822-1487. Please note, you must review the TIRF REMS Access Education Program and successfully complete the Knowledge Assessment to complete enrollment. If you have not completed the Knowledge Assessment online, please include it with this enrollment form. You will receive enrollment confirmation via email or fax.

I understand that TIRF medicines are only available through the TIRF REMS (Risk Evaluation and Mitigation Strategy) Access program and that I must comply with the program requirements. In addition, as the designated authorized independent outpatient pharmacy representative, I acknowledge that:

1. I have reviewed the TIRF REMS Access Education Program, and I have completed the Knowledge Assessment. I understand the risks and benefits associated with TIRF medicines and the requirements of the TIRF REMS Access program for pharmacies.
2. I will ensure that all pharmacy staff who participate in dispensing TIRF medicines are educated on the risks associated with TIRF medicines and the requirements of the TIRF REMS Access program, as described in the TIRF REMS Access Education Program. This training should be documented and is subject to audit.
3. I understand that converting patients from one TIRF medicine to a different TIRF medicine must not be done on a microgram-per-microgram basis. I understand that TIRF medicines are not interchangeable with each other, regardless of route of administration, and that conversion may result in fatal overdose, unless conversion is done in accordance with labeled product-specific conversion recommendations (refer to the list of currently approved TIRF products located on the TIRF REMS Access website at www.TIRFREMSaccess.com/TirfUI/ProductList). Note, a branded TIRF medicine and its specific generic product(s) are interchangeable.
4. I understand that TIRF medicines are contraindicated for use in opioid non-tolerant patients.
5. I understand that the initial starting dose for TIRF medicines for all patients is the lowest dose, unless individual product labels provide product-specific conversion recommendations, and I understand that patients must be titrated individually.
6. I understand the importance of discussing the risks and benefits of TIRF medicines with patients and their caregivers, and in particular the importance of taking the drug as prescribed, not sharing with others, and proper disposal.
7. I understand that the product-specific Medication Guide must be given to the patient or their caregiver each time a TIRF medicine is dispensed.
8. I understand that a TIRF medicine will not be dispensed without verifying through our pharmacy management system that the prescriber and pharmacy are enrolled and active, and that the patient has not been inactivated in the program.
9. I understand that ALL TIRF medicine prescriptions, regardless of the method of payment, must be processed through our pharmacy management system.
10. I understand that all dispensing locations must be enrolled in the TIRF REMS Access program to dispense TIRF medicines.
11. I understand that TIRF medicines can only be obtained from wholesalers/distributors that are enrolled in the TIRF REMS Access program.

Pharmacist Name* (please print):_____

For more information about TIRF medicines, please see Full Prescribing Information, including BOXED WARNINGS

95. Prior to submitting a prescription for filling by a pharmacy, the physician must discuss and have signed by the patient a Patient-Prescriber Agreement Form, which also lists the risks and responsibilities associated with the drug.

96. TIRF prescribers and pharmacies must re-enroll every two years, and may only have their TIRF prescriptions filled through pharmacies certified to do so.

V. INSYS' OFF-LABEL MARKETING SCHEME

97. INSYS waged a multi-pronged approach to build Subsys' market share, including direct and affirmative off-label promotion to potential prescribers.

98. INSYS' campaign bore success, gaining Subsys roughly 50% market share among TIRF drugs only two years after its FDA approval, though more than 80% of Subsys prescriptions cited off-label uses.

99. Although expressly contraindicated, INSYS promotes Subsys for post-surgical pain, resulting in off-label prescriptions. INSYS also promotes Subsys for musculoskeletal pain, fibromyalgia, neck pain, and back pain, all of which are off-label. Subsys has not been shown to be either safe or effective for these conditions. In fact, prescribing opioids for back and neck pain is often harmful and may ultimately lead to increased pain, dysfunction, and disability.

100. Relator expressed concerns to sales managers on several occasions, regarding the over-prescription of Subsys to non-Cancer patients who may have been better served by a less dangerous and less addictive analgesic. On one occasion, Relator told her Sales Manager, SM #1, that she wanted to increase her sales, but feared the consequences for patients whose opioid-tolerance and potential for addiction might increase unnecessarily. SM #1 responded incredulously, stating: "They are already addicts." Rather than treat Relator's concerns about potential over-prescription seriously, SM #1 dismissed those concerns and advised Relator to behave more sexually toward

pain-management physicians, to stroke their hands while literally begging for prescriptions. SM #1 advised Relator to ask physicians to prescribe Subsys as "a favor." SM #1 told Relator that these patients would not get worse as a consequence of unnecessarily taking Subsys,that they were already addicts and their prospects were therefore essentially rock-bottom.

101. INSYS encourage its sales staff, including Relator, to advise doctors to start patients on high doses of Subsys and push existing patients to "titrate up" to higher levels of medication usage and maintain their use round-the-clock, rather than as a response to breakthrough instances of pain.

102. In spite of the unnecessary dangers posed to non-cancer patients, INSYS instructed its sales staff to enroll new prescribers in the TIRF-REMS program and lavish them with constant attention, free meals and other remuneration in order to increase Subsys prescriptions to pain management patients.

A. Promotion of Subsys for Off-Label Indications

103. From Subsys' approval in 2012, INSYS promoted the drug for off-label indications, by targeting pain management specialists and internists and neurologists with the majority of its sales staff and reserving a smaller (now defunct) sales wing for calling on oncologists.

104. Upon beginning work at INSYS in 2014, Relator received marketing materials referencing only cancer patients, yet she was advised during training that

oncologists do not tend to prescribe pain management drugs, and that she should find a general prescriber of TIRFs and "live in their office," in order to educate an internist or pain-management physician about prescribing Subsys for an off-label use.

105. Relator received further advice as to which practice specialties and physician personality types she should target. INSYS sales trainers provided four targets, besides internists: "(1) Physiatrists (PM&R (Pain Management and Rehabilitation)); (2) Anesthesiologists; (3) Neurologists (neuropathic pain/migraine); and (4) Psychiatrists."

106. INSYS sales staff targeted prescribers of other TIRF drugs (including Cephalon's Actiq) for the sale of Subsys, despite the fact that sales representatives knew many of those physicians prescribe TIRF drugs for off-label uses. By the close of 2014, approximately 80% of Subsys prescriptions were filled for off-label uses.

107. As an incentive to its sales force, INSYS offered bounties of between $500 and $800 for each instance in which the sales representative was successful in having a patient switch to Subsys from another TIRF drug. INSYS paid this bounty irrespective of the type of use for which the drug was prescribed.

108. During her time at INSYS, Relator found that oncologists began to shy away from prescribing Subsys for BTcP, as the drug had developed a stigma. Physicians associated Subsys with INSYS' unscrupulous sales practices and considered its indication for cancer pain a mere pretext for its actual intended use, off-label pain management for opioid addicts.

109. Relator was advised to offer free Subsys for non-cancer patients where necessary to ensure coverage for the drug by payors, including government healthcare programs. In doing so, INSYS informed Relator that (1) authorization would be more likely after three months to a year of use, and (2) the patient would grow dependent on the medication during that time, ensuring a long prescribing relationship.

B. INSYS Advised Prescription of Off-Label Doses of Subsys

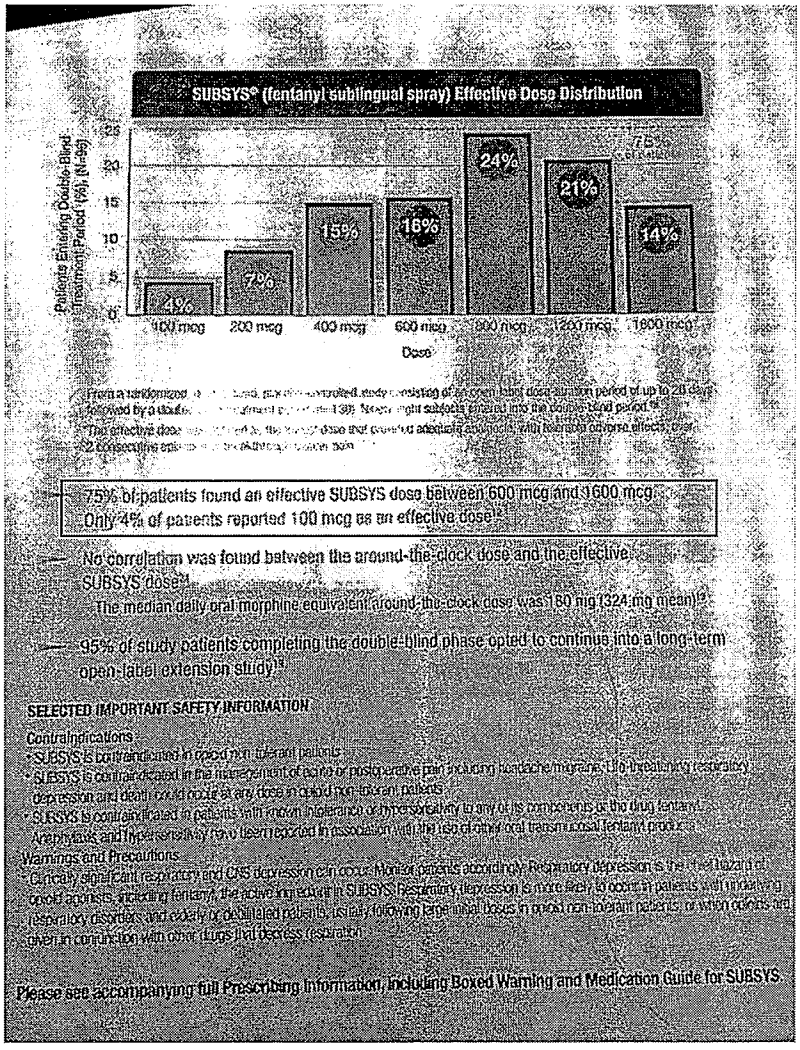
110. INSYS sales staff, led by management, consistently sought to increase revenue through promoting (1) medically unnecessary high doses of Subsys, and (2) the prescription of Subsys for continuous, rather than emergency, use.

111. INSYS sales managers lectured sales staff, repeatedly, that the key to making more money was successfully encouraging physicians and patients to use higher doses of Subsys. Quite simply, the higher the Subsys dose, the more revenue generated by INSYS and, therefore, greater sales commissions to be earned by Subsys' sales representatives. Notably, INSYS' compensation structure is unique in that sales representatives earn relatively low salaries (i.e., $40,000 per year) while maintaining the right to generate substantially more income through incentive-laden commissions.

112. Subsys' FDA-approved labeling states that new patients are to begin using Subsys in 100 Mcg increments. (Subsys Label).

113. However, INSYS sales staff stressed to physicians that the 100 Mcg dose was ineffective for all but 4% of patients. (See Subsys Dose Chart). Sales staff were

taught to disregard the fact that the entry titration dose is intended to be small, and thus safe, and instead instructed to convince physicians to double the entry dose, so that patients would immediately "feel the drug working." Sales managers complained that the 100 Mcg initial dose risked causing patients to think the drug ineffective. As such, they disregarded the label and promoted the off-label dose.



114. In fact, INSYS sales representatives were instructed to recommend beginning patients on a 200 Mcg dose. One sales manager advised relator that some

patients begin at a 400 Mcg dose. In line with INSYS policy, sales representatives, including Relator, advised prescribers to begin at 200 Mcg and expect an increase to at least 400 Mcg through titration during the first month of use. INSYS directed Relator and other sales representatives advised titration to an eventual dosage between 600 Mcg and 1600 Mcg.

115. Sales managers directed sales representatives, including Relator, to advise patients directly that they should begin at 200 Mcg, wait 30 minutes, and repeat the same dose if still in pain. Representatives were to advise patients that they should increase to the next dose (in 200 Mcg increments) after four hours and try again if symptoms remained. This contradicts Subsys' label, which states "When you are first prescribed Subsys, your healthcare provider will start you with the lowest strength medicine, and change that dose until you and your healthcare provider find the right dose for you."

116. Further, INSYS sales staff advised physicians and patients that patients should manage the titration without informing the treating physician of dosing changes during the titration process. This directly contradicts Subsys' label.

117. Joe Rowan, INSYS' Director of Sales for the East Coast, advised sales representatives, including Relator, that patients should be pushed to a baseline dosage of 400-800 Mcg, in hopes that continued use would increase the baseline toward 1600 Mcg. He lectured, during a sales meeting, that sales representatives would make their bonuses by the patient titrating closer and closer to 1600 Mcg.

118. In meetings and on "ride-along" drives with other sales staff, Relator was encouraged to inform doctors and patients that an average effective dose was between 600 and 1600 Mcg. According to studies included in the drug's FDA label, however, breakthrough pain is managed in approximately 25% of patients at 400 Mcg or fewer.

C. Use of IRC to Authorize Insurance Reimbursement for Off-Label Uses

119. In order to ensure authorization of payment for a Subsys prescription by a patient's insurer and the drug's dispensing by a pharmacy, INSYS provided its sales staff with a Patient Authorization & Referral ("Prior Authorization") form, the ability to provide as much as a year of free Subsys to establish a pattern of use, an INSYS Reimbursement Center ("IRC") to persuade insurers, and a pattern appeal letter, to be provided to the physician in the event of denial. Each of these methods breached FDA regulations.

120. INSYS employs a group known as the "INSYS Reimbursement Center," ("IRC") to communicate with pharmacies and insurers on behalf of the doctor and patient, to ensure authorization and dispensing of Subsys. According to Relator, sales representatives understood that IRC staff are known to do whatever is necessary, including lying, to ensure prior authorization for Subsys prescriptions.

121. At the outset of a sales relationship, INSYS sales representatives attempt to enroll healthcare providers in the INSYS Patient Services Center, by providing HIPAA waivers for likely Subsys patients to the IRC. Once this has occurred, the sales

representative supplies the potential prescriber with INSYS Prior Authorization forms, documents which, when filled with doctor and patient specific information and signatures, allows the IRC to attempt to gain prior authorization. Finally, the physician, like the pharmacy which will eventually fill the prescription, must enroll in the TIRF-REMS access program, by taking an online exam and signing liability waivers, all intended to mitigate the risks associated with prescribing drugs like Subsys.

122. Once a physician qualifies to prescribe Subsys and writes a prescription to do so, the IRC's prior authorization mechanism unfolds in the following manner:

a. INSYS' sales representative provides a partially pre-populated INSYS Prior Authorization form to patient, and assists in its completion.

b. Prescribing physician completes the Prior Authorization form and returns it to INSYS' sales representative.

c. INSYS' sales representative or physician's office staff faxes the form to IRC.

d. IRC staff contact the relevant Medicare Part D insurer (or other insurer) and plead INSYS' case for reimbursement of the cost of Subsys.

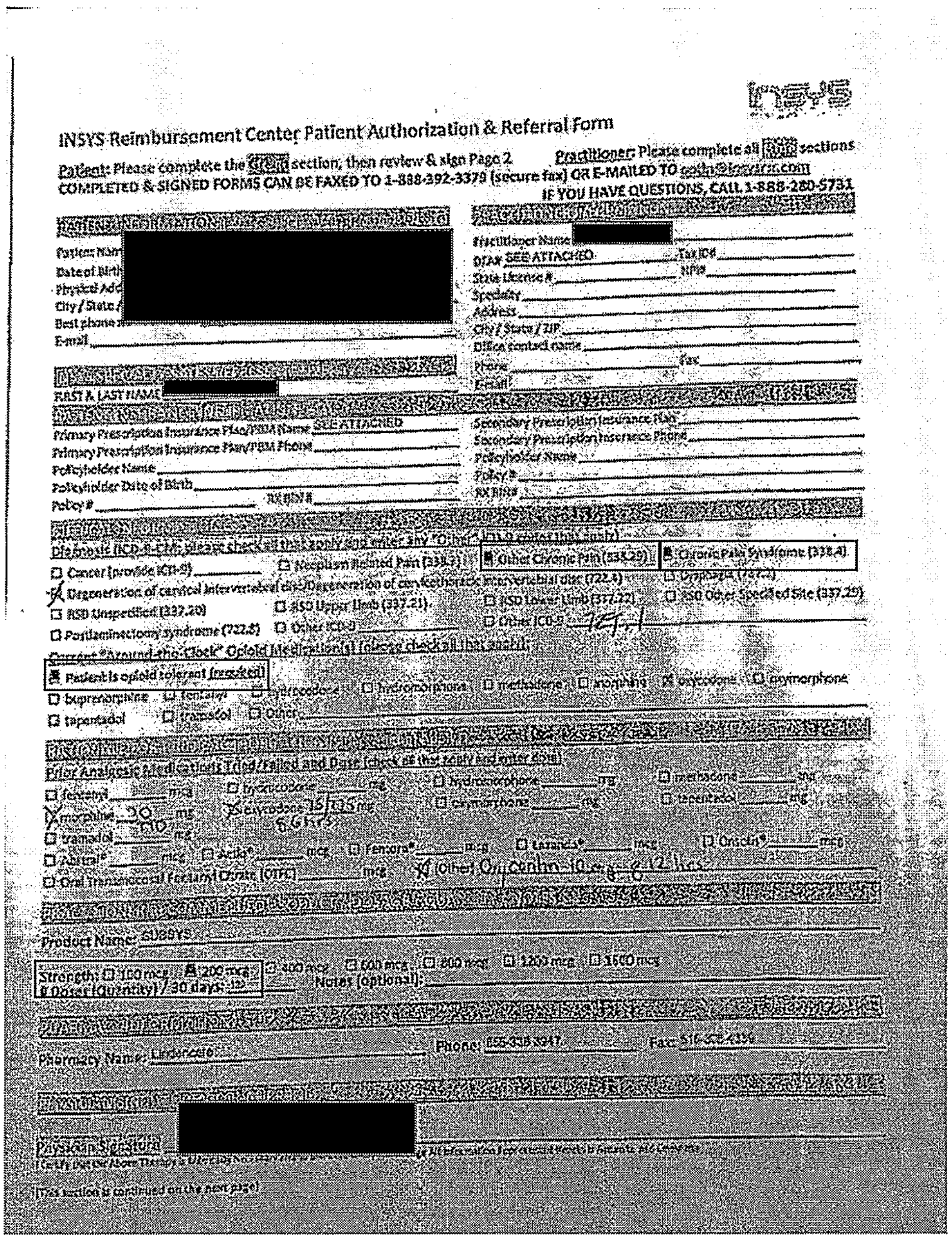
e. If the insurer agrees to reimburse, the drug is dispensed.

f. If the insurer refuses to reimburse, INSYS provides up to a year of free Subsys to the patient. After months of Subsys use by the patient, during

which time the patient has likely become dependent on the drug, INSYS re-submits the request for reimbursement, citing the three months of use. Relator reports that this regularly worked, that INSYS won reimbursement by providing three months of free product, recouping its outlay in the process.

123. Upon information and belief, this process has afforded INSYS a radically higher rate of insurer authorization than corresponding figures for any of the five other TIRF drugs now sold.

124. During Relator's initial training, Relator's field sales trainer, Sales Representative #1 ("SR #1") showed Relator folders she had prepared for individual physicians, containing pre-populated prior authorization forms. Later, Sales Representative #2 (SR #2), another of Relator's local colleagues, showed Relator prepopulated forms up close. Relator and her colleagues pre-populated the form (below) at the lines with filled in squares: "Diagnosis: Other chronic pain," "Diagnosis: chronic pain syndrome," "Patient is Opioid Tolerant," and "Strength: 200 Mcg." That is, INSYS sales staff pre-populated the form with off-label indications and an off-label initial dosage.



INSYS Reimbursement Center Patient Authorization & Referral Form

Patient: Please complete the GREEN section, then review & sign Page 2 Practitioner: Please complete all BLUE sections

COMPLETED & SIGNED FORMS CAN BE FAXED TO 1-888-392-3379 (secure fax) OR E-MAILED TO

IF YOU HAVE QUESTIONS, CALL 1-888-280-5731

Patient Name [redacted]

E-mail

Practitioner Name [redacted]

DEA# SEE ATTACHED Tax ID# NPI#

State License # Specialty Address City / State / ZIP Office contact name Phone Fax E-mail

FIRST & LAST NAME [redacted]

Primary Prescription Insurance Plan/PBM Name SEE ATTACHED

Primary Prescription Insurance Plan/PBM Phone

Policyholder Name

Policyholder Date of Birth

Policy # RX BIN #

Secondary Prescription Insurance Plan

Secondary Prescription Insurance Phone

Policyholder Name Policy # RX BIN #

Diagnosis (ICD-9-CM): please check all that apply and enter any "Other" ICD-9 codes that apply

☐ Cancer (provide ICD-9) ☐ Neoplasm Related Pain (338.3) ☒ Other Chronic Pain (338.29) ☒ Chronic Pain Syndrome (338.4)

☒ Degeneration of cervical intervertebral disc/Degeneration of cervicothoracic intervertebral disc (722.4) ☐ Dysphagia (787.2)

☐ RSD Unspecified (337.20) ☐ RSD Upper Limb (337.21) ☐ RSD Lower Limb (337.22) ☐ RSD Other Specified Site (337.29)

☐ Postlaminectomy syndrome (722.8) ☐ Other ICD-9 ☐ Other ICD-9 723.1

Current "Around-the-Clock" Opioid Medication(s) (please check all that apply):

☒ Patient is opioid tolerant (required)

☐ buprenorphine ☐ fentanyl ☐ hydrocodone ☐ hydromorphone ☐ methadone ☐ morphine ☒ oxycodone ☐ oxymorphone

☐ tapentadol ☐ tramadol ☐ Other

Prior Analgesic Medication(s) Tried/Failed and Dose (check all that apply and enter dose)

☐ fentanyl ___ mcg ☐ hydrocodone ___ mg ☐ hydromorphone ___ mg ☐ methadone ___ mg

☒ morphine 30 mg 100 ☒ oxycodone 15/10 5 mg 6 hrs ☐ oxymorphone ___ mg ☐ tapentadol ___ mg

☐ tramadol ___ mg

☐ Abstral® ___ mcg ☐ Actiq® ___ mcg ☐ Fentora® ___ mcg ☐ Lazanda® ___ mcg ☐ Onsolis® ___ mcg

☐ Oral Transmucosal Fentanyl Citrate (OTFC) ___ mcg ☒ Other Oxycontin 10 mg ε 12 hrs

Product Name: SUBSYS

Strength: ☐ 100 mcg ☒ 200 mcg ☐ 400 mcg ☐ 600 mcg ☐ 800 mcg ☐ 1200 mcg ☐ 1600 mcg

Doses (Quantity) / 30 days: 120 Notes (optional):

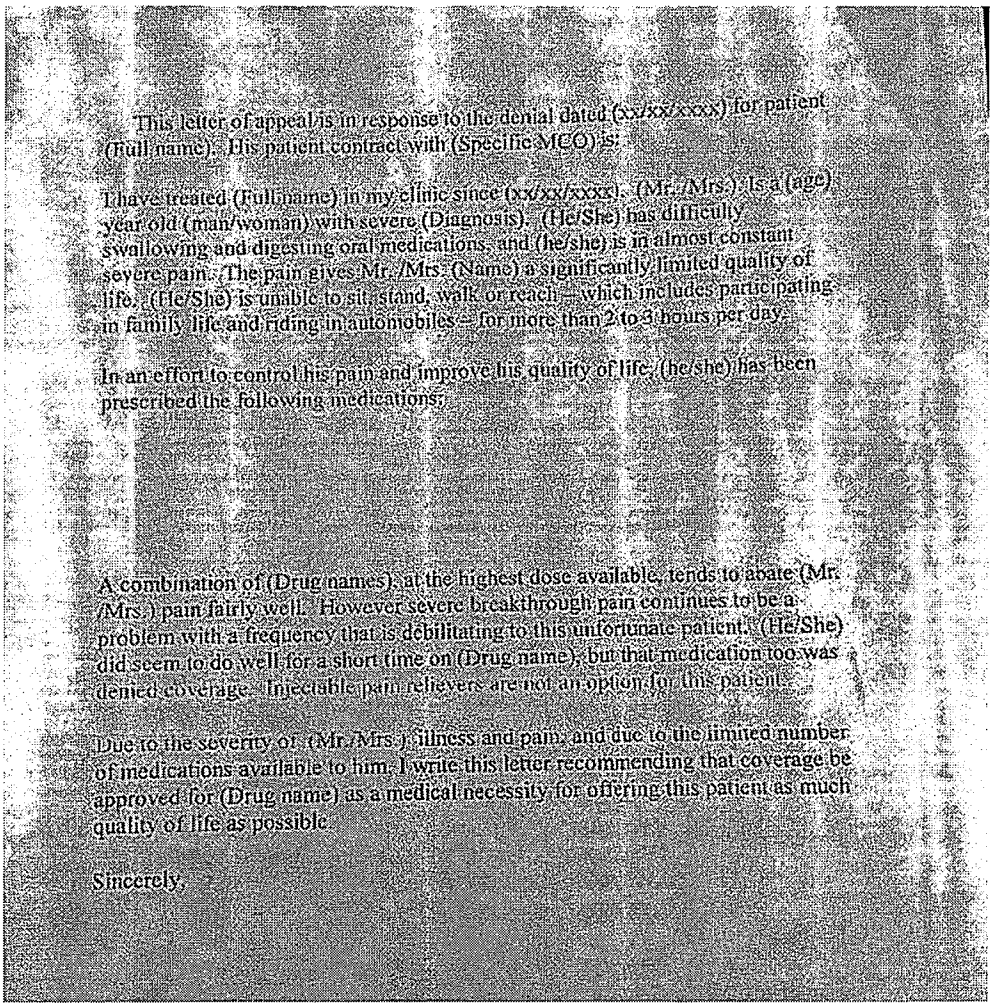
Pharmacy Name: Linden Care Phone: 855-338-3947 Fax: 516-308-4356

Physician Signature [redacted]

(This section is continued on the next page)

125. On October 13, 2014, Relator-Plaintiff, feeling uncomfortable about the process, asked SR #1 if she was permitted to fill out the prior authorization form on behalf of the patient or physician, and received a text in return, stating, "No, but yes." Pursuant to this instruction by an INSYS representative, Relator met with patient and partially filled out the prior authorization form for the doctor.

126. When the prior authorization process was not successful, INSYS instructed its sales staff to provide physicians an appeal letter, to be filled out and forwarded to IRC for submission to the insurer. This letter (below) does not mention cancer. Rather, it provides a general scheme by which someone with any foreseeable off-label intended used might argue that they should have the drug authorized by their insurer.



This letter of appeal is in response to the denial dated (xx/xx/xxxx) for patient (Full name). His patient contract with (Specific MCO) is:

I have treated (Full name) in my clinic since (xx/xx/xxxx). (Mr./Mrs.) is a (age) year old (man/woman) with severe (Diagnosis). (He/She) has difficulty swallowing and digesting oral medications, and (he/she) is in almost constant severe pain. The pain gives Mr./Mrs. (Name) a significantly limited quality of life. (He/She) is unable to sit, stand, walk or reach – which includes participating in family life and riding in automobiles – for more than 2 to 3 hours per day.

In an effort to control his pain and improve his quality of life, (he/she) has been prescribed the following medications:

A combination of (Drug names), at the highest dose available, tends to abate (Mr./Mrs.) pain fairly well. However severe breakthrough pain continues to be a problem with a frequency that is debilitating to this unfortunate patient. (He/She) did seem to do well for a short time on (Drug name), but that medication too was denied coverage. Injectable pain relievers are not an option for this patient.

Due to the severity of (Mr./Mrs.) illness and pain, and due to the limited number of medications available to him, I write this letter recommending that coverage be approved for (Drug name) as a medical necessity for offering this patient as much quality of life as possible.

Sincerely,

127. Where neither prior authorization nor appeal succeeded, INSYS instructed and permitted Relator to provide free Subsys to a given patient for up to three months.

128. INSYS sales mangers advised sales staff to bargain with physicians leery of undergoing the authorization process. As Relator noted during her training, "Give us 1 wk – Doesn't get approved we will give pt free meds."

129. Relator provided free medication to patients for up to a year. During that time, the IRC attempted prior authorization again to increase the likelihood that the prescription claims would be paid including by government healthcare programs.

D. Evasion of TIRF-REMS

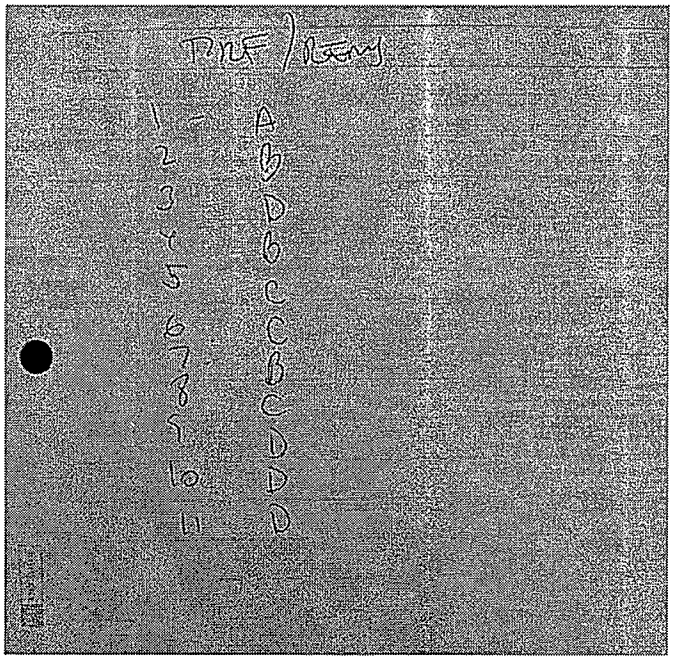
130. Fentanyl's deadly potency motivated the FDA to mandate that prescribers and pharmacists enroll in TIRF-REMS prior to putting TIRF drugs in the hands of patients. TIRF-REMS requires prescriber/pharmacist accreditation and forces prescribers and pharmacists to pass an exam and make a series of certifications in order to become accredited. INSYS' sales managers instructed sales staff to enroll physicians in TIRF-REMS, a necessary predicate to prescribing Subsys. To assist in this effort, sales staff continually circulated "cheat sheets" with TIRF-REMS educational assessment answers, to relieve potential prescribers of their duty to read the TIRF-REMS website and to ensure that the prescriber would be qualified.

131. INSYS assigned Relator a territory with only a few physicians who were qualified to write scripts for Subsys under the TIRF-REMS program.

132. Given the requirement that prescribing physicians comply with TIRF-REMS by enrolling in the program, taking the exam, and signing the acknowledgment, INSYS

management instructed sales staff to "do whatever it takes" to enroll potential prescribers in the program.

133. These efforts included supplying prescribers and their staff with "cheat sheets". Relator learned of the "cheat sheets" from Sales Representative #3 ("SR #3"). Relator received the answers from a colleague on a sheet of notebook paper and gave that paper to office staff, considering it common practice. A copy of one such "cheat sheet" is illustrated below:



134. As a result of INSYS' distribution of the answers to the test, INSYS caused physicians to circumvent the educational requirement of the TIRF-REMS program which was intended to ensure that prescribers understood the dangerous potential downsides to opioid prescriptions, particularly for unintended uses.

135. The educational component was designed to ensure that physicians would write prescriptions for Subsys responsibly and protect patients against injury.

136. If the United States had known that physicians were making false certifications to the TIRF-REMS program, the Government Healthcare Programs would not have paid for prescriptions written by them.

E. INSYS' Off-Label Promotion Amounted to Misbranding

137. INSYS misbranded Subsys by advising doctors to prescribe high doses, to prescribe for off-label uses, and to prescribe to non-cancer patients. These actions manifested an "intended use" separate from that approved by the FDA, one which Subsys' label directions fail to render safe by a lay user.

138. A drug is misbranded if its labelling fails to provide "adequate directions for use." 21 U.S.C. § 352(f). Adequate directions are those which will allow a lay patient to safely use the drug for its "intended use." 21 C.F.R. §201.5.

139. A drug's "intended use" is that use manifested by those who label and distribute it. 21 C.F.R. § 201.6.

140. With respect to Subsys, INSYS sent its sales staff to "live" in the offices of internists, physiatrists who do not focus on cancer-pain treatment, neurologists, and psychiatrists. Of the twenty sales representatives at Relator's initial training, only four were tasked with marketing Subsys (at that time INSYS' only approved drug) to oncologists. The remaining sales representatives were hired to the "Pain Management"

wing of the sales staff. During the course of Relator's employ, INSYS joined the oncology and pain management wings.

141. The result, unsurprisingly, was off-label prescriptions. The off-label Subsys uses amounted to approximately 80 to 90% of the drug INSYS sold.

142. INSYS facilitated this off-label promotion by hiring additional sales staff to find new prescribers. When Relator was hired, she received an "expansion territory." That is, other sales representatives in Relator's territory gave up work with two to four TIRF-REMS qualified prescribers, and Relator began selling to those physicians. INSYS provided Relator a list of physicians in her area which included many internal medicine practitioners mislabeled as oncologists, and tasked Relator with selling to them as well. By handing out new territories to new sales reps without existing prescribers, INSYS encouraged them to promote the message which resulted in off-label prescriptions.

143. With most prescriptions not written for the Subsys indication, INSYS has expanded the list of intended uses for Subsys to include non-cancer pain and post-operative pain, among other uses.

144. Further, INSYS expanded the type of pain for which the drug was used, from BTcP, to breakthrough pain in non-cancer patients, to persistent pain. The expansion to persistent pain raised revenues dramatically, as it led to the use of Subsys every four hours, independent of the scale of pain the patient felt at any given time. Thus,

INSYS turned Subsys, an analgesic roughly 100 times as powerful as morphine, into a maintenance opioid, like OxyContin or Oxycodone.

145. This amounts to misbranding by INSYS as Subsys' FDA-approved label does not provide adequate directions for these uses. Neither the label nor any TIRF-REMS documentation provide information which will allow a lay patient to safely use the drug for these purposes. In fact, the label clearly indicates that the drug is contraindicated for use of the drug for migraines, post-operative pain, and dental pain. The label states, "If the patient experiences greater than four breakthrough pain episodes per day, the dose of the maintenance (around-the-clock) opioid used for persistent pain should be re-evaluated." INSYS' misbranding rendered this precaution inert, and serves as clear evidence of the substitution of a different, dangerous use for the original FDA-approved indication.

146. Relator was instructed to hand out materials concerning the use of Subsys to all patients regardless of indication. For the majority of these patients, the marketing materials and label did not apply. Patient #1, as discussed later in more detail, was the patient of a prescriber that Relator called upon. Patient #1 did not have cancer and received twice the FDA-approved starting dose of Subsys.

147. INSYS misbranded Subsys by promoting it for off-label uses for which it would assuredly be used as a maintenance medication. Subsys' approval for BTcP, and INSYS' promotion of the drug for chronic, non-cancer pain, coupled with INSYS'

assistance of physicians who prescribed the drug for continuous use, rather than "As Needed", created a situation in which the drug's labeling could not provide adequate instructions to ensure the safety of its intended uses.

F. Improper Payment by Government Healthcare Programs

148. INSYS' off-label marketing efforts caused potentially hundreds of thousands of prescriptions to be improperly paid for by Government Healthcare Programs.

149. In the Medicaid Program, States will not receive FFP ("Federal Financial Participation") if a drug, as prescribed, is not for a medically acceptable use. FFP is available to states only for "covered outpatient drugs." 42 U.S.C. § 1396b(i)(10). As a result, States' own laws and pharmacy regulations require that drugs must be used for a medically accepted use and therefore fit the definition of a covered outpatient drug. "Covered outpatient drugs" do not include drugs that are used for a medical indication which is not a medically accepted indication. 42 U.S.C. § 1396r-8(k)(3).

150. A medically accepted indication is defined as a use "which is approved under the Federal Food Drug and Cosmetic Act" ("FDCA") or which is "supported by one or more citations included or approved for inclusion" in specified drug compendia. 42 U.S.C. § 1396r-8(k)(6). 42 U.S.C.§ 1396r-8(g)(1)(B)(I) identifies the compendia to be consulted: American Hospital Formulary Service Drug Information; United States

Pharmacopeia-Drug Information; the DRUGDEX Information System; and the peer-reviewed medical literature.

151. Medicare Part A generally pays for inpatient services for eligible beneficiaries in hospital, hospice and skilled nursing facilities, as well as some home healthcare services. 42 U.S.C. §§1395e - 42 U.S.C. §§1395i-5. Prescription drugs are covered under Medicare Part A only if they are administered on an inpatient basis in a hospital or similar setting, and are "reasonable and necessary."

152. Medicare Part B pays for some types of prescription drugs that are not administered in a hospital setting, and that are "reasonable and necessary." 42 U.S.C. §1395k(a); 42 U.S.C. §1395x(s)(2); 42 C.F.R. §405.517. These typically include drugs administered by a physician or other provider in an outpatient setting, some orally administered anti-cancer drugs and antiemetics, and drugs administered through durable medical equipment such as a nebulizer. 42 U.S.C. §1395k(a); 42 U.S.C. §1395x(s)(2); 42 C.F.R. §405.517.

153. The Medicare Part D drug benefit program covers all drugs that are considered "covered outpatient drugs" under 42 U.S.C. §1396r-8(k).

154. The off-label uses discussed herein are not supported by "clinical research that appears in peer-reviewed medical literature," and could not, under any circumstances, be determined to be "medically accepted as safe and effective" or

"reasonable and necessary" for such uses. Claims for such off-label uses were therefore not covered by Medicare either.

155. INSYS was aware that the natural and probable consequence of its promotion of off-label uses of Subsys was that health care providers would submit claims for payment to Government Healthcare Programs for the off-label use.

156. Notwithstanding this knowledge, INSYS illegally, vigorously, and without any thought to the possible negative health effects to which it subjected patients, promoted these off-label uses. INSYS was aware that its illegal promotion did in fact result in false claims to these and other government payors for the off-label uses. INSYS was aware that its promotion activities were a substantial factor in producing the claims.

157. When LINDEN CARE and other pharmacies and healthcare providers submitted claims based upon a physician's prescription for Subsys for off-label uses, the claims they submitted were false because such off-label uses were not supported by a citation in one of the Drug Compendia specified by 42 U.S.C. § 1396r-8(g)(1)(B)(I), (Medicaid) not supported by "peer-reviewed medical literature," and could not, under any circumstances, be determined to be "medically accepted generally as safe and effective "or "reasonable and necessary." (Medicare) and not covered by other Government Healthcare Programs, See, e.g., TRICARE Policy Manual 6010.47-M, Chapter 7, Section 7.1 (B) (2) (March 15, 2002); CHAMPVA Policy Manual, Chapter 2, Section 22.1, Art. II (A)(2) (June 6, 2002).

158. INSYS' off-label marketing directly and proximately caused the off-label prescribing for which these claims to government healthcare programs were filed. INSYS caused the submission of these claims, since healthcare providers submitted Pharmacy Claim Forms and CMS-1500 Forms to Government Healthcare Programs, and the states submitted Form CMS-64 to the Federal Government, all claiming reimbursement for Subsys for such off-label uses.

VI. INSYS' KICKBACK SCHEME

159. From the moment Subsys entered the TIRF market, INSYS made clear to its sales staff that the drug would be sold by paying physicians for off-label prescriptions through sham "speaker" programs, in-kind donations, and other forms of illegal kickbacks.

160. At Relator's initial training, INSYS sales trainers educated her and her colleagues on how to identify potential prescribers as those to whom "money talks." When questioned as to what this meant, trainers stated that the way to generate prescriptions was to sign up and pay speakers.

161. In order to find these physicians, Relator was directed to search public disclosure data for those doctors who had accepted high speaking fees for presentations on behalf of fentanyl and other opioids.

162. In sales trainings, INSYS taught sales staff to classify physicians according to their perceived willingness to receive money for prescriptions.

163. INSYS sales managers taught sales staff to color code doctors, "green" being the most likely to accept kickbacks, "yellow" less so, and "red" unlikely, on the basis of personality traits. During Relator's field training, she learned to associate the likelihood of physicians becoming prescription writers with the dollar amounts attributed to them on propublica.org.

164. When sales districts failed to generate large numbers of new prescriptions, INSYS classified them as "low performing," and teamed them with "high performing" districts. Sales managers from "high performing" districts instructed sales staff from "low performing" districts to buy prescriptions by arranging for individuals to act as paid speakers on behalf of Subsys.

165. INSYS management participated in, encouraged, and authorized the unlawful payment of illegal kickbacks to physicians and pharmacists.

166. INSYS' kickback scheme had several components, including, but not limited to:

a. Paying prescribing physicians sham "speaking" fees to reward prescribers of Subsys for off-label uses;

b. Adding or removing presenters from speaking engagements based upon their propensity to prescribe Subsys;

c. Performing unpaid office work in prescribing physicians' offices, for the purpose of inducing prescriptions for off-label uses; and

d. Paying unauthorized speakers with restaurant and retail gift cards to reward Subsys prescriptions.

167. At Relator's initial training, directed by Alec Burlakoff, INSYS' Director of Sales, trainers told trainee sales representatives to find three to five doctors for routine visits, as well as one doctor who "wants you around at all times."

168. Burlakoff also lectured Relator and her colleagues to do whatever it took to be around the doctors, including providing office work at no cost. Relator and other sales representatives were trained to tell doctors to focus on identifying patients while ensuring the doctor that the sales representative will "run" the patient with the staff and pharmacy.

169. Alec Burlakoff, exhorted sales staff, including Relator, to do office work for potential prescribers including, for example, faxing documents related to prescription authorizations. .

170. INSYS also promoted sham "speaker" programs to improperly pay doctors and pharmacists to convince other doctors and pharmacists to prescribe Subsys for off-label uses.

171. Relator attended several "speaker" programs where no presentation was ever made yet the "speaker" was paid by INSYS.

172. For example, at 7:00 PM on October 2, 2014, Relator attended a speaker dinner at a popular steakhouse near her sales territory. Four sales representatives –

Relator, SR #1, SR #2, and SR #3 - attended along with four physicians – Doctor #2, Doctor #3, and two physicians whose names are not known. Though Doctor #2 received payment from INSYS for providing a presentation, he did not provide one. Rather, the meeting, held in a noisy steakhouse, consisted of dinner table discussion between the physicians and sales representatives present. The event was a sham, an excuse to pay Doctor #2 a large speaking fee in remuneration for his prescriptions and to buy dinner for the others present.

173. According to probublica.org, Doctor #2 accepted $46,482.00 in speaking fees, food and beverage, and travel and lodging on behalf of Subsys' promotion between August 2013 and the end of 2014. INSYS reported payments to Doctor #2 the surrounding the evening of the steakhouse dinner:

a. $127 in food and beverages on October 1, 2014;

b. $124 in food and beverage on October 2, 2014;

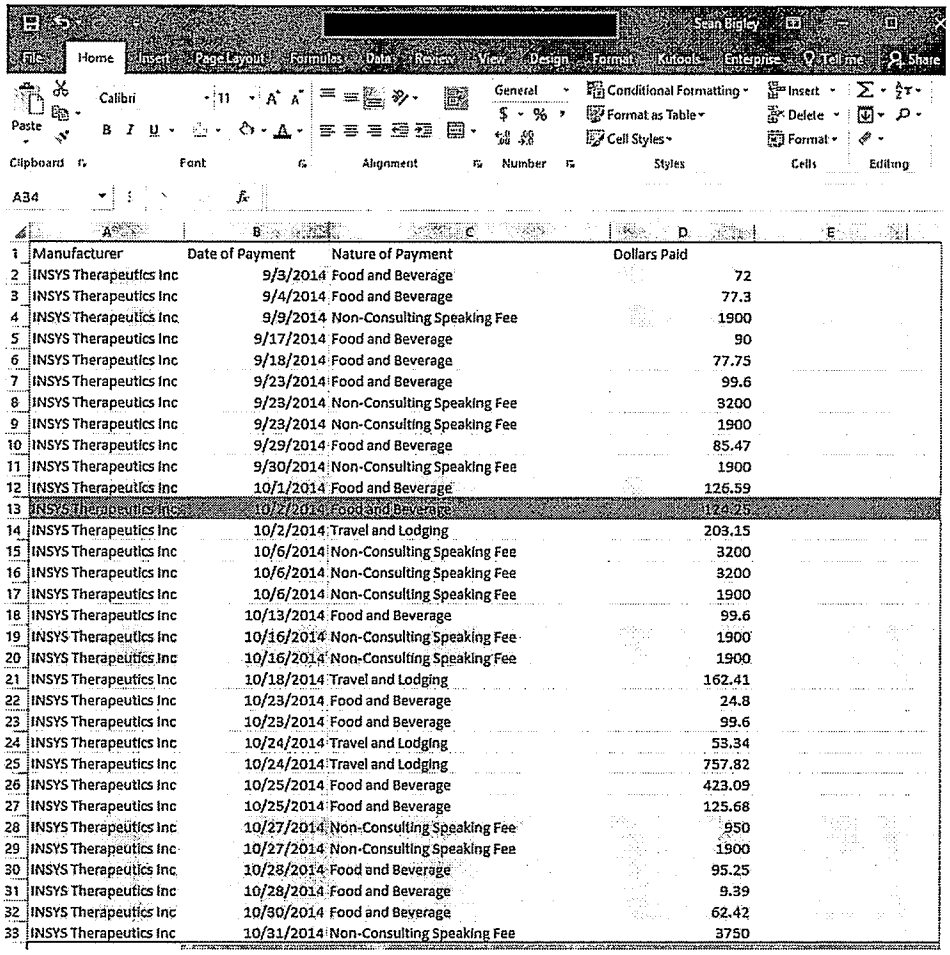
c. $203 in travel and lodging on October 2, 2014; and

d. $1900, $3200, and $3200 in Promotion Speaking/Other on October 6, 2014.

174. According to propublica.org, Doctor #3 accepted $28,854.00 in speaking fees, food and beverage, and travel and lodging on behalf of Subsys' promotion between August 2013 and the end of 2014. INSYS reported a payment of $124 for food and beverage for Doctor #3 on October 2, 2014, the day of the steakhouse dinner. The following spreadsheets compare the events for which Doctor #2 (first picture) and

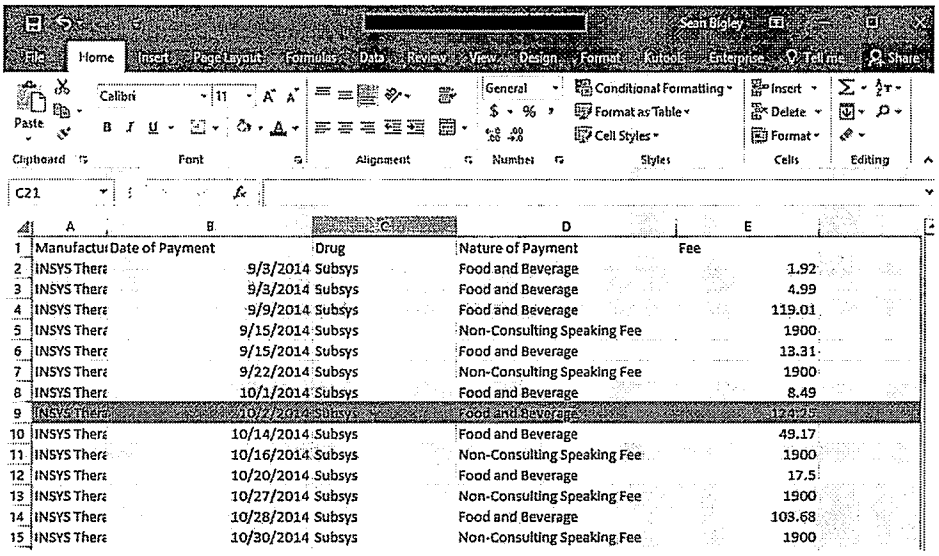
Doctor #3 (second picture) received payment from INSYS during the months of September and October 2014.

a.



	Manufacturer	Date of Payment	Nature of Payment	Dollars Paid
2	INSYS Therapeutics Inc	9/3/2014	Food and Beverage	72
3	INSYS Therapeutics Inc	9/4/2014	Food and Beverage	77.3
4	INSYS Therapeutics Inc	9/9/2014	Non-Consulting Speaking Fee	1900
5	INSYS Therapeutics Inc	9/17/2014	Food and Beverage	90
6	INSYS Therapeutics Inc	9/18/2014	Food and Beverage	77.75
7	INSYS Therapeutics Inc	9/23/2014	Food and Beverage	99.6
8	INSYS Therapeutics Inc	9/23/2014	Non-Consulting Speaking Fee	3200
9	INSYS Therapeutics Inc	9/23/2014	Non-Consulting Speaking Fee	1900
10	INSYS Therapeutics Inc	9/29/2014	Food and Beverage	85.47
11	INSYS Therapeutics Inc	9/30/2014	Non-Consulting Speaking Fee	1900
12	INSYS Therapeutics Inc	10/1/2014	Food and Beverage	126.59
13	INSYS Therapeutics Inc	10/2/2014	Food and Beverage	124.25
14	INSYS Therapeutics Inc	10/2/2014	Travel and Lodging	203.15
15	INSYS Therapeutics Inc	10/6/2014	Non-Consulting Speaking Fee	3200
16	INSYS Therapeutics Inc	10/6/2014	Non-Consulting Speaking Fee	3200
17	INSYS Therapeutics Inc	10/6/2014	Non-Consulting Speaking Fee	1900
18	INSYS Therapeutics Inc	10/13/2014	Food and Beverage	99.6
19	INSYS Therapeutics Inc	10/16/2014	Non-Consulting Speaking Fee	1900
20	INSYS Therapeutics Inc	10/16/2014	Non-Consulting Speaking Fee	1900
21	INSYS Therapeutics Inc	10/18/2014	Travel and Lodging	162.41
22	INSYS Therapeutics Inc	10/23/2014	Food and Beverage	24.8
23	INSYS Therapeutics Inc	10/23/2014	Food and Beverage	99.6
24	INSYS Therapeutics Inc	10/24/2014	Travel and Lodging	53.34
25	INSYS Therapeutics Inc	10/24/2014	Travel and Lodging	757.82
26	INSYS Therapeutics Inc	10/25/2014	Food and Beverage	423.09
27	INSYS Therapeutics Inc	10/25/2014	Food and Beverage	125.68
28	INSYS Therapeutics Inc	10/27/2014	Non-Consulting Speaking Fee	950
29	INSYS Therapeutics Inc	10/27/2014	Non-Consulting Speaking Fee	1900
30	INSYS Therapeutics Inc	10/28/2014	Food and Beverage	95.25
31	INSYS Therapeutics Inc	10/28/2014	Food and Beverage	9.39
32	INSYS Therapeutics Inc	10/30/2014	Food and Beverage	62.42
33	INSYS Therapeutics Inc	10/31/2014	Non-Consulting Speaking Fee	3750

b.



	A	B	C	D	E
1	Manufactur	Date of Payment	Drug	Nature of Payment	Fee
2	INSYS There	9/3/2014	Subsys	Food and Beverage	1.92
3	INSYS There	9/3/2014	Subsys	Food and Beverage	4.99
4	INSYS There	9/9/2014	Subsys	Food and Beverage	119.01
5	INSYS There	9/15/2014	Subsys	Non-Consulting Speaking Fee	1900
6	INSYS There	9/15/2014	Subsys	Food and Beverage	13.31
7	INSYS There	9/22/2014	Subsys	Non-Consulting Speaking Fee	1900
8	INSYS There	10/1/2014	Subsys	Food and Beverage	8.49
9	INSYS There	10/7/2014	Subsys	Food and Beverage	124.25
10	INSYS There	10/14/2014	Subsys	Food and Beverage	49.17
11	INSYS There	10/16/2014	Subsys	Non-Consulting Speaking Fee	1900
12	INSYS There	10/20/2014	Subsys	Food and Beverage	17.5
13	INSYS There	10/27/2014	Subsys	Non-Consulting Speaking Fee	1900
14	INSYS There	10/28/2014	Subsys	Food and Beverage	103.68
15	INSYS There	10/30/2014	Subsys	Non-Consulting Speaking Fee	1900

175. Relator observed that INSYS used its "speaker" programs as a conduit to pay doctors for prescribing Subsys, plain and simple. Relator witnessed sales staff and other INSYS personnel eliminate physicians from approved lists of paid speakers when they failed to prescribe sufficient amounts of Subsys. For example, SR #3 explained to Relator that he had previously arranged for Doctor #4 to receive payments to speak on behalf of Subsys, beginning upon its FDA approval, but that Doctor #4 did not "play ball" by writing prescriptions for the drug. SR #3 handed off INSYS' relationship with Doctor #4 to Relator, given the lack of prescriptions. Doctor #4 told Relator that SR #3 informed him he had to write prescriptions for the drug, in return for the speaking fees INSYS had paid him.

176. Another form of illegal kickbacks involved INSYS' use of gift cards. Relator was encouraged to give gift cards to prescribing physicians to encourage them to continue to prescribe Subsys. Specifically, SM #1, who formerly worked as an INSYS

sales representative, explained how she and other sales representatives were able to carry out this scheme. SM #1 told Relator how to purchase gift cards at local delicatessens whose owners she knew, and how to induce store owners to create fraudulent receipts for the value of the purchase price of the cards, which instead showed purchases of coffee and other sundries which might be permissibly dropped at physicians' offices. SM #1 then submitted the fraudulent receipts for reimbursement by INSYS and used the cards to pay illegal and untraceable kickbacks to physicians prescribing Subsys. SM #1 informed Relator that she used her business relations manager, BRM #1, to physically transact kickbacks like these on many occasions. After several INSYS sales staff were arrested in early 2016, SM #1 asked an INSYS attorney, during a conference call regarding the arrests, "Are BRMs going to be protected, as well?"

177. INSYS colleagues advised Relator, repeatedly, that these practices were encouraged by upper management and that INSYS sales managers had engaged in the same schemes before getting promoted.

178. For example, SR #1, a sales representative who took Relator on some of her "ride along" sales calls at the beginning of her employ, advised Relator to search public disclosure data for physicians who received the largest amounts of money from drug manufacturers to speak on behalf of oxycodone, morphine, and fentanyl in her sales area. SR #1 advised that this was a good method of finding physicians interested in making extra money through INSYS' sham speaker programs. As she put it, this search would

answer the questions, "Does money talk to them?" SR #1 and other sales staff repeatedly advised Relator that signing a physician on to receive payment for speaking engagements would lead to prescriptions by that physician.

179. Similarly, during a sales meeting in Arizona, SM #2, an INSYS sales representative (later a sales manager) providing training at the event, advised sales representatives that speakers would write prescriptions in return for speaking fees. When asked for clarification on how the two were related, SM #2 said, slowing her speech for emphasis, "Just get speakers."

180. On information and belief, Relator avers that the complained of illegal kickback schemes were national in scope.

A. Pricing Violations

181. Pharmaceutical manufacturers participating in Medicaid programs must rebate to the states a certain statutorily-prescribed portion of the price of drugs purchased by each Medicaid program in each state. *See* 42 U.S.C. §1396r-8(a)(1). Manufacturers do this because the Medicaid statute, 42 U.S.C. §§1396a-u, permits the federal government to partially reimburse states only for drugs purchased from manufacturers who have agreed to pay statutorily specified rebates to those states. *See* 42 U.S.C. §1396r-8. Thus, pharmaceutical manufacturers that want their drugs available to Medicaid beneficiaries under the Medicaid program enter into a Rebate

Agreement with the Department of Health and Human Services ("HHS") Secretary to provide rebates. *See* 42 U.S.C. §1396r-8(a)(1).

182. The Rebate Agreement requires manufacturers to submit a Quarterly Report (Form CMS-367). The Quarterly Report includes information regarding each of the manufacturers' "Covered" Drugs, including such information as its "Average Manufacturer Price" ("AMP"), "Baseline AMP," and its "Best Price." Based upon this information, HHS, through its component agency, The Centers for Medicare & Medicaid Services ("CMS"), then tells the states how much rebate the state is entitled to collect with respect to each drug.

183. INSYS entered into a Rebate Agreement with HHS. In that Agreement, INSYS agreed to comply with 42 U.S.C. §1396r-8, and hence:

a. Agreed to report its Best Price, inclusive of cash discounts, free goods contingent upon any purchase requirements, volume discounts and rebates, etc.;

b. Agreed that it would determine its Best Price based upon its AMP, calculated as "net sales divided by numbers of units sold, excluding free goods (i.e., drugs or any other items given away, but not contingent on any purchase requirements)" and that it would include that in the calculation, cash discounts and all other price reductions "which reduce the actual price paid"; and,

c. Agreed that the Best Price would not take into account nominal prices, defined as prices that are less than 10 percent of the AMP in that quarter, so long as the sale of product at a nominal price was not contingent on any other sale.

184. After execution of this Agreement, INSYS reported its AMP and/or Best Price in each quarter, to the Medicaid Program on an electronic form of Form CMS-367.

185. In the instant case, Defendant failed to take into account the Kickbacks and free prescriptions it provided when reporting its Best Price.

186. As a result, INSYS's Best Price, for quarterly reports submitted since 2012, were inflated, which reduced the percentage difference between AMP and Best Price, thereby reducing the rebate amount that Defendant ultimately paid to each state Medicaid program. Defendant artificially inflated its Best Price, by calculating its Best Price without taking into account its inducement activities described in this Complaint, which reduced the true cost of its drugs. Defendant knowingly set and reported its Best Price for these drugs at levels far higher than the actual Best Price, in Form CMS-367, submitted quarterly to CMS since 2012. By doing so, Defendant has violated the Federal (and applicable state) False Claims Acts, by knowingly making, using, or causing to be made or used, a false record to conceal, avoid, or decrease an obligation to pay or transmit money to federal and state governments.

187. Under the Veterans Health Care Act of 1992 ("VHCA"), drug manufacturers are required to enter a pricing agreement with the Secretary of HHS for the section 340B Drug Pricing Program, and with the Department of Veterans Affairs (VA) and other Department of Defense programs.

188. Once a labeler/manufacturer enters into such a pricing agreement, its drugs are listed on the Federal Supply Schedule ("FSS"), a price list containing over twenty-thousand pharmaceutical products. The VA and other Government Programs depend on the FSS for most of its drug purchases, with the exception of several national contracts awarded for specific drugs considered to be therapeutically interchangeable.

189. Under the VHCA, drug manufacturers must comply with 38 U.S.C. § 8126. Subsection (a)(2) requires that "the price charged during the one-year period beginning on the date on which the agreement takes effect may not exceed 76 percent of the non-Federal average manufacturer price (less the amount of any additional discount required under subsection (c)) ...."

190. In the instant case, INSYS failed to take into account its inducements when reporting the non-Federal average manufacturer price. INSYS therefore violated 38 U.S.C. §8126 causing damage to the VA program, and by not giving its best price as set forth in subsection (a)(2), INSYS became ineligible for Medicare and other federal program reimbursement.

VII. LINDEN CARE'S ILLEGAL DISTRIBUTION OF SUBSYS

A. Misbranding by Breach of TIRF-REMS Protocol

191. LINDEN CARE misbranded Subsys by distributing it for contra-indicated and off-label uses, distributing it at initial doses at least twice the FDA-approved limit, and dispensing it for use six times daily, 150% of the FDA-approved limit. LINDEN CARE's hardcopy labels, the sticker on a given package of pharmaceutical products, contained directions directly contravening the product's FDA approved label. This rendered the product unsafe for use.

192. LINDEN CARE is a TIRF-REMS enrolled pharmacy. A 2014 LINDEN CARE press release stated that "key to LINDEN CARE's success is the ability to provide solutions for today's complex pain therapies requiring Risk Evaluation and Mitigation Strategies (REMS) such as [TIRFs] and extended release opioids."

193. It is believed and averred that from 2012 to the present LINDEN CARE was one of the largest dispensers of Subsys nationwide.

194. This is how LINDEN CARE describes itself on its own website. "Linden Care is a full service pharmacy that can provide you with all the medications that your doctor prescribes. Many of our patients face chronic pain and need a dedicated pharmacy to help them to help relieve the pain." Further, "Linden Care understands that today's insurance plans are often confusing. Our patient care representatives work with your doctor and your insurance company to get you the medications you need. We offer prior

authorizations and work closely with your doctor to give you best in class pharmacy service."[3]

195. Clearly, with the advent of Subsys, LINDEN CARE fulfilled its mission of dispensing Subsys for chronic pain patients and ensured that its representatives obtained prior authorizations from insurers in order to receive government payment for off-label use of Subsys. This is a group knowingly taking advantage of the opioid epidemic for their own advantage.

196. Before being able to dispense Subsys and other TIRFs approved only for cancer patients, enrolled pharmacies must comply with terms of TIRF-REMS program. The FDCA provides the statutory justification for REMS programs, in 21 U.S.C. §355-1. That section authorizes their use in drugs which stand a good chance of endangering the public health, in order to deliver a worthwhile benefit. 21 U.S.C. §331 explains the prohibitions of the FDCA, including the prohibition against misbranding. Failure of a pharmacy to ensure compliance with TIRF-REMS, if it leads to a product which cannot be used safely for its intended purpose, constitutes misbranding. TIRF-REMS imposes a duty on pharmacists to counsel patients, and provides resources for them to do so. During enrollment in TIRF-REMS Access, they agree to educate their staff, and they certify that they understand the terms of the program.

[3] Linden Care, LLC Website, Available at: https://www.lindencare.com/ (Last Visited: October 6, 2016).

197. The TIRF-REMS Enrollment Form requires that pharmacists certify, among other things, that:

a. They will ensure that their staff "are educated on the risks associated with TIRF medicines and the requirements of the TIRF-REMS Access program;"

b. They understand TIRF drugs to be "contraindicated for use in opioid non-tolerant patients;"

c. They "understand that the initial starting dose for TIRF medicines for all patients is the lowest dose, unless individual product labels provide product-specific conversion recommendations…;"

d. They will discuss "the risks and benefits of TIRF medicines with patients and caregivers, and in particular the importance of taking the drug as prescribed, not sharing with others, and proper disposal."

198. Subsys' label concurs with the TIRF-REMS requirements, stating, in the "Indications and Usage" section:

a. Patients must require and use around-the-clock opioids when taking SUBSYS;

b. Initial dose of SUBSYS: 100mcg;

c. Individuals titrate to a tolerable dose that provides adequate analgesia using a single SUBSYS dose per breakthrough cancer pain episode;

d. No more than two doses can be taken per breakthrough pain episode;

e. Wait at least 4 hours before treating another episode of breakthrough pain with SUBSYS;

f. Limit consumption to four or fewer doses per day once successful dose is found.

199. The titration instruction, above, indicates that a move to the next highest dosage is warranted if the patient is unsuccessful at managing breakthrough pain. A successful dose for patients limits consumption to four or fewer doses per day, however. As such, if patients require more than four doses per day to treat breakthrough pain, the answer is not more Subsys, but more around-the-clock opioids. As the label states, "If the patient experiences greater than four breakthrough pain episodes per day, the dose of the maintenance (around-the-clock) opioid used for persistent pain should be reevaluated. In addition, if pain worsens, re-evaluate the patient for changes in the underlying condition."

200. LINDEN CARE breached the TIRF-REMS protocol with respect to Subsys by:

a. Dispensing Subsys for contra-indicated and off-label uses, without discussing the drug or its safe usage with patients;

b. Dispensing "initial starting doses" of 200 Mcg, rather than the mandated initial maximum dosage of 100 Mcg;

c. Dispensing Subsys with directions to consume the drug six times daily, independent of pain.

201. Because LINDEN CARE misbranded a pharmaceutical product, and that product was paid for through government insurance, a violation of the FCA has occurred.

B. Repeated Breach of the Controlled Substances Act ("CSA")

202. The Controlled Substances Act ("CSA"), 21 U.S.C. §801 et sec, regulates the manufacture, importation, possession, use and distribution of controlled substances. The CSA relies upon rules and definitions contained in the Food Drug and Cosmetics Act ("FDCA"), 21 U.S.C. §301 et seq. Chapter II of Title 21 of the Code of Federal Regulations ("CFR") covers controlled substances regulation by the Drug Enforcement Administration and the Department of Justice, and gives regulatory life to the CSA and FDCA with respect to controlled substances.

203. LINDEN CARE violated the CSA each time it dispensed or distributed a Schedule II controlled substance without a valid prescription as required under the statute and accompanying regulations. Each instance was a violation of 21 U.S.C. § 842(a)(1).

204. The CSA renders it unlawful for "a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], [to] be dispensed without the written prescription of a practitioner,"21 U.S.C. 829(a). This provision applies to Schedule II opioids, including Subsys, and also mandates that paper receipts be retained by the pharmacy.

205. "A pharmacist may dispense directly a controlled substance listed in Schedule II that is a prescription drug [...] only pursuant to a written prescription signed by the practitioner, except as provided in paragraph (d) of this section. A paper prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy via facsimile equipment, provided that the original manually signed prescription is presented to a pharmacist for review prior to the actual dispensing of the controlled substance [.] 21 C.F.R. §1306.11(a).

206. Relator avers that LINDEN CARE dispensed Subsys on behalf of Patient #1, discussed below, on the basis of faxed prescriptions and without first receiving the paper prescription, on at least six occasions.

207. Further, Relator avers that those prescriptions carried instructions for use which misbranded the medication and led to the patient's death.

208. "The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." 21 C.F.R. §1306.04(a).

209. "The pharmacist filling a written or emergency oral prescription for a controlled substance listed in Schedule II shall affix to the package a label showing date of filling, the pharmacy name and address, the serial number of the prescription, the name of the patient, the name of the prescribing practitioner, and directions for use and

cautionary statements, if any, contained in such prescription or required by law." 21 C.F.R. §1306.14(a).

210. LINDEN CARE violated both the spirit and the letter of the CSA by enabling the practitioner to order narcotics, and pharmacists to dispense these narcotics, without confirmation that a practitioner had exercised his/her medical judgment about whether these controlled substances were issued for a legitimate medical purpose and appropriate in form, strength and quantity for the resident. This occurred each time LINDEN CARE received a faxed prescription for Patient #1's Subsys, and dispensed the drug without first receiving the original, signed prescription from her physician's office. 21 C.F.R. §1304.04(f)(1) - (2); 21 C.F.R. §1306.11(a). LINDEN CARE violated the CSA each time it dispensed or distributed a Schedule II controlled substance without a valid prescription as required under the statute and accompanying regulations. Each instance was a violation of 21 U.S.C. § 842(a)(1).

211. After dispensing Schedule II drugs without a valid prescription, LINDEN CARE then caused claims for these drugs to be submitted to the Medicare program. LINDEN CARE did so notwithstanding that it knew or recklessly disregarded the fact that: (i) Schedule II controlled substances could not be legally dispensed without a valid prescription; (ii) Linden Care's pharmacists were dispensing Schedule II controlled substances without a valid prescription; and (iii) drugs dispensed without a valid prescription are not payable under Medicare Part D. As a direct, proximate and

foreseeable result of Linden Care's dispensing of Schedule II drugs without a valid prescription, LINDEN CARE knowingly caused false claims to be submitted to the Medicare program and made or caused false statements to be made that were material to such claims.

VIII. DEATH BY SUBSYS: OVERDOSE OF PATIENT #1

212. Through her work at INSYS, Relator interacted with the Patient and Physician described below, and learned the following facts, which exemplify INSYS' off-label promotion and misbranding of Subsys and its use of kickbacks to promote the drug, as well as LINDEN CARE's misbranding of the drug and repeated breach of the TIRF-REMS protocol and the CSA.

213. Patient #1 met Doctor #1 for an initial consultation on August 13, 2014, related to pain associated with degenerative disc disorder, kidney stones, migraines, fibromyalgia, and assorted other illnesses. Patient #1 bore injuries from two car accidents, and, as a consequence of chronic pain, grew dependent on the opioids she had taken for several years.

214. Doctor #1 practices internal medicine, diabetic management, holistic medicine, and weight control. She does not advertise an expertise or accreditation in either oncology or pain management.

215. INSYS trained and instructed Relator to use various techniques to promote Subsys to Doctor #1, including invitations to multiple speaker programs and dinners with Relator's regional sales manager.

216. Further, in compliance with the training she received from INSYS, Relator made regular trips to Doctor #1's office, dropping off breakfast and lunch and boxes of coffee for the staff, and attempting to convince the Doctor #1 to prescribe Subsys to one of her patients. As Relator noted in a Business Plan she drafted for her sales manager, Doctor #1 was an "A" target, and Relator did the following: "weekly visits/staff and Dr. aware of benefits of Subsys and is looking for appropriate patient types…"

217. In December, 2014, Doctor #1 found what she and INSYS considered to be an "appropriate patient type," a patient without cancer, who suffered from "chronic, intractable pain." Doctor #1 contacted Relator and scheduled a meeting with Patient #1.

A. INSYS' Complicity

218. INSYS, through Relator and its IRC, (1) advised Doctor #1 to prescribe Subsys at an improperly high introductory dosage and with improper instructions for use, (2) advised Patient #1 to change doses during titration without consulting her physician, and (3) pre-populated the prior authorization form with off-label indication and off-label dose.

219. On January 5, 2015, Doctor #1 saw Patient #1 for medication monitoring, and noted in Patient #1's records the order of two prescriptions of Subsys 200 Mcg, to

be taken "every four hours for a script of 30 units, second script for 120 units[.]" Doctor #1 arranged for Patient #1 and her father to meet with Relator immediately after this consultation, for instruction on the use of Subsys. At this time, Doctor #1 and Patient #1 executed a TIRF REMS Patient-Prescriber Agreement Form, a necessary predicate to the authorization and dispensation of the Subsys prescriptions.

220. Relator met with Patient #1 and her father that same day. Doctor #1 did not join them. At the meeting, Relator provided a partially completed INSYS Reimbursement Center Patient Authorization & Referral Form ("Prior Authorization Form"), to which Patient #1's father added Patient #1's name, date of birth, gender, social security number, address, and phone number. Though Relator never filled this section out for a patient, she was advised by her sales manager at the time, SM #3, that other sales representatives did so, but that they made sure that the handwriting looked different to avoid detection by regulators. Relator pre-populated the dosage line, checking the box for 200 Mcg, and the indication section, checking boxes for "patient is opioid tolerant", "other chronic pain," and "chronic pain syndrome." (See form at ¶ 123).

221. The standard INSYS prior authorization form lists both approved and off-label medical diagnoses among its rationales for prescribing Subsys. One of the potential diagnosis is even contraindicated on the label. Subsys' FDA-approved label contraindicates "post-operative pain," yet INSYS' prior authorization form includes

"Post-laminectomy syndrome," also known as Failed Back Syndrome (FBS). FBS is a catch-all diagnosis for patients whose pain persists after spinal surgery. When questioned regarding this, Relator was unaware that a contraindicated diagnosis appeared on the form, but explained that her training by INSYS was so focused on sales, rather than the consultative services emphasized by other pharmaceutical sales departments, that she and her colleagues received little to no explanation of the diagnoses for which the drug was contraindicated.

222. Relator also instructed Patient #1 on the use of Subsys and INSYS' recommended method of titration for determining effective dosage. Relator handed marketing materials to Patient #1, including (1) a brochure titled "Are Your Patients Getting Relief From Their Breakthrough Cancer Pain?" (hereinafter the "BTcP Brochure") and (2) the Titration Process and Schedule booklet.

223. In the course of educating Patient #1 on the use of Subsys, as directed by INSYS management, Relator advised Patient #1 and her father that neither the 100 Mcg dose nor the 200 Mcg dose would have the desired effect, that she would need to "titrate up" to her minimum effective dose. Ultimately, INSYS sales representatives were trained to make sure their prescriptions reached doses of 400 Mcg or higher through titration, as INSYS circulated a daily report of prescriptions below 400 Mcg, to serve as a list of doctors in need of "education" from sales representatives on proper dosing.

224. The BTcP Brochure is targeted at prescribers. Relator received no direction from INSYS management on what to do with marketing materials during patient meetings, so she used them to educate the patients on the use of the drug. The BTcP Brochure provides instructions on how to "titrate up" to an effective pain relief dosage. Relator used the brochure, as well as the titration guide, along with notes she took during her week of training. She showed Patient #1 a chart from the BTcP Brochure which states that a majority of patients achieve an effective dose of Subsys between 600 Mcg and 1600 Mcg, and advised the patient to begin use of Subsys by taking a 200 mcg dose upon having her first pain episode. Relator advised Patient #1 that if pain remained after thirty minutes, she could take another 200 Mcg dose. Relator further advised, based on her limited training, that Patient #1 should double the dose, taking 400 Mcg, after four hours elapsed.

225. Relator's advice to Patient #1 regarding her initial dosage was undoubtedly off-label promotion. Relator, based on INSYS training, led Patient #1 to believe that a 100 mcg dose would have no effect on her pain, though the 100 mcg dose is the only FDA approved initial dosage. INSYS, in fact, instructed Relator and her colleagues that the FDA-approved 100 Mcg dose was below the threshold of what any opioid-tolerant adult would benefit from, and that the patient population would cease using the drug if they were not able to feel its effects more dramatically, by beginning with the 200 mcg dose.

226. Relator's advice to Patient #1 regarding the alteration of dosage during titration is further evidence of INSYS' systemic off label promotion of Subsys. At the direction of INSYS management, Relator advised Patient #1 to change her own dosage on the basis of her relative pain levels during titration, without contacting her physician prior to or after the change. INSYS instructed Relator and her colleagues to do this during their initial training. In doing so, INSYS trained its employees to directly contradict Subsys' FDA-approved label, which tells patients to contact their prescribing physician before altering their dosage. The FDA-approved label advises patients to take this precaution because of the severity of the drug's side-effects, which include death.

227. When Relator showed Patient #1 a BTcP brochure containing a chart claiming that 3 out of 4 patients achieve an effective dose between 600 mcg and 1600 mcg, she was also following INSYS policy. By providing this information to patients, INSYS prepared patients to be unsatisfied by the initial dose. This sales protocol approaches what micro-economists call "price framing." When sales people "price frame" they present higher than expected prices to a potential purchaser, in order to raise the purchaser's perception of what an acceptable price would be. When INSYS sales staff advised patients and physicians that the FDA-approved 100 Mcg starting dose would be imperceptible, they pushed patients to consume higher and higher doses of a dangerous and addictive opioid.

228. After Relator's meeting with Patient #1, Doctor #1's office staff faxed copies of the prescriptions to LINDEN CARE Pharmacy, and Relator submitted the parties' Patient-Prescriber Agreement Form and Prior Authorization Form to INSYS' Reimbursement Center ("IRC") representatives on proper dosing.

229. On January 8, 2015, Envision Pharmaceutical Services (now "EnvisionRx") authorized Medicare reimbursement for Prescription # 2080916-01N/D, one hundred and twenty units of Subsys 200 Mcg spray, written on behalf of Patient #1 by Doctor #1. LINDEN CARE dispensed the prescription to Patient #1 that same day, without first receiving the original prescription from Doctor #1. LINDEN CARE priced the 20 day, 120 dose prescription of Subsys at approximately $6,667.60. Patient #1 was responsible for $6.60 and EnvisionRx paid $5,509.52.

230. EnvisionRx, the Medicare Part D insurer responsible for either authorizing or refusing reimbursement for Patient's Subsys, requires a journal article for off-label prescriptions. INSYS' Reimbursement Center handled all contract between INSYS staff and EnvisionRx, so Relator has no information on what was said or provided by INSYS to ensure reimbursement, however Relator does recall that sales staff agreed that certain members of the IRC staff had better results than others.

231. Patient #1 received approval for an exception from Envision because of the prior authorization form. This is the only method for gaining approval where a patient seeks to use the drug for an off-label purpose.

232. EnvisionRx's Medicare Part D Eldercare plan served as the Third Party Payor for the transaction.

233. Between January 26, 2015 and March 21, 2016, Doctor #1 drafted, EnvisionRx authorized, and LINDEN CARE dispensed seventeen additional Subsys prescriptions for Patient #1, each for 600 Mcg spray, nine (9) of these for one hundred and twenty (120) doses and the remaining eight (8) prescriptions for one hundred and eighty (180) doses.

234. Befitting her training by INSYS, Relator did not mention to Patient #1 the label's limitation to only patients with BTcP. Rather, she provided Patient #1 directions for using Subsys, and guided her to begin at the 200 Mcg dose and begin titrating up without first consulting the prescribing physician, Doctor #1. In doing so, Relator behaved as trained and directed by INSYS management.

235. Patient #1 continued to take a 600 mcg dose until her death. The prescription was initially for a 20-day supply with a quantity of 120. On August 25, 2015, and thereafter, the prescription was for a 30-day supply with a quantity of 180.

B. LINDEN CARE's Complicity

236. When LINDEN CARE received Patient #1's first prescription for Subsys, the dosage and wording should have immediately raised a red flag with pharmacists on duty. Patient's #1's physician (Doctor #1) prescribed the 200 mcg dosage, in direct contravention of the product's FDA approved label and the TIRF-REMS guidelines, both of which mandate an initial 100 mcg dose in an effort to allow patients to titrate up to

their optimal dosage safely. Despite certifying that it would start all patients at the lowest dose, LINDEN CARE dispensed Patient #1 her first prescription of Subsys at twice that dosage.

237. When LINDEN CARE received Patient #1's second prescription for Subsys, it again acceded to the written directions unlawfully and without question or complaint. LINDEN CARE dispensed 600 mcg Subsys spray to Patient #1, despite the fact that Subsys' label recommends a 400 mcg dose. Further, and even more troubling, LINDEN CARE distributed the drug for an off-label use – "Chronic Intractable Pain" – and without proper directions in the memo line of the prescription. The prescription's hardcopy label states, "Use 1 Spray Under Tongue Every Four Hours." It does not say "PRN," or "As Needed." Rather, the label instructed Patient #1 to use Subsys as a maintenance opioid. The directions on the hardcopy label came, verbatim, from the handwritten prescription Doctor #1's staff faxed to LINDEN CARE. Thus, the treating physician prescribed Subsys with patently improper and unsafe directions for use, INSYS' IRC forwarded said those directions to the pharmacy, and then LINDEN CARE dispensed the drugs to Patient #1 with no apparent scrutiny or oversight.

238. No pharmacist should have dispensed the second prescription - and certainly no TIRF-REMS certified pharmacist - because it was not prescribed as needed - a serious medication error. LINDEN CARE failed to satisfy its duty, under TIRF-REMS, the

FDCA, and the CSA, to guard against prescription errors, especially with respect to drugs so dangerous as Subsys and other TIRFs.

239. LINDEN CARE dispensed Patient #1's second prescription for Subsys on January 26, 2015, and two additional prescriptions, also for 600 mcg Subsys, on February 27 and March 26, before adding the language "As Needed" to Patient's fifth prescription on April 17, 2015. A review of Doctor #1's prescription pad reveals what was apparent with the January 26, 2015 prescription, that LINDEN CARE employees merely transcribed whatever the physician wrote, independent of whether these directions were inherently dangerous and contrary to those approved by the FDA and taught by the TIRF-REMS Access program.

240. On May 28, 2015, LINDEN CARE again failed to include any "As Needed" language.

241. Even when, on September 22, 2015, Doctor #1's prescription pad memo stated "PRN," LINDEN CARE's hardcopy label failed to include the "As Needed" language. To the contrary, the label stated, "Use 1 Spray Under Tongue Every 4 Hours."

242. Incredibly, based on the prescription written by the Doctor #1 and filled by LINDEN CARE, Patient #1 could consume a 600 mcg dose of Subsys every four hours, every day, independent of what pain she felt or did not feel. Her physician and pharmacist, alike, advised her to do so. This is because, rather than raise the dosage of Patient's maintenance opioid, or change the maintenance opioid, the prescribing

physician prescribed enough Subsys for Patient to consume it six times daily. Patient #1, an opioid addict suffering from severe, chronic pain, set an alarm clock each night, to make sure that she took the scheduled dose that fell in the middle of her sleep schedule.

243. TIRF-REMS, like Subsys' label, states that the drug should not be prescribed for more than four daily doses. Subsys is not a maintenance opioid. It is a powerful analgesic, one which can easily kill patients who abuse it.

244. Patient #1's Subsys prescription, filled by LINDEN CARE, directed her to abuse the drug, which led to her death.

245. On October 30, 2015, Virtua West Jersey Hospital ("Virtua Voorhees") admitted and discharged Patient #1 from its Emergency Department, where Patient #1 presented with chest pain. At the time of discharge, Patient #1's treating physician advised her to "wean her medications down."

246. On January 17, 2016, Virtua Voorhees admitted and discharged Patient #1 from its Emergency Department, where Patient #1 presented with a wound on her left leg. On discharge, Patient #1's treating physician noted the following: "Pt somnolent but arousable on exam; pt took 600 mcg of fentanyl in the exam room; after arousing pt she requested something additional for pain; explained at this time given somnolence explained to pt that it was not appropriate at this time."

247. Doctor #1 met with Patient #1 on January 18, 2016, the day following her final visit to Virtua Voorhees' Emergency Department. On that date, Doctor #1

prescribed additional medication, noting: "Med admin: Subsys 600 mcg q 4, #180 doses, OxyContin 10 mg q 12 #60, no evidence of substance abuse or aberrant behavior activities of daily living the patient can function with medications njrx cked and confirmed."

248. On March 25, 2016, Patient #1's boyfriend woke to find her dead on the couple's bedroom floor. Subsequent toxicology reports caused her death to be ruled accidental, the result of adverse effects of drugs. Patient #1's blood contained high levels of fentanyl and norfentanyl (the prime fentanyl metabolite).

249. LINDEN CARE abrogated its duty to ensure that no extra medication was dispensed to Patient #1. LINDEN CARE also failed to educate both patient and prescriber, as it certified would occur. These failures began with the first prescription LINDEN CARE filled for Patient #1, and continued until her death, eighteen prescriptions and $250,544.62 in Medicare copayments later.

250. In sum, LINDEN CARE dispensed nine Subsys prescriptions to Patient #1 which failed to include any "As Needed" language. These labels directed the patient to use the drug every four hours, independent of pain.

251. The preceding facts demonstrate that LINDEN CARE lacked a competent compliance program during the period of January 26, 2015 and March 21, 2016, the time between Patient's first prescription of Subsys and her death from its misuse. It is

believed and, therefore, averred that LINDEN CARE's failures as detailed herein were systemic in nature.

252. By failing to comply with TIRF-REMS, and submitting its bills to government healthcare programs for repayment, LINDEN CARE committed eighteen FCA violations with respect to Patient #1, alone.

253. Relator believes and, therefore, avers that her experience with calling on Doctor #1 and the resulting prescriptions to Patient #1 were illustrative of Defendants INSYS' and LINDEN CARE's unlawful marketing, sale, and dispensing of Subsys on a nationwide basis.

IX. CONCLUSION

254. Defendant INSYS willfully promoted Subsys for off-label uses, and paid kickbacks to physicians in order to increase the revenues it received from Government Healthcare Programs. LINDEN CARE acted willingly and in concert with INSYS and, in doing so, Defendants engaged in a systemic fraudulent scheme that caused physicians to neglect the welfare of their patients and expand the use and abuse of a highly addictive and potent form of fentanyl. Upon information and belief, the illegal and unjust activities of Defendants continue unabated.

COUNT ONE
Violations of the False Claims Act,
31 U.S.C. § 3729(a)(1)(A)

255. Relator-Plaintiff restates and incorporates each and every allegation above as if the same were fully set forth herein

256. The False Claims Act, 31 U.S.C. § 3729(a)(1)(A), provides in relevant part that any person who:

> knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval…
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 … plus three times the amount of damages which the Government sustains because of the act of the person.

257. By virtue of the acts described above, Defendants knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval of Subsys, or treatments involving Subsys, to officers, employees or agents of the United States government. Defendants knew that these claims for payment or approval were false or fraudulent, or were deliberately ignorant of the truth or falsity of the claims, or acted in reckless disregard for whether the claims were true or false.

258. The United States, unaware of Defendants' false or fraudulent representations, and the falsity or fraudulence of claims presented or caused to be

presented by Defendants, has paid and continues to pay the false claims submitted that would otherwise not have been allowed.

259. The United States has made and will make payment upon false and fraudulent claims presented by Defendants and thereby have and will continue to suffer damages. The United States is entitled to full recovery of the amounts paid to Defendants by the Government Healthcare Programs pursuant to the submission of false claims, which Defendants presented or caused to be presented.

260. Relator-Plaintiff believes and avers that she is an original source of the facts and information upon which this action is based.

COUNT TWO
Violations of the False Claims Act, 31 U.S.C. § 3729(a)(1)(B)

261. Relator-Plaintiff restates and incorporates each and every allegation above as if the same were fully set forth herein.

262. The False Claims Act, 31 U.S.C. § 3729(a)(1)(B), provides in relevant part that any person who:

> knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim…is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 …
>
> plus three times the amount of damages which the Government sustains because of the act of the person.

263. By virtue of the acts described above, Defendants knowingly made and/or used, or caused to be made or used, false records and/or statements material to false or

fraudulent claims for payment or approval of Subsys, or treatments involving Subsys, to officers, employees or agents of the United States government, and continues to make, use or cause false records and statements to be made or used to get false or fraudulent claims paid or approved by the United States.

264. The United States, unaware of the falsity of the records and/or statements caused to be made and used by Defendants, and in reliance on the accuracy thereof, have paid and approved, and continue to pay and approve, claims that were ineligible for reimbursement and would not have been paid or approved if any part of the truth were known.

265. The amounts of the false or fraudulent claims caused by Defendants to be submitted to the United States were material.

266. As a direct and proximate consequence of Defendants' conspiratorial conduct, the United States has suffered significant, material financial damages in an amount to be proved at trial.

COUNT THREE
Violations of the False Claims Act, 31 U.S.C. § 3729(a)(1)(G)

267. Relator-Plaintiff restates and incorporates each and every allegation above as if the same were fully set forth herein.

268. The False Claims Act, 31 U.S.C. § 3729(a)(1)(G), provides in relevant part that any person who:

> knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government …
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 … plus three times the amount of damages which the Government sustains because of the act of the person.

269. By virtue of the acts described above, Defendants knowingly concealed and/or knowingly and improperly avoided an obligation to pay or transmit money or property to the Government for improper reimbursements the Government has provided for the use of Subsys, in violation of 31 U.S.C. § 3729(a)(1)(G).

270. As a direct and proximate consequence of Defendants' conduct, the United States has suffered significant, material financial damages in an amount to be proved at trial.

COUNT FOUR
Violations of the California False Claims Act
California Government Code § 12651 *et seq.*

271. Relator-Plaintiff restates and incorporates each and every allegation above as if the same were fully set forth herein.

272. This is a claim for treble damages and penalties under the California False Claims Act.

273. Cal. Gov't Code §12651(a) provides liability for the costs of a civil action, a civil penalty of up to $10,000 and treble damages for all damages sustained by the state for any person who-

> (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 any political subdivision;
>
> ***
>
> (8) is a beneficiary of an inadvertent submission of a false claim, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim.

274. By virtue of the acts described above, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the California State Government for payment or approval and has knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the government to approve and pay such false and fraudulent claims.

275. Specifically, Defendants have:

- caused false claims to be presented to the State of California,
- knowingly made, used or caused to be made or used false records or statements to get false claims paid, and,

- failed to disclose the existence of the false claims and statements it has caused to be presented.

276. Each representation or certification of compliance with the applicable laws and regulations by medical professionals and treating facilities while using Subsys, as well as each claim presented or caused to be presented for reimbursement of treatments involving Subsys, represents a false or fraudulent record or statement. Each claim for reimbursement of treatment involving the non-medically accepted uses submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

277. Compliance with applicable Medicare, Medi-Cal and various other Federal and State laws was a condition of payment of claims submitted to the California State Government.

278. The California State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false statements and representations concerning the use of Subsys.

279. By reason of Defendants' acts, the California State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

280. The State of California is entitled to the maximum penalty for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

281. Relator-Plaintiff believes and avers that she is an "original source" of the facts and information on which this action is based.

282. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same nexus of facts as the federal claim, and merely asserts separate damage to the State of California in the operation of its Medi-Cal program.

COUNT FIVE
Violations of the Colorado Medicaid False Claims Act
C.R.S.A. § 25.5-4-304 *et seq.*

283. Relator-Plaintiff restates and incorporates each and every allegation above as if the same were fully set forth herein.

284. This is a claim for treble damages and penalties under the Colorado Medicaid False Claims Act.

285. Colorado Medicaid False Claims Act, C.R.S.A. § 25.5-4-305, in pertinent part provides for liability for any person who -

> (a) Knowingly presents, or causes to be presented, to an officer or employee of the state 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;
> * * *
>
> (f) 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 in connection with the "Colorado Medical Assistance Act", or knowingly conceals or

> knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state in connection with the "Colorado Medical Assistance Act";

286. By virtue of the acts described above, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the Colorado State Government for payment or approval and has knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the government to approve and pay such false and fraudulent claims.

287. Specifically, Defendants have:

- caused false claims to be presented to the State of Colorado,
- knowingly made, used or caused to be made or used false records or statements to get false claims paid, and,
- failed to disclose the existence of the false claims and statements it has caused to be presented.

288. Each representation or certification of compliance with the applicable laws and regulations by medical professionals and treating facilities while using Subsys, as well as each claim presented or caused to be presented for reimbursement of treatments involving Subsys, represents a false or fraudulent record or statement. Each claim for reimbursement of treatment involving the non-medically accepted uses submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

289. Compliance with applicable Medicare, Medicaid and various other Federal and State laws was a condition of payment of claims submitted to the Colorado State Government.

290. The Colorado State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false statements and representations concerning the use of Subsys.

291. By reason of Defendants' acts, the Colorado State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

292. The State of Colorado is entitled to the maximum penalty for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

293. Relator-Plaintiff believes and avers that she is an "original source" of the facts and information on which this action is based.

294. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same nexus of facts as the federal claim, and merely asserts separate damage to the State of Colorado in the operation of its Medicaid program.

COUNT SIX
Violations of the Connecticut False Claims Act
C.G.S.A. § 2-274 *et seq.*

295. Relator-Plaintiff restates and incorporates each and every allegation above as if the same were fully set forth herein.

296. This is a claim for treble damages and penalties under the Connecticut False Claims Act, C.G.S.A § 2-274 *et seq*.

297. C.G.S.A. § 2-275 in pertinent part provides for liability as follows:

> (a) No person shall:
>
> (1) Knowingly present, or cause to be presented, a false or fraudulent claim for payment or approval under a state-administered health or human services program;
>
> (2) Knowingly make, use or cause to be made or used, a false record or statement material to a false or fraudulent claim under a state-administered health or human services program;
>
> ***
>
> (8) Knowingly conceal or knowingly and improperly avoid or decrease an obligation to pay or transmit money or property to the state under a state-administered health or human services program.

298. By virtue of the acts described above, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the Connecticut State Government for payment or approval and has knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the government to approve and pay such false and fraudulent claims.

299. Specifically, Defendants have:

- caused false claims to be presented to the State of Connecticut,

- knowingly made, used or caused to be made or used false records or statements to get false claims paid, and,

- failed to disclose the existence of the false claims and statements it has caused to be presented.

300. Each representation or certification of compliance with the applicable laws and regulations by medical professionals and treating facilities while using Subsys, as well as each claim presented or caused to be presented for reimbursement of treatments involving Subsys, represents a false or fraudulent record or statement. Each claim for reimbursement of treatment involving the non-medically accepted uses submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

301. Compliance with applicable Medicare, Medicaid and various other Federal and State laws was a condition of payment of claims submitted to the Connecticut State Government.

302. The Connecticut State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false statements and representations concerning the use of Subsys.

303. By reason of Defendants' acts, the Connecticut State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

304. The State of Connecticut is entitled to the maximum penalty for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

305. Relator-Plaintiff believes and avers that she is an "original source" of the facts and information on which this action is based.

306. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same nexus of facts as the federal claim, and merely asserts separate damage to the State of Connecticut in the operation of its Medicaid program.

COUNT SEVEN
Violations of the Delaware False Claims and Reporting Act
6 DEL. C. § 1201 *et seq.*

307. Relator-Plaintiff restates and incorporates each and every allegation above as if the same were fully set forth herein.

308. This is a claim for treble damages and penalties under the Delaware False Claims and Reporting Act.

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

> knowingly presents or causes to be presented, directly or indirectly, to an officer or employee of the Government a false or fraudulent claim for payment or approval; . . . shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus 3 times the amount of the actual damages

> which the Government sustains because of the act of that person.

310. The Delaware False Claims and Reporting Act, 6 Del. C. §1201(a)(2) provides for liability for any person who:

> knowingly makes, uses or causes to be made or used, directly or indirectly, a false record or statement to get a false or fraudulent claim paid or approved; …shall be liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each act constituting a violation of this section, plus 3 times the amount of the actual damages which the Government sustains because of the act of that person.

311. By virtue of the acts described above, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the Delaware State Government for payment or approval and has knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the government to approve and pay such false and fraudulent claims.

312. Specifically, Defendants have:

- caused false claims to be presented to the State of Delaware,
- knowingly made, used or caused to be made or used false records or statements to get false claims paid, and,
- failed to disclose the existence of the false claims and statements it has caused to be presented.

313. Each representation or certification of compliance with the applicable laws and regulations by medical professionals and treating facilities while using Subsys, as well as each claim presented or caused to be presented for reimbursement of treatments

involving Subsys, represents a false or fraudulent record or statement. Each claim for reimbursement of treatment involving the non-medically accepted uses submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

314. Compliance with applicable Medicare, Medicaid and various other Federal and State laws was a condition of payment of claims submitted to the Delware State Government.

315. The Delaware State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false statements and representations concerning the use of Subsys.

316. By reason of Defendants' acts, the Delaware State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

317. The State of Delaware is entitled to the maximum penalty for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

318. Relator-Plaintiff believes and avers that she is an "original source" of the facts and information on which this action is based.

319. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same nexus of facts as the federal claim, and

merely asserts separate damage to the State of Delaware in the operation of its Medicaid program.

COUNT EIGHT
Violations of the Florida False Claims Act
FL. STAT. ANN. § 68.081 *et seq.*

320. Relator-Plaintiff restates and incorporates each and every allegation above as if the same were fully set forth herein.

321. This is a claim for treble damages and penalties under the Florida False Claims Act.

322. The Florida False Claims Act, Fla. Stat § 68.082(2)(a)-(c) provide 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; … Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by an agency; . . . is liable to the state for a civil penalty of not less than $5,500 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.
>
> (b) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by an agency; . . . is liable to the state for a civil penalty of not less than $5,500 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.

***

> (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 state, or knowingly conceals or knowingly and improperly avoids or decreases 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 and for treble the amount of damages the agency sustains because of the act or omission of that person.

323. By virtue of the acts described above, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the Florida State Government for payment or approval and has knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the government to approve and pay such false and fraudulent claims.

324. Specifically, Defendants have:

- caused false claims to be presented to the State of Florida,
- knowingly made, used or caused to be made or used false records or statements to get false claims paid, and,
- failed to disclose the existence of the false claims and statements it has caused to be presented.

325. Each representation or certification of compliance with the applicable laws and regulations by medical professionals and treating facilities while using Subsys, as well as each claim presented or caused to be presented for reimbursement of treatments involving Subsys, represents a false or fraudulent record or statement. Each claim for

reimbursement of treatment involving the non-medically accepted uses submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

326. Compliance with applicable Medicare, Medicaid and various other Federal and State laws was a condition of payment of claims submitted to the Florida State Government.

327. The Florida State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false statements and representations concerning the use of Subsys.

328. By reason of Defendants' acts, the Florida State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

329. The State of Florida is entitled to the maximum penalty for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

330. Relator-Plaintiff believes and avers that she is an "original source" of the facts and information on which this action is based.

331. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same nexus of facts as the federal claim, and merely asserts separate damage to the State of Florida in the operation of its Medicaid program.

COUNT NINE
Violations of the Georgia State False Medicaid Claims Act
O.C.G.A. § 49-4-168 *et seq.*

332. Relator-Plaintiff restates and incorporates each and every allegation above as if the same were fully set forth herein.

333. This is a claim for treble damages and penalties under the Florida False Claims Act.

334. The Georgia State False Medicaid Claims Act, O.C.G.A. § 49-4-168.1(a), specifically provides in part:

> (a) Any person who:
>
> (1) Knowingly presents or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval;
>
> (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;
>
> ***
>
> (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 local government, or knowingly conceals, knowingly and improperly avoids, or decreases an obligation to pay or transmit money or property to the state or a local government.
>
> 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.

335. By virtue of the acts described above, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the Georgia State Government for payment or approval and has knowingly made, used, or caused to be made or used, false records and statements, and omitted material facts, to induce the government to approve and pay such false and fraudulent claims.

336. Specifically, Defendants have:

- caused false claims to be presented to the State of Georgia,
- knowingly made, used or caused to be made or used false records or statements to get false claims paid, and,
- failed to disclose the existence of the false claims and statements it has caused to be presented.

337. Each representation or certification of compliance with the applicable laws and regulations by medical professionals and treating facilities while using Subsys, as well as each claim presented or caused to be presented for reimbursement of treatments involving Subsys, represents a false or fraudulent record or statement. Each claim for reimbursement of treatment involving the non-medically accepted uses submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

338. Compliance with applicable Medicare, Medicaid and various other Federal and State laws was a condition of payment of claims submitted to the Georgia State Government.

339. The Georgia State Government, unaware of the falsity of the records, statements, and claims made, or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' false statements and representations concerning the use of Subsys.

340. By reason of Defendants' acts, the Georgia State Government has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

341. The State of Georgia is entitled to the maximum penalty for each and every false or fraudulent claim, record, or statement made, used, presented, or caused to be made, used, or presented by Defendants.

342. Relator-Plaintiff believes and avers that she is an "original source" of the facts and information on which this action is based.

343. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same nexus of facts as the federal claim, and merely asserts separate damage to the State of Georgia in the operation of its Medicaid program.

COUNT TEN
Violations of the Hawaii False Claims Act
HAW. REV. STAT. § 661-21 *et seq.*

344. Relator-Plaintiff restates and incorporates each and every allegation above as if the same were fully set forth herein.