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CHRISTOPHER S. PORRINO, ATTORNEY GENERAL OF NEW JERSEY, on behalf of the State of New Jersey, and SHARON M. JOYCE, ACTING DIRECTOR OF THE NEW JERSEY DIVISION OF CONSUMER AFFAIRS,

Plaintiffs,

v.

INSYS THERAPEUTICS, INC., a Delaware corporation,

Defendant.

SUPERIOR COURT OF NEW JERSEY
CHANCERY DIVISION
MIDDLESEX VICINAGE

Civil Action

COMPLAINT FOR VIOLATION OF THE NEW JERSEY FALSE CLAIMS ACT, N.J.S.A. 2A: 32C-1, ET SEQ., AS WELL AS OTHER CLAIMS

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The State of New Jersey, by and through Christopher S. Porrino, Attorney General of New Jersey (the "Attorney General"), and Sharon M. Joyce, the Acting Director of the New Jersey Division of Consumer Affairs (the "Director" and together with the Attorney General, "Plaintiffs"), by way of Complaint, allege as follows:

GENERAL ALLEGATIONS

I. INTRODUCTION

1. This case is about a greedy pharmaceutical company's blatant disregard for the law and the health and safety of its consumers in favor of increased market share and maximized profits.

2. Defendant Insys Therapeutics, Inc. ("Insys" or "Defendant") peddles one of the most dangerous consumer products on the market—Subsys, an opioid-fentanyl drug approximately fifty times stronger than heroin and one hundred times more potent than morphine. It is part of a special class of drugs, known as transmucosal immediate release fentanyl ("TIRF"), which are approved by the Food and Drug Administration ("FDA") for the single use of managing breakthrough cancer pain in patients who are tolerant to around-the-clock opioid therapy.

3. Cognizant that selling Subsys only in compliance with its FDA-approved label would not generate the substantial revenue that it desired, Insys devised a subversive and illegal plan to promote Subsys for uses beyond the sole, narrow indication for which it sought and received FDA approval.

4. Specifically, and as set forth in great detail below, Insys (i) directed its sales force to push healthcare providers to write Subsys prescriptions for more patients and at higher doses to treat chronic pain of any type, despite the attendant dangers; (ii) paid those prescribers with,

among other things, sham speaking and consulting fees; and (iii) fraudulently induced insurers to pay for the off-label prescriptions, including by misrepresenting patients' diagnoses and treatment histories.

5. The viability of Insys as a company depended on the success of Subsys. From its launch in 2012 to the present, Subsys sales account for approximately 98% of Insys's net revenues. Accordingly, Insys and its leadership were willing to do whatever was necessary to drive Subsys sales.

6. In the State of New Jersey ("New Jersey" or "State") alone, despite the explicit restrictions on the appropriate use of Subsys, and the paucity of appropriate potential Subsys patients, Insys sold approximately $74.2 million of Subsys from 2012 through the third quarter of 2016. Of that $74.2 million, the State Health Benefits Program ("SHBP") and School Employees' Health Benefits Program ("SEHBP") paid approximately $10.3 million, and the State Workers' Compensation Program paid $300,000.

7. Insys's greed has led to the death of at least one New Jersey resident, and it put hundreds of other lives in jeopardy. In 2016, 32-year-old Sarah Fuller, a resident of Camden County, died from a Subsys-related overdose. She had been prescribed the drug to treat fibromyalgia by a New Jersey physician; that physician claims an Insys sales representative misled her to believe Subsys was appropriate for treating chronic non-cancer pain.

8. Plaintiffs now seek injunctive relief and other redress pursuant to the New Jersey Consumer Fraud Act, for the harm that Insys's reprehensible conduct has caused New Jersey's residents. The Attorney General also seeks relief under the New Jersey False Claims Act for the financial harm to the State because Insys caused the submission of false claims for payment to the SHBP/SEHBP and the State Workers' Compensation Program.

II. THE PARTIES, JURISDICTION AND VENUE

A. The State of New Jersey

10. Pursuant to N.J.S.A. 52:17A-4, the Attorney General is charged with the duty to enforce the laws of the State and is empowered to bring actions in the Superior Court of New Jersey against persons and entities who have engaged in violations of the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 et seq. ("CFA"), and the New Jersey False Claims Act, N.J.S.A. 2A:32C-1, et seq. ("FCA"). The Director is charged with the responsibility to administer the CFA.

11. Plaintiffs bring this action pursuant to their authority under the CFA, specifically N.J.S.A. 56:8-8, 56:8-11, 56:8-13 and 56:8-19.

12. The Attorney General brings this action pursuant to his authority under the FCA, specifically N.J.S.A. 2A:32C-5.a because Insys caused the submission of false claims to the (i) Division of Pensions and Benefits in the New Jersey Department of the Treasury, which administers SHBP/SEHBP, both of which are self-funded by the State; and (ii) Division of Risk Management in the New Jersey Department of the Treasury, which administers the State's Workers' Compensation Program for State employees.

B. Insys Therapeutics, Inc.

13. Insys is a publicly-traded company incorporated in the State of Delaware with its principal place of business at 1333 South Spectrum Boulevard, Chandler, Arizona.

14. Despite selling tens of millions of dollars of Subsys in New Jersey, and employing numerous sales representatives to promote Subsys throughout the State, Insys is not, and has never, registered to do business in New Jersey.

15. Insys describes itself as a "specialty pharmaceutical company that develops and seeks to commercialize innovative pharmaceutical products that target the unmet needs of cancer

patients" and has "assembled a product pipeline targeting cancer-supportive care and cancer therapy[.]" At all times relevant to this Complaint, as explained below, Insys's principal product and source of revenue was, and remains, Subsys, a transmucosal immediate-release formulation of fentanyl, packed in a single-dose spray device intended for oral sublingual administration.

C. Jurisdiction and Venue

16. The Court has personal jurisdiction over Defendant because, as set forth in detail below, it has regularly transacted business in New Jersey, purposely directed business activities into New Jersey, maintained employees in New Jersey, and engaged in unlawful practices in New Jersey against New Jersey consumers.

17. Pursuant to Rule 4:3-2 of the New Jersey Rules of Court, venue is proper in Middlesex County because it is a county in which Defendant has transacted business.

III. NEW JERSEY'S OPIOID EPIDEMIC

18. Like the rest of the Nation, the State of New Jersey is suffering from a grave public health crisis: an epidemic of opioid abuse and addiction. In 2010, 843 people in New Jersey died due to heroin or opioid abuse. That number is expected to more than double for 2016, with over 1,000 confirmed deaths in the first half of 2016 alone.

19. During this time period, treatment centers have been inundated with heroin and opioid abuse cases. In 2012, 33,507 people were admitted to State-licensed or certified substance abuse treatment programs due to such abuse. In 2016, admissions climbed to 38,334.

20. Many afflicted by this epidemic are first seduced by legally-prescribed pain medications. According to the National Institute on Drug Abuse, eighty percent of new heroin users began their addictions by misusing prescription pain medications. Tragically, opioid-related deaths in the United States have more than quadrupled since 1999, according to the Centers for Disease Control.

21. Fentanyl—a synthetic opioid analgesic fifty times stronger than heroin and a hundred times more potent than morphine—is exacerbating the epidemic. In March 2015, the United States Drug Enforcement Administration issued nationwide alerts that identified fentanyl as a significant threat to public health and safety.

22. In New Jersey, fentanyl-related deaths increased ninefold from 2013 to 2015, and fentanyl has caused nearly as many New Jersey deaths during the first six months of 2016 alone as during all of 2015.

23. Like other opioids, the use of fentanyl in any form can lead to severe physical and/or psychological dependence, and may also result in sedation, nausea, vomiting, respiratory depression, circulatory depression, substance abuse, addiction, and death.

24. Based upon these dangers and the potential for abuse, the New Jersey Controlled Dangerous Substances Act, N.J.S.A. 24:21-1 et seq., classifies fentanyl as a Schedule II narcotic, restricting the manner in which it may be legally sold in the State. See N.J.S.A. 24:21-6(d)(6).

IV. INSYS OBTAINS FDA APPROVAL TO SELL AND MARKET ITS HIGHLY-POTENT FENTANYL PRODUCT FOR A SINGLE, NARROW INDICATION: THE MANAGEMENT OF BREAKTHROUGH CANCER PAIN IN ADULT OPIOID-TOLERANT PATIENTS.

A. The Approval Process for a New Drug Application

25. Pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. § 301 et seq., a drug manufacturer, like Insys, may not sell and market a new drug unless that drug has been evaluated and approved by the FDA. *See generally* 21 U.S.C.A. § 355. The FDA may approve a drug if, among other things, it concludes that there are "adequate and well-controlled clinical trials" that demonstrate the drug's safety and efficacy for "the conditions of use prescribed, recommended, or suggested" in its proposed labeling, which the FDA must also review and approve. See 21 U.S.C.A. § 355(d). The required labeling includes, among other things, the

drug's approved indication(s), dosages, "clinically significant adverse reactions," "other potential safety hazards," and "limitations in use imposed by them." See 21 C.F.R. § 201.57.

26. As a precondition to, and ongoing requirement of, approval of a new drug application ("NDA"), the FDA may require the drug manufacturer to implement a "risk evaluation and mitigation strategy" ("REMS") if the FDA determines such a strategy "is necessary to ensure that the benefits of the drug outweigh the risks of the drug." 21 U.S.C.A. § 355-1(a)(1). As part of a REMS, the FDA may require that the drug manufacturer "develop for distribution [a Medication Guide] to each patient when the drug is dispensed," 21 U.S.C.A. § 355-1(e)(2), if it determines the drug "pose[s] a serious and significant public health concern requiring distribution of FDA-approved patient information," 21 C.F.R. § 208.1.

27. Some drugs are more dangerous than others, and as such, may cause the FDA to impose additional restrictions as a condition of approval. For drugs deemed to have "inherent toxicity or potential harmfulness" and to be "associated with a serious adverse drug experience," the FDA may require that a REMS include "elements as are necessary to assure safe use of the drug" to "mitigate a specific serious risk listed in [its] labeling[.]" 21 U.S.C.A. § 355-1(f)(1)(A). Such elements may include, without limitation, a requirement that "health care practitioners who prescribe the drug have particular training or experience, or are specially certified," that "the drug be dispensed to patients with evidence or other documentation of safe-use conditions," and that "each patient using the drug be subject to certain monitoring [or] be enrolled in a registry." 21 U.S.C.A. § 355-1(f)(3).

B. The Prohibition Against Off-Label Marketing and the Making of False and Misleading Statements Regarding an FDA-Approved Drug

28. Following FDA approval of its NDA, a drug manufacturer, like Insys, may not market and promote the drug for a non-approved indication or in a manner inconsistent with the

drug's FDA-approved labeling, and its marketing and promotional materials may not contain false or misleading statements about the drug. See, e.g., 21 U.S.C.A. §§ 331, 352; 21 C.F.R. § 314.81. This restriction pertains to the clinical indications for which the FDA approved the drug, the dosing regimen that is supported by the clinical trials conducted to establish its safety and efficacy, as well as any other information appearing on the drug's approved labeling.

29. If a drug manufacturer, like Insys, believes that its FDA-approved drug should be sold, marketed, or otherwise promoted for indications different than those listed on its FDA-approved labeling, the law provides a way: the manufacturer must conduct additional "adequate and well-controlled clinical trials" to test the drug's safety and efficacy for the newly proposed indications, and file a supplemental NDA with the FDA. See 21 U.S.C.A. § 355(c)(5); 21 C.F.R. § 314.54.

30. Unless and until the FDA approves the drug for additional indications, any unapproved use is called "off-label," a term that refers to the use of an approved drug for an indication, or in any manner, other than what is described in the drug's approved labeling.

31. The above-mentioned restrictions on marketing, advertising, and false and misleading statements are in place to "protect the public health by ensuring that . . . drugs are safe and effective," 21 U.S.C. § 393(b)(2)(B), as well as guard against consumer abuse by profit-driven corporations, like Insys.

C. Subsys and the Highly-Potent "TIRF" Class of Fentanyl Drugs

32. TIRF medicines are formulations of fentanyl that deliver the drug nearly instantaneously to their users via the oral mucosa. At the time Insys submitted its March 4, 2011 NDA for Subsys, there were five available TIRF medications: Abstral (fentanyl sublingual tablet), Actiq and its generic equivalents (fentanyl citrate oral transmucosal lozenge), Fentora

(fentanyl buccal tablet), Lazanda (fentanyl nasal spray), and Onsolis (fentanyl buccal soluble film).

33. On January 4, 2012, the FDA approved Insys's NDA for Subsys, making it the sixth TIRF drug, and approved it for "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."

34. The FDA explained that the indication for all TIRF substances, including Subsys, is "narrow" for the following reasons:

> [T]he population identified has a specific need for a treatment to address cancer-associated breakthrough pain, which is characterized by a quick onset, often high severity, and relatively short duration. These formulations of fentanyl are designed to have a relatively rapid rise to [maximum concentration] and a relatively short duration of effect. Fentanyl is a very potent opioid that can cause respiratory depression in microgram quantities. For this reason, the indication also reflects the need for patients to be opioid-tolerant, a physiological state in which patients are more tolerant to the CNS [Central Nervous System] depression and respiratory depression associated with opioids.

35. To "ensure the benefits of the drug outweigh the risks of misuse, abuse, addiction, overdose, and serious complications due to medication errors," the FDA concluded that the approval of Subsys demanded the implementation of a REMS. Because the FDA found that Subsys "poses a serious and significant public health concern," it mandated, as one element of the required REMS, the "distribution of a Medication Guide," which it deemed to be "**necessary for patients' safe and effective use of Subsys.**" (Emphasis added.) In so doing, the FDA concluded that Subsys "is a product for which patient labeling could help prevent serious adverse effects and that has serious risks (relative to benefits) of which patients should be made aware" because such information "could affect patients' decisions to use, or continue to use Subsys."

36. Insys's proposed Subsys labeling, submitted as part of its NDA and approved by the FDA, contains repeated warnings about its dangers, as well as instructions that must be followed to ensure its safe use and to mitigate its risks. Specifically, for example, Subsys's Full Prescribing Information states, among other things, as follows:

> **WARNING: RISK OF RESPIRATORY DEPRESSION, MEDICATION ERRORS, ABUSE POTENTIAL**
>
> **Respiratory Depression**
>
> **Fatal respiratory depression has occurred in patients treated with transmucosal immediate-release fentanyl products such as SUBSYS, including following use in opioid non-tolerant patients and improper dosing. The substitution of SUBSYS for any other fentanyl product may result in fatal overdose.**
>
> . . .
>
> **Medication Errors**
>
> **Substantial differences exist in the pharmacokinetic profile of SUBSYS compared to other fentanyl products that result in clinically important differences in the extent of absorption of fentanyl that could result in fatal overdose.**
>
> . . .
>
> **Abuse Potential**
>
> SUBSYS contains fentanyl, an opioid agonist and a Schedule II controlled substance, with an abuse liability similar to other opioid analgesics. SUBSYS can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing SUBSYS in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse or diversion.
>
> [Emphases in original.]

37. Subsys's label makes unequivocally clear the class of prescribers who could appropriately prescribe Subsys, and also establishes the only appropriate initial starting dose:

> 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.
>
> . . .
>
> 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.
>
> . . .
>
> The initial dose of SUBSYS to treat episodes of breakthrough cancer pain is **always** 100 mcg.
>
> [Emphasis in original.]

38. Subsys's label also warned that it is prohibited and highly dangerous to convert patients on a one-to-one dosage basis from other formulations of fentanyl:

> Important Information Regarding Prescribing and Dispensing
>
> **SUBSYS is not bioequivalent with other fentanyl products. Do not convert patients on a mcg per mcg basis from other fentanyl products.**
>
> **When dispensing, DO NOT substitute a SUBSYS prescription for any other fentanyl product.** Substantial differences exist in the pharmacokinetic profile of SUBSYS compared to other fentanyl products that result in clinically important differences in the rate and extent of absorption of fentanyl. **As a result of these differences, the substitution of the same dose of SUBSYS for the same dose of any other fentanyl products may result in a fatal overdose.**
>
> **There are no conversion directions available for patients on any other fentanyl products. (Note: This includes oral, transdermal, or parenteral formulations of fentanyl.) All patients should be titrated from the 100 mcg dose.** Titrate each patient individually to provide adequate analgesia while minimizing side effects.
>
> [Emphases in original.]

39. Reflecting the grave dangers Subsys poses to public health and safety, the FDA determined that Subsys could be approved "***only if*** elements necessary to assure safe use are required as part of a REMS to mitigate the risks of misuse, abuse, addiction, overdose, and serious complications due to medication errors that are listed in the labeling." Such elements, the FDA found, "***will help assure proper patient selection and dispensing of Subsys.***" (Emphases added.)

40. The result was Insys's inclusion in the TIRF REMS Access Program ("TIRF REMS Access Program" or "Program")—a restricted distribution regulatory regime applicable to all TIRFs. As its name suggests, the Program governs the healthcare industry's *access* to TIRF drugs. All prescribers, pharmacies, distributors, and consumers seeking, respectively, to prescribe, dispense, distribute, and consume TIRFs must, by law, first enroll in the Program. To enroll, each must, among other things, acknowledge that TIRF drugs are available only through the Program and agree to comply with the Program's requirements.

41. With regard specifically to prescribers and pharmacies, who, upon enrollment, are granted the power to prescribe and dispense, respectively, enrollment means, among other things, that they must successfully complete a "knowledge assessment" (a quiz consisting of eleven multiple-choice questions) and acknowledge having read the Program's "Education Program for Prescribers and Pharmacists," which states, among other things, as follows:

> Appropriate Patient Selection
>
> Indication
>
> TIRF medicines are indicated only for the management of breakthrough pain in adult patients with cancer 18 years of age and older **who are already receiving and who are tolerant to regular opioid therapy for underlying persistent cancer pain.**
>
> . . .

> TIRF medicines are intended to be used only in the care of opioid-tolerant patients with cancer and only by healthcare professionals who are knowledgeable of, and skilled in, the use of Schedule II opioids to treat cancer pain.
>
> . . .
>
> Risk of Misuse, Abuse, Addiction, and Overdose
>
> TIRF medicines contain fentanyl, an opioid agonist and Schedule II controlled substance. TIRF medicines can be abused in a manner similar to other opioid agonists, legal and illicit.
>
> These risks should be considered when prescribing or dispensing TIRF medicines in situations where the prescriber or pharmacist is concerned about an increased risk of misuse, abuse, addiction, or overdose.
>
> Risk factors for opioid abuse include:
>
> - A history of past or current alcohol or drug abuse
> - A history of psychiatric illness
> - A family history of illicit drug use or alcohol abuse[.]
>
> [Emphases in original.]

42. On July 31, 2013, more than a year after Insys began to sell and market Subsys throughout the United States, the FDA approved a supplemental NDA submitted by Insys that slightly changed Subsys's labeling to reflect the following:

> **Patients on Actiq**
>
> The initial dose of SUBSYS is always 100 mcg with the only exception of [sic] patients already using Actiq.
>
> . . .
>
> For patients being converted from Actiq, prescribers must use the Initial Dosing Recommendations for Patients on Actiq table below[.] . . .

Current ACTIQ Dose (mcg)	Initial SUBSYS Dose (mcg)
200	100 mcg spray
400	100 mcg spray
600	200 mcg spray
800	200 mcg spray
1200	400 mcg spray
1600	400 mcg spray

. . .

All Other Patients

> 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[.]
>
> [Emphases in original.]

43. Upon the FDA's approval of Subsys, Insys issued a press release hailing Subsys as a novel and revolutionary drug for treating breakthrough cancer pain ("BTCP"). In that press release, among others, Jeffrey A. Gudin, M.D., a New Jersey-based anesthesiologist and pain management specialist and paid Insys consultant, was quoted as follows: "With the early onset of action, greater bioavailability, and broadest range of approved strengths, SUBSYS is poised to match the onset and intensity of a breakthrough cancer pain episode."

44. Since its launch in March 2012, Subsys was, and remains, extremely expensive, especially as dosage strengths increase from 100 mcg to 1600 mcg. Every year since its launch, Insys has increased Subsys's prices. The chart below summarizes the cost of a 120-dose supply of Subsys at each available dosage as of the month and year indicated:

Strength (mcg)	December 2012	December 2013	December 2014	December 2015
100	$2,830.08	$3,350.40	$3,960.98	$4,336.80
200	$3,577.20	$4,232.40	$5,002.82	$5,478.00
400	$5,192.88	$6,144.00	$7,263.43	$7,953.60
600	$6,742.56	$7,977.60	$9,430.67	$10,326.00
800	$8,302.80	$9,828.00	$11,617.56	$12,721.20
1200	$11,470.80	$13,536.00	$18,861.34	$20,652.00
1600	$14,638.80	$17,275.20	$23,235.12	$25,442.40

D. Coverage of Subsys Under New Jersey's SHBP, SEHBP and Workers' Compensation Program

45. The State provides comprehensive healthcare benefits, including prescription drug coverage, to its current and retired employees and their dependents through SHBP/SEHBP. The State is also responsible for paying its share of work-related claims, including prescription drug coverage, through its Workers' Compensation Program.

46. The SHBP/SEHBP and the Workers' Compensation Program provide coverage for prescription drugs, such as Subsys, only when prescribed by a healthcare provider as "medically necessary." Indeed, according to the SHBP/SEHBP Prescription Drug Plans Member Handbook, coverage does not extend to "[p]rescription drugs which do not meet medical necessity and appropriateness criteria." And in the definition of "Medical Necessity and Appropriateness," the Handbook states that "[e]ligible prescription drugs must meet federal Food and Drug Administration **(FDA) approved indications** and **be safe and effective for their intended use**." (Emphasis added.)

47. Insys's illicit and misleading marketing scheme to push Subsys off-label materially affected the State's decision to provide reimbursement for Subsys claims.

V. UPON THE FDA'S APPROVAL OF SUBSYS, INSYS IMMEDIATELY EMBARKED UPON A SOPHISTICATED, MULTIFACETED, AND PURPOSEFUL SCHEME TO EXPAND SUBSYS'S OFF-LABEL PRESCRIPTIONS—AND INSYS'S PROFITS—WITHOUT REGARD TO THE LAW OR CONSUMER SAFETY.

48. With deliberate disregard of the health, safety, and welfare of consumers to whom its highly-potent and dangerous opioid product would be prescribed, Insys aggressively sought to grow profits by illegally increasing Subsys's off-label use.

49. Insys effectuated its scheme in three primary ways:

a. One, Insys marketed Subsys in direct contravention of its FDA-approved label, including for initial prescriptions above the allowed 100 mcg dosage and prescriptions to treat non-BTCP.

b. Two, Insys paid for prescriber loyalty and production through various methods, including a sham speaker program through which the top 25 prescribers in New Jersey alone received at least $1.23 million in payments from 2012 to 2016.

c. And three, Insys went to great lengths to ensure its off-label prescriptions would be paid for by insurance companies, including by fraudulently misrepresenting patients' diagnoses and treatment histories.

A. Insys Employed a Sophisticated Approach to Market Subsys Off-Label.

1. Insys Deliberately Targeted High-Volume Opioid Prescribers Whom It Knew, Or Should Have Known, Did Not Treat BTCP Patients.

50. From the outset, Insys knew that the calculated targeting of high-volume opioid prescribers was critical to Subsys's success and trained its sales force accordingly. In particular, Insys targeted certain high-volume opioid prescribers, particularly high-dose prescribers of Actiq (and its generics), which Insys knew was mostly prescribed to non-cancer patients. Insys devised and instituted a focused targeting strategy designed, in tandem with its incentive

compensation structure and other marketing tactics described below, to promote the writing of Subsys prescriptions for off-label use.

51. Throughout the course of its illicit scheme, for example, Insys routinely provided its sales force with "target lists" ranking by "deciles" healthcare providers, including dentists and podiatrists, who could write prescriptions for controlled dangerous substances. Using third-party data and myriad metrics, such as a potential prescriber's history of prescribing specific opioids, like Actiq or Fentora, or a certain class of opioids, like short acting and rapid acting opioids, Insys ranked each prescriber by likelihood of becoming a high-volume, high-dose (and, thus, more lucrative) Subsys prescriber.

52. Contrary to its repeated public acknowledgments that appropriate targets of its marketing efforts would be oncologists, the target lists Insys provided to its sales force focused on high-decile opioid prescribers—not necessarily and, indeed rarely, oncologists—with few, if any, BTCP patients. Indeed, Insys's express marketing strategy, upon launch, was to "focus efforts on" high-decile prescribers, and then, "secondarily" to "expand efforts to oncologists[.]"

53. Insys's initial, pre-launch target lists underscore that strategy. For example, a "Hyper Target List" that Insys gave its sales force in May 2012, contained "ROO [or Rapid Onset Opioids] targets" who would likely prescribe Subsys. Of the New Jersey prescribers, nearly half specialized in Physical Medicine and Rehabilitation, and only one specialized in oncology. Based on a review of Insys documents, a small percentage of New Jersey Physical Medicine and Rehabilitation doctors prescribed Subsys to cancer patients and, of those patients, even fewer had BTCP.

54. Tellingly, it was not until more than a year after launch that Insys finally made some effort to target oncologists by hiring oncology-specific sales representatives ("SSPs") and

creating oncology-specific target lists. Insys's actions, however, reveal that those efforts were secondary to its goal to push Subsys off-label.

55. First, Insys employed thirty oncology-specific SSPs out of a total sales force that, at its height, exceeded approximately 250.

56. Second, Insys consistently noted internally that most oncologists were ranked with deciles of 1 or 2, placing them squarely *outside* the class of practitioners Insys routinely told its sales force were the "Right Prescriber[s]."

57. Indeed, Insys identified as an "issue" with its "oncology penetration" strategy that few oncologists, only two to three percent nationwide, prescribed ROOs, and most oncologists were reluctant to refer patients to pain doctors.

58. After poor performance in the oncology market, Insys disbanded its small oncology sales force approximately two years after creating it.

59. Insys knew, and, on information and belief, has always known, that exceptional Subsys sales could only be achieved by expanding the universe of patients prescribed Subsys beyond the BTCP patient population by (i) misleading healthcare providers and patients about the safety and efficacy of off-label use; and/or (ii) finding healthcare providers who cared less about patient safety than their own profits.

2. Insys Aggressively Pushed Prescribers to Write Initial Subsys Prescriptions Above The Permitted 100 mcg Dose In Blatant Disregard of Subsys's FDA-Approved Label and Patient Safety.

60. According to the FDA-approved Subsys label and for the express purpose of protecting patient safety, patients must be started on Subsys at a 100 mcg dose and titrated to a dose that adequately relieves the patient's BTCP.

61. This portion of the FDA-approved label negatively impacted Insys's profitability in two ways. First, as evidenced by Insys's internal communications, Insys management quickly

realized it would not have the same level of success converting patients to long-term Subsys users if they started at 100 mcg, as opposed to higher doses. Second, higher doses of Subsys are exponentially more expensive and, therefore, much more profitable for Insys.

62. Accordingly, under the direction of former CEO, Michael Babich ("Babich"), and Vice President of Sales, Alec Burlakoff ("Burlakoff")—both of whom have been criminally indicted by the U.S. Department of Justice on Insys-related charges of racketeering conspiracy, mail fraud conspiracy, wire fraud conspiracy, and conspiracy to violate the Anti-Kickback law—Insys employed several strategies that proved highly effective, including the (i) "effective dose" strategy, (ii) Subsys "Switch" program, and (iii) "Super Voucher" program.

63. Each of these programs is discussed briefly below.

i. The "Effective Dose" Strategy

64. On its face, the "effective dose" strategy was a push for prescribers to titrate patients to higher doses of Subsys. Titration may be appropriate for some BTCP patients who were initiated on Subsys using the starting dose of 100 mcg. That, however, was not Insys's approach to titration.

65. Rather, Insys pushed its sales force to ensure that prescribers would write initial prescriptions of Subsys at higher and, therefore, more lucrative doses. This was accomplished by pressure tactics from Insys's senior management.

66. By way of example, on August 29, 2012, Babich emailed all regional sales managers, stating as follows:

> We are seeing a number of 60 units of the 100 and 200 mcg still come through. **Our number 1 goal right now is effective dose and having reps promoting 60 units of the low strengths is not going to cut it**. . . .

> **Reps having doctors write scripts for 60 units at 100 mcg will be monitored.** I will let you know when the voucher is officially switched to block this.
>
> [Emphases added.]

67. Babich blind copied that email to John N. Kapoor Ph.D. ("Kapoor"), Insys's founder, principal shareholder, and then-Board chairperson. Kapoor is a billionaire pharmaceutical entrepreneur, who, the Wall Street Journal has reported, is "known for applying aggressive marketing tactics and sharp price increases on older drugs." Joseph Walker, Fentanyl Billionaire Comes Under Fire as Death Toll Mounts From Prescription Opioids, WALL STREET JOURNAL, November 22, 2016, at A8. The Department of Justice has identified Kapoor as an unindicted co-conspirator in its criminal prosecution of six former Insys executives and managers, including Babich and Burlakoff.

68. Shortly after Babich's email, on September 17, 2012, Burlakoff announced that the entire sales force would receive "daily" an email "each and every time a prescriber in [his or her] territory writes for a Subsys prescription at 100 mcg or 200 mcg." Within twenty-four hours, the sales representative was required to provide a report explaining "**WHY the low dose was used and HOW the doctor plans to titrate the patient to effective dose.**" (Emphasis added.) This became known as the "Daily Rep Report for Low Strength Usage."

69. In the same email, Burlakoff made clear that Insys had no intention of abiding by the requirement that all patients start Subsys at 100 mcg:

> We must educate our physicians how to ensure their patients find the "EFFECTIVE DOSE". I will go as far as to say that **we are truly better off dissuading a physician to prescribe Subsys for 100 and 200 mcg** until we have had ample time to review how clinical trial data with them via the Rauck study. After all, you only get once chance to make a **first impression**, is this the lackluster impression we want to make for our superior product?
>
> [Emphasis added.]

70. Significantly, while the Rauck study referenced in Burlakoff's email tested only the efficacy of Subsys in patients with BTCP, Insys endeavored to use its self-sponsored study as medical justification for healthcare providers to prescribe Subsys more broadly for all types of breakthrough pain.

ii. The Subsys "Switch" Program

71. In addition to the "effective dose" strategy, Insys marketed Subsys off-label through its implementation of the Subsys "Switch" program within the first year of Subsys's launch. That program had the express purpose of converting high-dosage (1200 mcg or 1600 mcg) Actiq patients (and later on, other TIRF patients) to the same high dosage of Subsys.

72. The Switch program was implemented in direct contravention of the Subsys label's explicit instruction that "SUBSYS is not bioequivalent with other fentanyl products. **Do not convert patients on a mcg per mcg basis from other fentanyl products. . . . [T]he substitution of the same dose of SUBSYS for the same dose of any other fentanyl product may result in a fatal overdose.**" (Emphasis added.)

73. In furtherance of the Switch program, in October 2012, Insys prepared and disseminated a standard operating procedure that made clear that the purpose of the program was to convert "115 patients" currently taking high-dose generic Actiq to the same dose of Subsys, and to maintain them on that dose for one year, which could generate between $15,829,704 and $20,201,544.

74. Insys's push for one-to-one off-label conversions from Actiq to Subsys was relentless and central to its marketing strategy. High-level executives routinely sent emails to the sales force regarding the Switch program and reminding them about the lucrative bonuses they would achieve upon successfully converting patients.

75. For example, on November 6, 2012, Babich emailed the sales force instructing them to "challenge your doctors who still use Actiq to try the switch program" and expressing that he is "anxious to sign that first 30K bonus check that quarter. It will be one of those big checks like they give out in gold [sic] tournaments. Happy Gilmore style!"

76. The "Switch Program" was especially nefarious because it was well-known to Insys at the time, especially to Burlakoff—who was formerly employed as an Actiq promoter—that most Actiq prescriptions were written off-label. Indeed, upon approving Subsys, the FDA noted that "the Actiq RiskMAP quarterly reports" show that "the use of Actiq in noncancer pain has exceeded its use in cancer pain" and that Actiq was "used primarily in opioid-tolerant patients with chronic **non-cancer pain**." (Emphasis added.)

77. Nonetheless, Insys directed its sales personnel to target Actiq prescribers. In April 2012, the month following Subsys's launch, Shawn Simon, then-Insys Vice President of Sales and Managed Markets, sent the entire Insys sales force an email providing guidance "[f]or those of you want to sell more faster . . . which is ALL OF YOU." In that email, among other things, Simon explained that a key "point of entry" for a physician considering placing a patient on Subsys is on "REFILLING a patient's Rx for Fentora or Actiq."

78. The next day, Frank Serra, Insys's former Northeast Regional Sales Manager, gave his sales team an even more focused target list of high volume and high dose Actiq prescribers, the vast majority of whom were not cancer specialists. Serra noted that this list provided a "tremendous amount of opportunity" to "maximiz[e] the chance to make money" and noted that "[t]here should be no reason we can't get at least 2 of these scripts per day."

79. On September 27, 2012, Burlakoff, using a colleague's email address, sent the sales force another focused target list of high-dose Actiq writers, highlighting the importance of the "Switch" program, particularly at converting higher dose prescriptions:

> As I am sure you know, **the "switch" program is our #1 sales undertaking at this juncture.** We have been working diligently to "fine tune" each individual sales representative's *Actiq 1200mcg and 1600mcg spreadsheet*, in order to provide you with the most detailed and focused sales tool to be utilized while visiting these highly viable targets in your territory – beginning tomorrow!
>
> [Emphasis in original.]

Burlakoff noted that he was "super excited" to announce this program, as it "affords us all a tremendous opportunity to get patients on Subsys." This "highly aggressive" program, Burlakoff further explained, has "one and only one goal in mind[:] **Your #1 initiative is to drive sales at all levels.**" (Emphasis in original.)

80. In New Jersey, Susan Beisler ("Beisler"), then a New Jersey-based Insys SSP, among others, put Insys's "Switch" program into effect. By email dated May 12, 2012, for example, Beisler informed Simon that one of her target doctors was going to "switch every [one of his] Actiq patients to 'Subsys' . . . as well as some Fentora patients."

81. In another example, on March 26, 2013, Beisler sent a colleague an opt-in form for a non-cancer chronic pain patient of a New Jersey physician, who had switched the patient from 1200 mcg of Actiq to 1200 mcg of Subsys—an off-label and highly dangerous one-to-one conversion.

82. In another example, Beisler proudly shared an email with Babich about her efforts to obtain insurance coverage for Subsys to treat "severe head trauma." Specifically, on June 6, 2013, Beisler emailed Babich stating that she "can't stop laughing" and that he "might want to share this [email] with the folks at the home office." Beisler continued that she "just helped [a

New Jersey doctor] gather 2nd level appeal docs for an IRC Fentora switch patient – she was rammed in the head by a bull . . . and now suffers from severe head trauma. Yup…she has serious Bull horn puncture wounds in her head . . . ."

83. Insys's efforts had a material impact on the prescriptions written by New Jersey healthcare providers. SHBP/SEHBP members, for example, were prescribed initial dosages of 100 mcg or another properly converted higher dose only twenty-four percent of the time; seventy-six percent of initial prescriptions were above the FDA-approved initial dosage.

84. Notably, Insys's Board of Directors, as well as Kapoor personally, actively monitored the Actiq conversions.

iii. The "Super Voucher" Program

85. A central component of the "Switch" program was its overlap with another of Insys's "patient assistance programs": the "Super Voucher" (or giveaway) program.

86. As a general matter, based on internal Insys documents and communications, Insys utilized the Super Voucher program to provide free Subsys prescriptions to prescribers, which (i) assisted the sales force in converting prescribers to Subsys, (ii) rewarded loyal and active prescribers, and (iii) allowed Insys to build a history of Subsys use for patients, thus making it easier to get prior authorizations from insurers.

87. In the case of the "Switch" program, the Insys sales force was encouraged heavily to use the Super Vouchers to secure Actiq (and other TIRF) conversions at the most lucrative high doses. Indeed, Burlakoff and others directed the sales representatives to focus on high-dose conversions: "In the spirit of providing the best product in class, Insys has agreed to grant patients across the nation who are currently taking 1200 mcg and 1600 mcg of Actiq an opportunity to 'switch' to Subsys. DROP EVERYTHING YOU ARE DOING, VISIT THESE TARGETS, AND GIVE AWAY FREE PRODUCT!"

88. In another email sent to each sales representative individually, Burlakoff instructed on how to succeed on the "Switch" program:

> Do me a favor, please be sure to utilize the attached list of specific doctors that Xun sent out. This list identifies the specific doctors in your territory whom [sic] have written a generic prescription of Actiq for 1200mcg or 1600mcg with in [sic] the last 12 weeks. What doctor would not jump at the opportunity to provide one of his or her patients a free "indefinite" prescription opportunity to "SWITCH" from a generic product that causes dental carries [sic] and increases the risk for death to children and pets[?]

89. Burlakoff further explained that "[t]he key" was to "have the doctor identify a 'switch' patient while you are in the office," then to call Insys corporate headquarters requesting that a "super voucher" be called into a pharmacy "under the doctor's name for a specific # of units and strength," and then "the physician sends the patient to the pharmacy." (Emphasis added.)

90. To be clear, the Super Vouchers could be used by patients to obtain at least a one-month supply of Subsys **at any dosage**, including 1200 mcg and 1600 mcg. Indeed, in the case of the higher doses, Insys continued to supply free Subsys on a month-to-month basis until it was able to secure a prior authorization from the insurer.

91. In sum, through its various programs, Insys repeatedly and purposefully marketed Subsys in direct contravention of its FDA-approved label, risking patients' lives in the process.

3. Insys Was Not Truthful About the Permissible Uses of Subsys and its Dangers.

92. In connection with Plaintiffs' investigation, a former New Jersey Subsys prescriber—among the top in New Jersey and the SHBP/SEHBP—testified under oath about, among other things, representations made by former Insys regional sales manager and New Jersey based sales representative, Michelle Breitenbach ("Breitenbach").

93. Specifically, the former prescriber testified that he was told to "prescribe Subsys for patients with chronic pain where other medications have previously failed" and that he "could try Subsys on chronic pain patients."

94. The former prescriber added that he wrote Subsys prescriptions off-label for chronic pain patients because of his sales representative's representations about the allegedly positive off-label uses of Subsys. He explained that he was told "that other physicians had tried prescribing Subsys off-label and it had worked for those physicians and their patients."

95. This former prescriber concluded that it was fair to say "that Michelle Breitenbach as the representative of Insys, relayed to [him] in some fashion or another that it was acceptable to prescribe Subsys off-label for chronic pain for patients who had taken other medications that had failed." Of course, the sales representatives made no mention of the risks attendant with the off-label use.

96. Based on records produced by Insys, this former New Jersey prescriber wrote Subsys prescriptions off-label ninety-six percent of the time, primarily for the treatment of chronic pain. In particular, out of the at least seventy prior authorization forms submitted on behalf of this former prescriber's patients, only three—or a mere four percent—indicated a patient diagnosis of cancer, one of which was for "Previous Breast Cancer."

97. Moreover, this former New Jersey prescribed routinely wrote Subsys prescriptions for new patients above the FDA-approved 100 mcg dosage—a key component of Insys's marketing strategy. By way of example, the former prescriber wrote Subsys prescriptions to six patients who were members of either the SHBP or SEHBP, all at an initial starting dosage of 400 mcg or 600 mcg. None of those patients was being converted to Subsys from another TIRF.

98. Similarly, another New Jersey doctor has alleged in a complaint against Insys and former Insys sales representative, Melina Ebu-Isaac, that Ebu-Isaac "encourage[d] her to prescribe Subsys for her patients—regardless of whether they suffered from breakthrough cancer pain" and, further, encouraged her to prescribe Subsys "for uses other than breakthrough cancer pain."

99. Insys's sales representatives even encouraged their speaker-prescribers to induce other healthcare providers to prescribe Subsys off-label. For example, as early as August 2012, New Jersey-based sales representative, Susan Beisler, updated Babich about one of her New Jersey-based doctors, who she represented would "write off label for chronic pain." That New Jersey doctor informed Beisler that he had asked another New Jersey doctor "to prescribe Subsys for chronic pain" but that there was "[s]ome hesitation on [the other doctor's] end." Ultimately, that doctor overcame his "hesitation" and began writing off-label Subsys prescriptions.

100. Pushing healthcare providers to prescribe Subsys off-label was an Insys-wide practice, as evidenced by one of Insys's presentations titled, "Overview of Managing Chronic Pain in Cancer Survivors: Benefit-Risk of Long-Term Opioid Therapy." Insys disseminated this PowerPoint to numerous doctors, many of whom were in New Jersey, to be presented to other healthcare providers to push the prescription of Subsys for the treatment of chronic—not breakthrough—pain, in cancer survivors, not cancer patients. And many of these healthcare providers ultimately gave this presentation at Insys sponsored lunches, dinners and other "educational programs."

4. Insys Utilized Untrue and Misleading Sample Letters of Medical Necessity to Facilitate Prior Authorization of Off-Label Subsys Prescriptions.

101. As part of Insys's off-label marketing scheme, Insys created and disseminated to prescribers across the Nation—including in New Jersey—several template letters of medical

necessity ("LMN") containing language it deemed sufficient to secure insurance reimbursement for off-label Subsys prescriptions. As Insys came to learn more about the prior authorization requirements for each insurer with whom it regularly communicated, these template LMNs grew increasingly more sophisticated and deceptive.

102. The first LMN—which Insys referred to as the "generic LMN"—contained language that purports to justify off-label Subsys prescribing for "severe pain" and "breakthrough pain"; it does not, however, mention cancer at all. This generic LMN, which Insys began to give its sales professionals as early as September 2012, appears below:

Medical Necessity Letter

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,

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103. As early as November 2012, high ranking Insys official, Elizabeth Gurrieri, the former manager of the IRC who pleaded guilty to one federal count of conspiracy to commit wire fraud in June 2017, emailed the generic LMN to SSP Breitenbach for use by New Jersey doctors.

104. In or around the first half of 2013, in apparent recognition that an insurer might seek a better written justification for the approval of off-label Subsys prescriptions—specifically for treating non-cancer breakthrough pain—Insys created and disseminated a more robust LMN, which it called the "strong LMN." The strong LMN purported to provide medical evidence in support of off-label uses, but it was replete with misleading and false information.

105. For example, the strong LMN represented that "[t]he literature since 2007 shows a favorable safety profile [for Rapid Onset Opioids]," but omitted any reference to opioid-induced hyperalgesia or any of the other dangers, such as addiction, respiratory depression and death, attendant to the use of a TIRF, such as Subsys.

106. The strong LMN also stated that "[a]rticles as well as recent studies which are peer reviewed are available by Lynn Webster, M.D.> [sic] et al showing efficacy of a rapid onset opioids [sic] in non-cancer patients . . . ." One New Jersey Subsys prescriber, who signed a strong LMN, testified that he had no knowledge of any such study.

107. The strong LMN also made representations about patients, which, in at least some New Jersey cases, Plaintiffs have confirmed were false. For example, it states that "[t]he patient has read the FDA letter issued to physicians, which was issued in 2007" and has "read and signed a special consent that includes off-label use information, and has been counseled on proper use." In addition, the letter states that "the patient has completed the REMS enrollment program." This language appeared verbatim in LMNs in doctors' records across the Nation. A former New Jersey prescriber testified that he had no knowledge of any 2007 FDA letter. Accordingly, his patients could not have read the FDA letter.

108. Insys's strong LMN also stated that the doctor submitting the LMN "would expect this necessity [to take Subsys] to continue for a life-long period." The same former New

Jersey prescriber in whose records such LMNs appear, however, testified under oath that he did not write that sentence and disagreed with its substance.

109. In addition, the strong LMN stated that the doctor who submitted it had "studied, lectured and written about chronic pain, including breakthrough pain," which was manifestly untrue in the case of the former New Jersey prescriber interviewed under oath.

110. Insys's use of these LMNs to secure insurance coverage for off-label Subsys prescriptions was pervasive. Indeed, these LMNs appear in medical records for patients residing in no fewer than ten states, including in Alabama, Arizona, California, Colorado, Connecticut, Florida, New Jersey, New York, Pennsylvania and Texas.

111. In New Jersey, LMNs with identical—or virtually identical—language appear in the records of over twenty New Jersey prescribers.

112. Underscoring Insys's use of the strong LMN for off-label uses, Insys utilized a separate LMN, which it named the "Perfect Cancer LMN," to be used exclusively for on-label purposes, namely a 100 mcg dose for patients suffering from BTCP who were already receiving and who were tolerant to around-the-clock opioid therapy. Accordingly, the strong LMN served no purpose other than to facilitate Insys's deceptive promotion of Subsys off-label.

5. Insys Utilized Company-Generated Insurance Forms That Misleadingly Represented It was Appropriate to Prescribe Subsys for Unapproved Indications.

113. To facilitate insurance coverage for off-label Subsys prescriptions, Insys created several iterations of what it called "Opt-In Forms" or "IRC forms." These forms also served to alleviate prescribers' frequently expressed concerns about the burdens of the prior authorization process, which Insys executives identified as a hurdle to securing increased Subsys prescriptions.

114. At least one widely-used version of these forms contained a pre-printed list of thirteen possible diagnoses for Subsys, of which only one was cancer. The other twelve were for

non-FDA-approved indications, including "Chronic Pain Syndrome," "Dysphagia," and "Degeneration of cervical intervertebral disc/Degeneration of cervicothoracic intervertebral disc."

115. In so doing, Insys misleadingly and deceptively represented to patients, insurers, and pharmacy benefit managers ("PBMs"), including the PBMs for SHBP/SEHBP and the Workers' Compensation Program, that it was appropriate and acceptable to prescribe Subsys for those off-label purposes.

116. For example, on February 27, 2013, top Insys executive Michael Gurry, emailed the entire sales team, enclosing a "completed IRC" form that he deemed to be a "good example of a completed 'opt in' form," which sales representatives could use to "coach HCP offices." The attached completed IRC form was for a non-cancer patient with chronic pain, a clear off-label indication for Subsys. Notably, perhaps aware of the inappropriateness of his email, Gurry attempted to recall it a few hours later.

117. It was Insys's express intent that these forms be used specifically to obtain off-label Subsys prescriptions and, on information and belief, to mislead patients, insurers, and PBMs. And it worked: Insys received completed IRC forms on behalf of over 850 patients.

6. Insys Directly Misled Patients to Promote Subsys for Off-Label Purposes.

118. Insys sales representatives went so far as to contact patients directly to push Subsys.

119. For example, on January 5, 2015, New Jersey-based sales professional, Melina Ebu-Isaac, met with patient and New Jersey resident, Sarah Fuller, to "teach" Ms. Fuller about Subsys and, more specifically, to explain how Subsys "would help her greatly with chronic pain," a clearly off-label indication. Ebu-Isaac misled Ms. Fuller about the safety and efficacy of

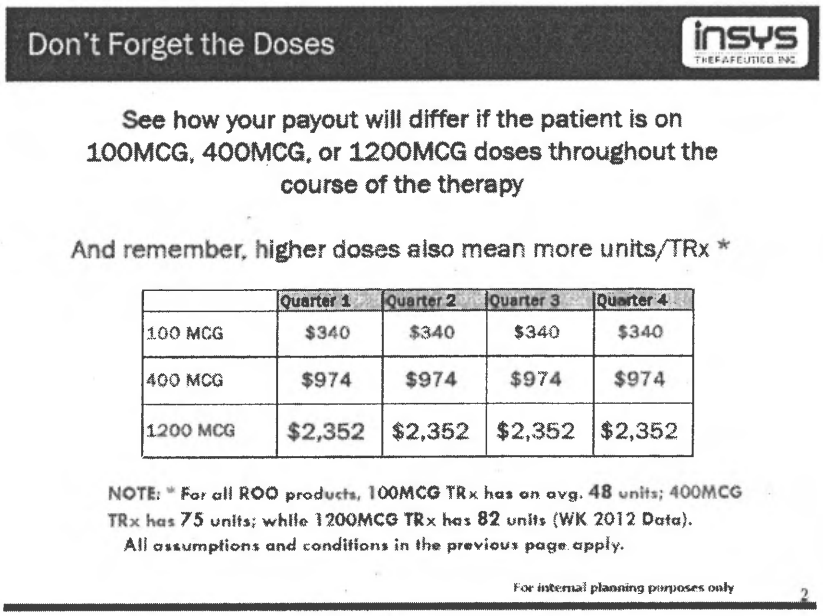
Subsys, its addictive traits, and its grave risks. Shortly thereafter, Ms. Fuller died of a Subsys-induced overdose.

120. In another example of the sales force's direct contact with patients, on June 3, 2013, SSP Beisler directly emailed a patient of a New Jersey doctor with a draft LMN requesting, in the name of the patient, insurance coverage of Subsys for the off-label purpose of "severe chronic intractable pain."

7. Insys Purposefully Compensated Its Sales Force In A Manner That It Knew, Or Should Have Known, Was Likely To Result In Illegal Conduct.

121. In furtherance of its illicit off-label marketing scheme, Insys motivated its sales force to unscrupulously sell Subsys by any means necessary, including through its compensation structure, which was heavily weighted on commissions and rewarded the achievement of certain goals known to the company to increase off-label Subsys prescriptions.

122. Indeed, Insys management took great pains to remind its sales force that "Higher Doses = Higher Payouts!" and "More Patients = More $$$!" They also routinely used incentive compensation-related charts like the one below to motivate its sales force to push higher doses of Subsys:



Don't Forget the Doses

insys THERAPEUTICS, INC.

See how your payout will differ if the patient is on 100MCG, 400MCG, or 1200MCG doses throughout the course of the therapy

And remember, higher doses also mean more units/TRx *

	Quarter 1	Quarter 2	Quarter 3	Quarter 4
100 MCG	$340	$340	$340	$340
400 MCG	$974	$974	$974	$974
1200 MCG	$2,352	$2,352	$2,352	$2,352

NOTE: * For all ROO products, 100MCG TRx has an avg. 48 units; 400MCG TRx has 75 units; while 1200MCG TRx has 82 units (WK 2012 Data).
All assumptions and conditions in the previous page apply.

For internal planning purposes only

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123. And in an industry in which bonus compensation and aggressive management are not unique, in or around 2016, an outside consulting firm concluded that Insys's incentive compensation structure was troubling because it incentivized non-compliant behavior and was "way outside the norm."

124. As recently as June 2016, in response to the consulting firm's findings, Insys Executive Vice President and former COO Daniel Brennan ("Brennan") emailed Kapoor to relay his serious concerns about Insys's "overall sales rep compensation" structure, as well as Insys's hiring of subpar pharmaceutical representatives. In particular, Brennan explained that Insys is "still creating an environment of non-compliance by paying a low base salary (barely above minimum wage) and then very high ratio of incentive pay as their overall comp."

125. Indeed, as Brennan explained to Kapoor, the consulting firm's interviews of Insys's employees revealed that they themselves found that Insys's "compensation structure encouraged inappropriate behavior," which Brennan assumed to mean "off label promotion and quid pro quo behavior." In Brennan's words, "with a potent pain product like [Subsys] ha[s], it

is dangerous to have so little previous pharma experience/training." Brennan "strongly recommended" a change in payment structure "that is more in line with industry standards and creates a more compliant-behaving sales organization (important given the scrutiny we have with DOJ and media coverage of our company – both affecting our reputation and trust with customers and our internal personnel)."

126. After Kapoor forwarded Brennan's email to Insys Board Member Patrick Fourteau, Fourteau replied to Brennan by stating that he did "not like either the tone or the substance of [Brennan's] message."

127. When Kapoor responded to Brennan's email the following day, he, among other things, attempted to shift the blame from Insys to Brennan: "To be entirely honest, I am a little concerned that your email directly follows on the heels of the recent termination discussions (and actions) related to your commercial team."

B. In Exchange for Off-Label and Continued Subsys Prescribing at High Doses, Insys Provided Kickbacks to New Jersey Prescribers.

128. To guarantee that healthcare providers continued to prescribe Subsys off-label to their patients at high doses, Insys paid them kickbacks. These payments, which amounted to millions of dollars over the years, were disguised as *bona fide* compensation for participation at sham Insys-organized and Insys-sponsored "informational events" and for serving as consultants or advisors on sham Insys-organized boards. Insys's payment of kickbacks to certain key healthcare providers was central to its scheme, and as such, Insys devoted a substantial amount of its budget to bribing them.

129. The primary way Insys bribed Subsys prescribers was its so-called "speaker bureau" ("ISB"). The ISB was established shortly after Subsys's market launch purportedly to "support [Insys's] marketed prescription drugs products." According to an Insys-generated

standard operating procedure document from November 2012, "[s]peakers selected to participate in bureaus are responsible for delivering INSYS Speaker Programs (ISPs), with the objective of educating and informing healthcare professionals (HCPs) in the medical community about marketed INSYS products in a fair and balanced manner." That document claimed that an "HCP must never be engaged as a speaker in order to induce, influence, or reward him or her for using any INSYS product."

130. The reality, however, was far different. Contrary to the ISB's professed purpose of "educating and informing healthcare professionals," Insys routinely equated successful "speaker programs" or "ISPs" with a high "return on investment" or "ROI." Moreover, as demonstrated by Insys's own documents, it intended that its "speakers" would write Subsys prescriptions in exchange for more ISB events.

131. For example, by email dated March 14, 2013, Burlakoff noted that the only sales representatives to whom Insys should allocate "ISP funds" are those who "get the most bang for their buck using our money." In that email, he griped that "I am tired of giving money to reps whom [*sic*] produce zero return on investment" and stated that "[t]hose whom [*sic*] do not produce ROI from programs should not be spending our ISP dollars[.]"

132. Similarly, Insys management regularly instructed its sales representatives to offer speaking engagements to the "docs" who show a "**willingness to prescribe**," which, as Serra explained to his sales force in August 2012, "**is basically why we have jobs.**" (Emphasis added.) Notably, in that same email, Serra **expressly discouraged his sales representatives from targeting oncologists as possible speakers**, instead instructing them to focus their efforts elsewhere because "[r]ight now there are way too many Pain Targets that need to prescribe."

133. The next month, Burlakoff emailed the entire sales force, with a blind carbon copy to Kapoor, to reiterate this point: "If you cannot guarantee that [a speaker] program will yield positive results, the program should not take place." Burlakoff explained that "[t]hese programs have been offered to you as the #1 opportunity to grow your business" and reminded them that they "get paid to produce tangible results."

134. Burlakoff proceeded to instruct the sales force on how to guarantee success of an ISP: "Your program will absolutely NEVER be successful if your speaker does not have at least 10 times more clinical experience than all of your attendees combined! If your speaker is not an expert with the utilization of Subsys in his or her clinical practice, then your speaker need not speak for Insys anymore."

135. In a reply to a sales representative's response to this email, Burlakoff wrote: **"Your local speaker should be your 'business partner'. You do not work for him, nor does he work for you. You are partners in this endeavor, if your speaker does not see it this way[,] then it is time to identify another speaker."** (Emphasis added.)

136. Insys leadership's insistence on speakers with significant "clinical experience" had nothing to do with those speakers' ability to better educate speaker program attendees. Indeed, Insys paid New Jersey doctors for speaking engagements **that they gave to themselves**, without anyone else present. For example, one New Jersey doctor ("NJ Speaker"), who was one of the top prescribers of Subsys in New Jersey, as well as one of the highest paid speakers for Insys in New Jersey, was supposed to do a speaking engagement for an audience of one—another New Jersey doctor who worked at the same location as the NJ Speaker. The Program Sign-In Sheet, however, reflects that only the NJ Speaker was present at his own program. As this was merely a pretext for Insys to funnel a kickback to the NJ Speaker as a reward for his

writing Subsys prescriptions, it did not matter that he gave the presentation to himself; Insys paid him $1,600 for his speaking engagement.

137. When considered together with the conduct, statements, and expectations of other Insys executives and representatives, as well as the reality that most, if not all of the ISPs were shams in which no actual educational presentation was made, it becomes clear that Burlakoff's reference to "clinical experience" means that a speaker's admission to the Speaker Bureau was, and remained, contingent upon the speaker's demonstration of loyalty to Insys by writing Subsys prescriptions.

138. Insys relentlessly drummed the "clinical experience" mantra into its sales force, i.e., offer speaking engagements only to loyal Subsys prescription writers. For example, as early as April 2012, the second month Subsys was on the market, Shawn Simon, then Vice President of Sales, emailed the entire sales force to explain that doctors who had attended any "Consultant meetings" but who had not yet prescribed Subsys were "prime targets to ask to begin immediately in gaining their 'clinical experience' with SUBSYS." In an email sent only to Babich and regional sales managers on April 2, 2012, Simon stated that he had approached one of the top Insys "consultants" at the time who he claimed had "talke[d] a big game at the consultant meetings" but complained that he had not yet "put[] pen to paper." Simon explained that this doctor "**knew where I was coming from when I asked about his experience and quickly claimed he would start patients tomorrow**. We will have lots of these guys. . . There will be many like him who need a gentle reminder and a close for their business." (Emphasis added.)

139. In New Jersey, sales representative Susan Beisler rewarded her best prescribers with speaker programs. For example, in a February 7, 2013 email to a manager arguing that a

New Jersey nurse practitioner should receive more "speaker fees," Beisler wrote that the nurse practitioner **"has gained a ton of clinical experience in order to speak for us."** (Emphasis added.) After receiving approval to give the nurse practitioner speaking engagements, Beisler emailed the nurse practitioner to share the good news and emphasize that the speaking events were provided as a result of the nurse practitioner's Subsys prescriptions: "My company made an exception for you as we aren't starting up speaker programs again until April. **They see you're prescribing and gaining clinical experience with Subsys, so I asked for more programs asap – it worked :)**" Beisler also noted that she would be targeting two speaker lunches/dinners each week for the nurse practitioner. (Emphasis added.)

140. One week later, Beisler again emailed the nurse practitioner and, in the context of explaining why Beisler had decided to give her "the majority of [her] programs," confirmed Insys's definition and utilization of the term "clinical experience": "Some of these Doctors have written 1 or 2 Subsys scripts and they want to get paid for their expertise using Subsys. Seriously? I don't think so!! The money goes where the clinical experience is."

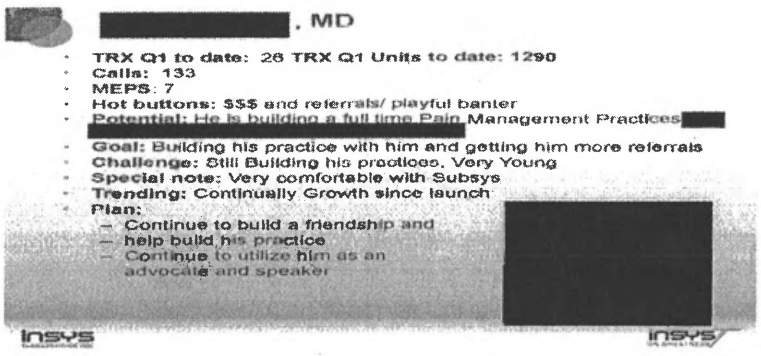
141. Meaningfully, in this email, as explained in more detail later, Beisler confirmed that these "speaker programs" were, in truth, shams designed to serve as a pretext for funneling money to prescribers: "I really appreciate all you've done for me, you are my best prescriber, . . . **I'll bring in donuts and a box of Joe and call it a programmy-day [sic] for you anytime.**" (Emphasis added.)

142. In another example, according to SSP Michelle Breitenbach, one of her New Jersey doctors told her "**he owes me a few scripts**" after the doctor missed a scheduled "virtual speaker training." (Emphasis added.) That doctor later became one of New Jersey's highest paid Insys speakers. In the second quarter of 2015, however, the doctor fell behind on his

Subsys prescription quota, causing Breitenbach's supervisor to email her the following: "You need to push/pull through whatever . . . PAID RXs you can [of the New Jersey doctor] btwn [*sic*] now and the 31st. [The New Jersey doctor] is like **30K short still just of breaking even.**" (Emphasis added.) Significantly, Breitenbach forwarded her supervisor's email to the New Jersey doctor's personal email address.

143. Similarly, Breitenbach forwarded this New Jersey doctor an October 2014 email from Linden Care Pharmacy that stated: "[W]e have not seen many scripts from [this New Jersey doctor], is there a problme [*sic*] or issue we should know about?"

144. Further, money was referenced in Insys's training materials. For example, in a draft PowerPoint for "breakout sessions" for Insys sales representatives at a National Sales Meeting, Breitenbach referred to "$$$" as a hot button for a New Jersey physiatrist who was a top recipient of Insys speaker fees, as well as the goal of "getting him more referrals":



145. Tellingly, in their personal communications, sales representatives frequently complained or expressed concern about Insys's bribery scheme and related misdeeds and, in so doing, revealed the true nature and purpose of the Insys Speaker Bureau.

146. For example, in various emails, Beisler complained that "**only Alec [Burlakoff]'s 'friends' are getting ahead because all their doctors are being paid off to write this dumb**

drug" and that "They WAY overdid it at Insys . . . Great job Alec ruining all our lives!!" (Emphasis added.)

147. In another example, on May 21, 2014, Beisler forwarded to a personal friend an email regarding a recent Insys-related investigation of prescribers, writing: "Yup. Fucked." In response to her friend's attempts to assuage her concerns by stating that "it's bad for the doc" and "not bad for your company," Beisler responded as follows: "**The thing is they bribed the shit out [o]f that guy to write. The complaint shows ten other docs they also bribed.**" (Emphasis added.)

148. Similarly, on June 27, 2015, Beisler forwarded another friend a news article regarding a guilty plea of a nurse practitioner in Connecticut who Insys had bribed to write Subsys. In the email chain that followed, Beisler expressed concern about her exposure to potential criminal liability, stating "**I just hope I don't get arrested since [a New Jersey doctor] is my doctor and our 'speaker' dinners are being investigated too.**" (Emphasis added.)

149. When Plaintiffs interviewed Beisler under oath, she invoked her Fifth Amendment privilege against self-incrimination in response to the following question: "[Y]ou arranged speakers' programs involving [the New Jersey doctor referred to in her June 2015 email] that funneled thousands of dollars to [the doctor] as a quid pro quo to write Subsys prescriptions off-label in New Jersey, isn't that right?" That was only one of more than 400 separate Fifth Amendment invocations Beisler made during her interview.

150. The kickbacks took other forms too.

151. Insys, for example, rewarded one of its top New Jersey prescribers and speakers by creating a brand new sales territory specifically for the purpose of hiring that prescriber's

brother. By email dated October 3, 2013, SSP Breitenbach emailed the resume of the New Jersey prescriber's brother to Burlakoff for consideration, to which Burlakoff replied: "I'll see what I can do." Eleven days later, on October 14, 2013, Xun (Sean) Yu emailed the prescriber's brother and Burlakoff revealing that he would be "working with [his] team to create a territory [for him] centered on Saratoga and Albany, with areas covering north & eastern NY, as well as possibly western Vermont and Massachusetts." That day, Burlakoff made sure that the New Jersey prescriber knew about this development by asking Breitenbach to forward Yu's email to him. The New Jersey prescriber replied, "Wonderful."

152. The next year, on March 11, 2014, the New Jersey prescriber specifically requested that his brother be assigned to serve as his and his nurse practitioner's sales representative, even though his brother's territory was in upstate New York and Connecticut. Insys complied.

153. Most strikingly, Insys's kickback scheme was highly effective in securing prescribers' continued writing of Subsys prescriptions. Specifically, based on data produced by Insys, in New Jersey, **the top ten prescribers from launch to November 11, 2016, wrote 46% of Insys prescriptions at a value of nearly $34 million, and they received about 50% of the Insys payments, totaling at least over $880,000**. Most of the top New Jersey-based recipients of Insys monies show a strong correlation between a speaker's receipt of Insys money and his or her Subsys prescribing.

C. Insys Established an Internal Business Unit Charged With Fraudulently Inducing Insurers and PBMs to Pay for Off-Label Subsys Prescriptions.

1. A High Approval Rate for Prior Authorization Requests is Critical to Insys's Profitability.

154. Because of Subsys's high cost, most consumers are not able to obtain it without insurance coverage. At all times relevant to this Complaint, Insys's financial success, therefore,

depended upon approval of Subsys prior authorization requests, often a prerequisite to insurance coverage for any costly and dangerous medication or therapy.

155. Initially, Insys encountered a significant obstacle to securing consistent insurance coverage for Subsys: Most third-party payers generally would not pay for Subsys unless, among other things, it was prescribed to manage BTCP. Because the population of BTCP patients is very small and, as Insys was well aware, comprised only a fraction of its prescriptions, Insys could not meet its lofty sales goals without facilitating insurance coverage approval for off-label Subsys prescriptions.

156. Indeed, around eight months post-launch, only approximately thirty to thirty-three percent of all Subsys prescriptions had received prior authorization.

157. Cognizant that this low number of successful Subsys prior authorizations threatened its business, Insys executives schemed to overcome this obstacle through the use of fraud, misrepresentations, and false pretenses.

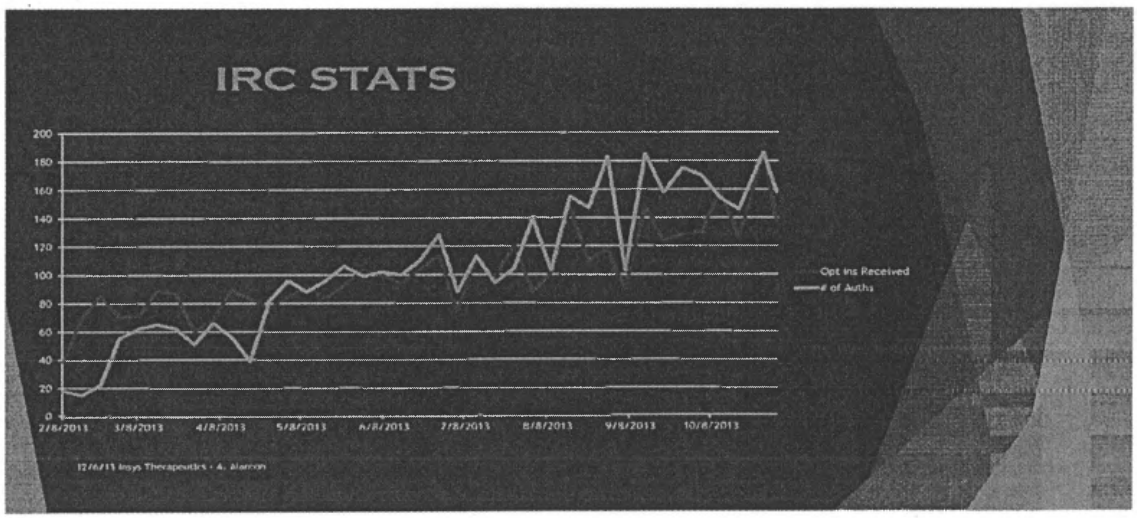
2. Insys Created the IRC to Systematically Manipulate the Prior Authorization Process.

158. In or around November 2012, Insys established an in-house business unit comprised of so-called "prior authorization specialists," whose sole purpose was to "do whatever it takes" to secure insurance coverage approval for all Subsys prescriptions, particularly those written off-label.

159. Insys, by and through this unit, initially known as the Insys Reimbursement Center ("IRC"), and later, as the Patient Services Center ("PSC"), engaged in pervasive insurance fraud to ensure third-party payer approval of the off-label Subsys prescriptions that inevitably resulted from Insys's illegal conduct (as described above).

160. When the IRC was first established, only twelve prescribers used it to obtain prior authorizations. Just over a year later, by December 2013, more than 950 prescribers nationwide had made use of the IRC's "services," and the IRC had secured approval for more than 90% of prior authorization requests that it processed.

161. The IRC's early success is illustrated well by the following chart from an internal IRC training PowerPoint entitled "Welcome to the IRC":



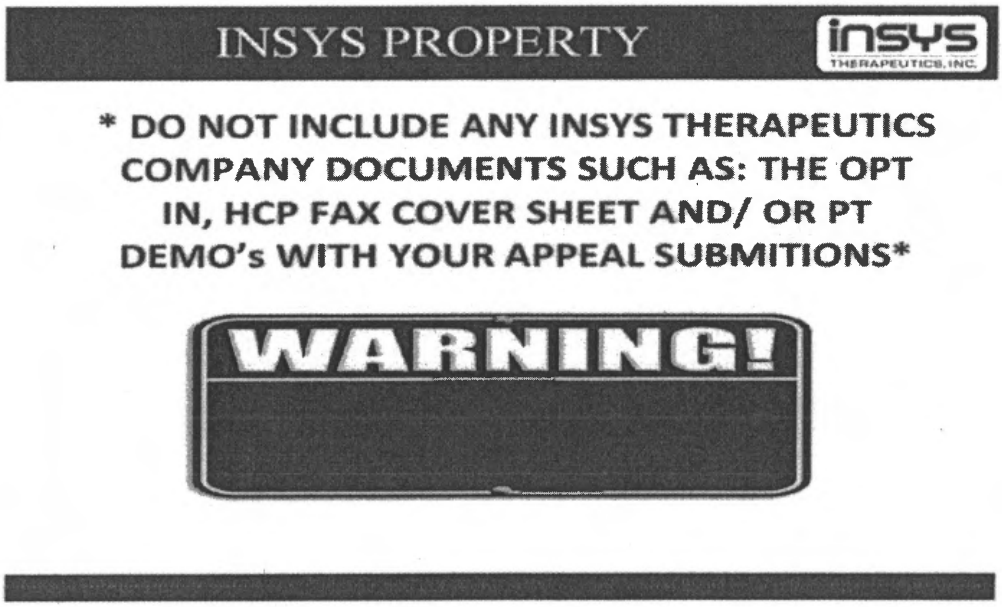
162. Insys, by and through the IRC, fraudulently induced insurers to pay for off-label Subsys prescriptions in three principals ways.

i. Insys Hid the Existence of the IRC and Misrepresented that Prior Authorization Calls Made by the IRC Were Coming from Healthcare Providers.

163. Insys concealed the IRC's existence, and, thus, Insys's role in the prior authorization process, from third-party payers by: (i) directing IRC employees to falsely represent to insurers and PBMs that they were employees of the prescriber; (ii) masking the IRC's telephone number during outgoing calls to maintain the illusion that IRC employees were calling from the prescriber's office; and (iii) instructing IRC employees, when handling appeals

from denials of prior authorization requests, never to mention Insys's name in any written materials submitted to a third-party.

164. Insys knew that the success of its scheme would be jeopardized if an insurer or PBM discovered that an Insys employee was contacting it to obtain prior authorization. And so, in an internal IRC training PowerPoint, Insys instructed that when handling appeals from denials of prior authorization requests, IRC employees should heed the following warning:



ii. Insys Falsely Represented, Both Verbally and in Writing, That Patients Had Cancer and Breakthrough Cancer Pain.

165. For those insurers and PBMs that allowed for the prior authorization process to occur via telephone, Insys instructed IRC personnel to follow scripts containing canned answers to questions commonly posed by major insurers and PBMs; answers that had "whatever it takes" to guarantee a successful prior authorization.

166. By email dated June 29, 2014, to Insys Senior Vice President of Operations Christopher Homrich, Elizabeth Gurrieri, the former manager of the IRC who pleaded guilty to

one federal count of conspiracy to commit wire fraud in June 2017, revealed the extent of the IRC's misconduct in this regard:

> I have attached the list of most common insurance payors and the details that coincide with each payor. I have created a tab for each insurance plan at the bottom of the spreadsheet.
>
> You will notice that most of the insurance plans indicate that the patient must have cancer, but in actuality, all plans are different. To the best of our abilities, we came up with a somewhat generalized list for you. . . .

167. In that same email, Gurrieri made clear that the purpose of her prepared script was to "assist us in getting prior authorizations approved through most insurance companies[.]" She explained:

> It is very helpful to have a diagnosis that includes pain, such as 338.29 (other Chronic Pain), 338.4 (Chronic Pain Syndrome), and/or 338.3 (Neoplasm Related pain). It is also helpful if the diagnosis of dysphagia (787.2) is attached as well. . . . ***Most*** insurance companies require that a combination of at least 3-5 long-acting opioids and short-acting opioids have been tried and failed (please see attached spreadsheet for the list of most common tried and failed medications). Generally speaking, the PA Specialists have a greater opportunity of getting an opt in approved through insurance when there is an extensive list of diagnoses along with a complete list of tried and failed medications (more information is always better than less).
>
> [Emphasis in original.]

168. Gurrieri also made clear that, despite the hurdles to obtaining prior authorization for off-label Subsys prescriptions, the IRC was up to the challenge:

> PLEASE NOTE *** Our PA Specialists are very confident, highly skilled, **and trained to work on ALL opt ins, for all diagnoses**, with all types of insurances plan.***
>
> [Emphasis added.]

169. As revealed by the attachment that Gurrieri included in that email (copied below), her pre-scripted answers to questions commonly posed by a leading PBM, OptumRx, instruct

IRC employees to mislead the PBM with respect to the question posed by nearly all third-party payers as part of the Subsys prior authorization process—Does the patient suffer from BTCP?

Required ICD-9 Codes	Required T/F	Required Details for Call/Q &A
338.3/All Cancer DX	Any combination of 3-4 of the following Long and Short-acting medications: 1. Oral Transmucosal Fentanyl Citrate 2. Morphine Sulfate 3. Hydromorphone 4. Fentanyl 5. Oxycodone 6. Morphine 7. Oxycontin 8. Tramadol 9. Methadone	*Is the medication being prescribed for the management of breakthrough cancer pain?
	Must have tried and failed Generic Fentanyl	* If asked the question above, IRC response: ' The physician is aware that the medication is intended for the management of breakthrough pain in cancer patients. The physician is treating the patient for their pain (or breakthrough pain, whichever is applicable).'

170. As scrutiny of Insys's conduct increased, Gurrieri emailed a colleague on May 30, 2015, attaching the script and other documents stating: "Think we should delete these? They have the spiel and the answers to questions. I put this together a long, long time ago." Less than a minute later, her colleague responded: "OMG DELETE!" And soon thereafter, Gurrieri replied: "Deleting it now."

171. With respect to New Jersey patients, Insys routinely engaged in the fraud described above by affirmatively misrepresenting that New Jersey patients suffered from BTCP, when in fact, they did not.

172. For example, in January 2015, as part of the prior authorization process for a non-BTCP New Jersey patient, J.S., Insys IRC employee, David Richardson, telephoned OptumRX and affirmatively misrepresented that he was an employee of a New Jersey doctor. Notably, the IRC employee mispronounced the doctor's name and incorrectly stated that the doctor's office was located in West New York, New York, when, in fact, it is located in West New York, New

Jersey. Although the patient at issue did not suffer from BTCP, when OptumRX asked Richardson whether the patient was prescribed Subsys for the management of BTCP, Richardson first responded with the canned answer above, and when OptumRx repeated the question, he affirmatively and falsely responded, "yup."

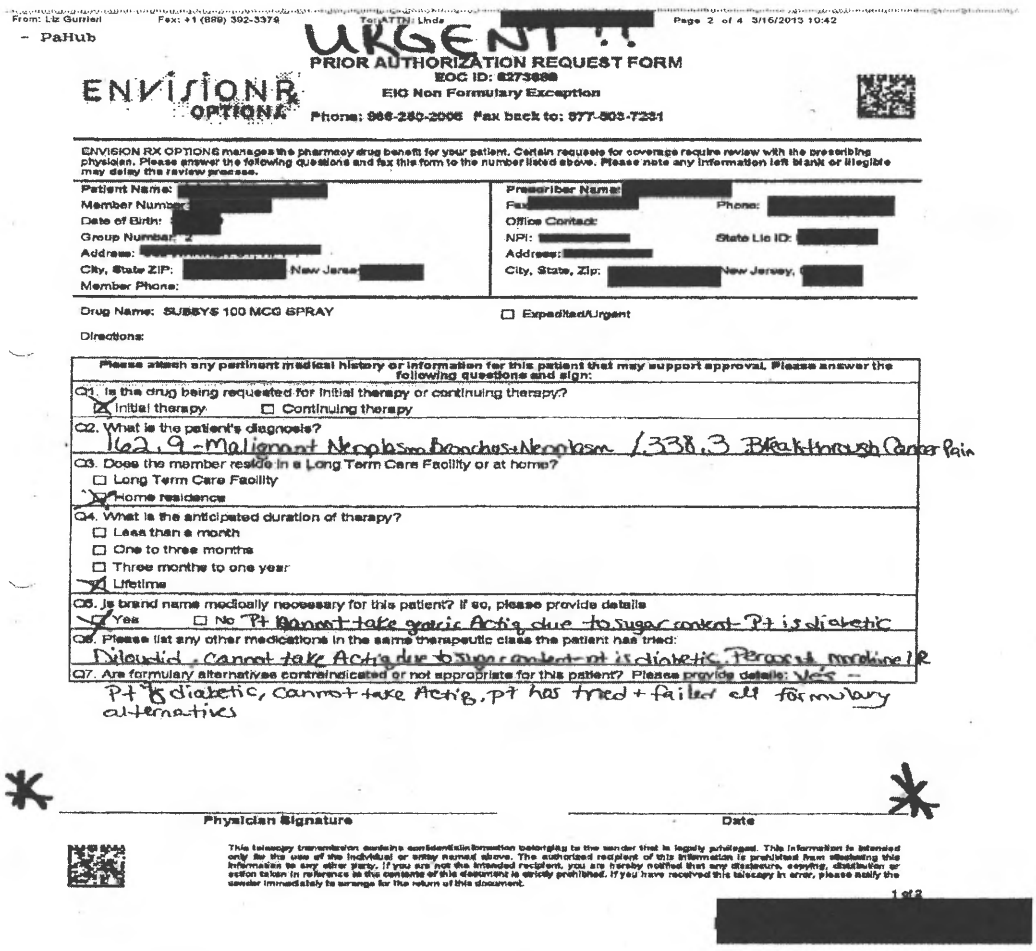
173. Similarly, and also in January 2015, IRC employee, Jeanna Flores, telephoned insurer EnvisionRx to request prior authorization, and affirmatively misrepresented that she was an employee of a different New Jersey doctor. When EnvisionRx asked whether the patient—who never had cancer and for whom the doctor had prescribed Subsys for the treatment of fibromyalgia—suffered from breakthrough cancer pain, Flores affirmatively responded "yeah."

174. Additionally, for those insurers and PBMs that allowed for the prior authorization process to occur via the submission of written prior authorization forms, Insys regularly completed the forms for prescribers writing Subsys for off-label purposes, and often included false information, such as false ICD diagnostic codes Insys knew would facilitate insurance coverage approval.

175. One New Jersey-specific example starkly illustrates this fraud. By fax dated March 15, 2013, Gurrieri sent a New Jersey doctor a "prior authorization request form"—which she had filled out completely, other than his signature—for a patient for whom the doctor had prescribed Subsys off-label. Gurrieri asked that the doctor sign and date the form. At the top of the form, Gurrieri wrote "URGENT!!," which she routinely did on several prior authorization forms that she pre-populated for prescribers.

176. And although this patient did not have a present diagnosis of cancer and BTCP, Gurrieri handwrote that this patient's diagnosis was "162.9 – Malignant Neoplasm" and "338.3

Breakthrough Cancer Pain," and merely indicated with asterisks where the doctor should sign and date.



From: Liz Gurrieri Fax: +1 (888) 392-3378 To: ATTN: Linda [redacted] Page: 2 of 4 3/16/2015 10:42

- PaHub

URGENT !!

PRIOR AUTHORIZATION REQUEST FORM

EOC ID: 8273688

ENVISIONRX OPTIONS

EIG Non Formulary Exception

Phone: 866-260-2006 Fax back to: 877-803-7231

ENVISION RX OPTIONS manages the pharmacy drug benefit for your patient. Certain requests for coverage require review with the prescribing physician. Please answer the following questions and fax this form to the number listed above. Please note any information left blank or illegible may delay the review process.

Patient Name: [redacted]	Prescriber Name: [redacted]
Member Number: [redacted]	Fax: [redacted] Phone: [redacted]
Date of Birth: [redacted]	Office Contact:
Group Number: [redacted]	NPI: [redacted] State Lic ID: [redacted]
Address: [redacted]	Address: [redacted]
City, State ZIP: [redacted] New Jersey [redacted]	City, State, Zip: [redacted] New Jersey, [redacted]
Member Phone:	

Drug Name: SUBSYS 100 MCG SPRAY ☐ Expedited/Urgent

Directions:

Please attach any pertinent medical history or information for this patient that may support approval. Please answer the following questions and sign:

Q1. Is the drug being requested for initial therapy or continuing therapy?
☒ Initial therapy ☐ Continuing therapy

Q2. What is the patient's diagnosis?
162.9-Malignant Neoplasm Bronchus+Neoplasm /338.3 Breakthrough Cancer Pain

Q3. Does the member reside in a Long Term Care Facility or at home?
☐ Long Term Care Facility
☒ Home residence

Q4. What is the anticipated duration of therapy?
☐ Less than a month
☐ One to three months
☐ Three months to one year
☒ Lifetime

Q5. Is brand name medically necessary for this patient? If so, please provide details
☒ Yes ☐ No Pt cannot take generic Actiq due to sugar content- Pt is diabetic

Q6. Please list any other medications in the same therapeutic class the patient has tried:
Dilaudid, cannot take Actiq due to sugar content- pt is diabetic, Percocet, morphine IR

Q7. Are formulary alternatives contraindicated or not appropriate for this patient? Please provide details: Yes -- Pt is diabetic, cannot take Actiq, pt has tried + failed all formulary alternatives

* _____ Physician Signature _____ Date *

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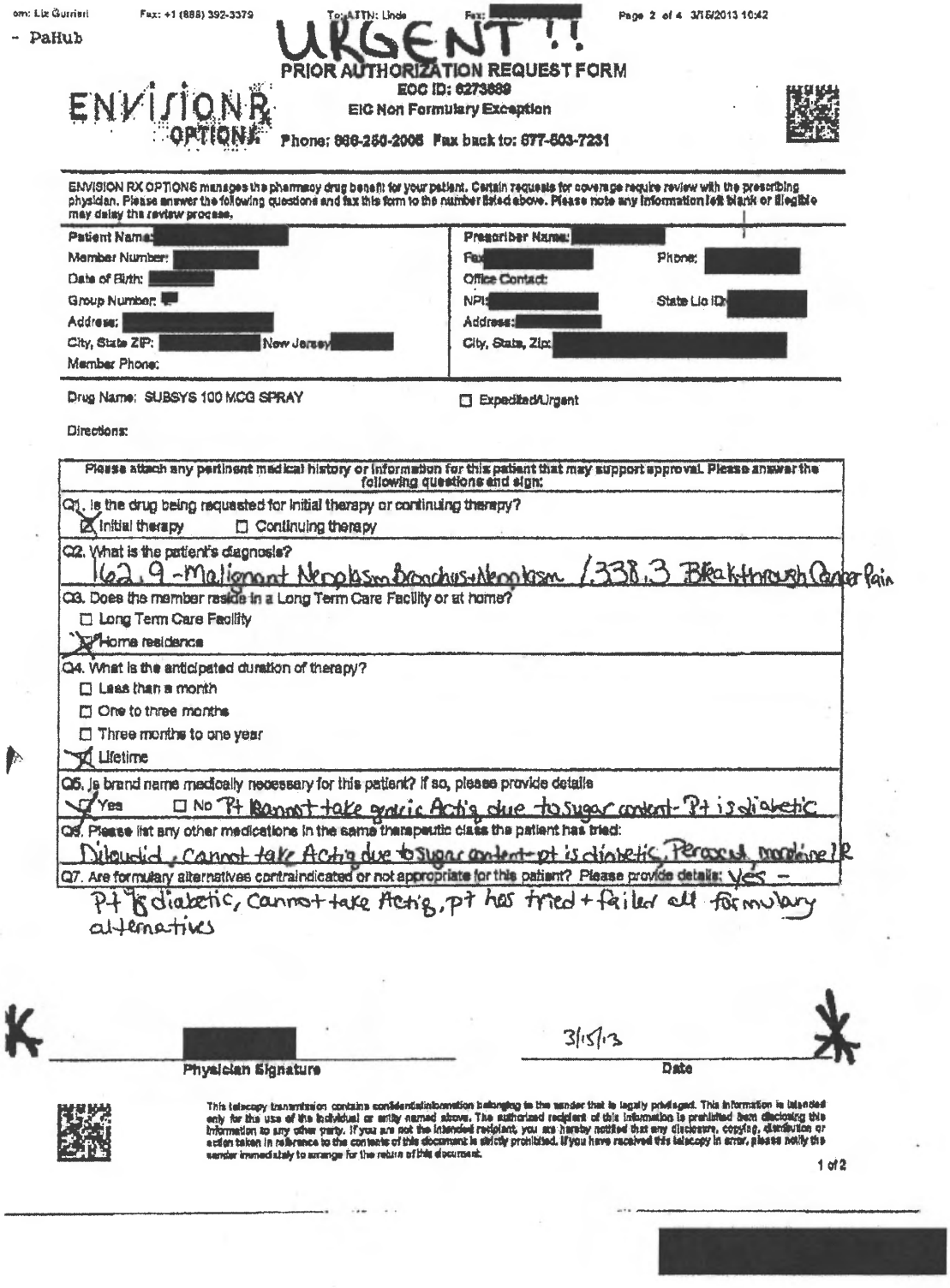
1 of 2 [redacted]

177. On that same day, the doctor signed the pre-populated form (copied above) and faxed it back to Gurrieri (copied below):



om: Liz Gurriel Fax: +1 (888) 392-3379 To: ATTN: Linda Fax: [redacted] Page 2 of 4 3/15/2013 10:42

- PaHub

URGENT !!

PRIOR AUTHORIZATION REQUEST FORM

EOC ID: 6273689

EIC Non Formulary Exception

ENVISIONRX OPTIONS

Phone: 866-250-2006 Fax back to: 877-503-7231

ENVISION RX OPTIONS manages the pharmacy drug benefit for your patient. Certain requests for coverage require review with the prescribing physician. Please answer the following questions and fax this form to the number listed above. Please note any information left blank or illegible may delay the review process.

Patient Name: [redacted]	Prescriber Name: [redacted]
Member Number: [redacted]	Fax [redacted] Phone: [redacted]
Date of Birth: [redacted]	Office Contact:
Group Number: [redacted]	NPI: [redacted] State Lic ID: [redacted]
Address: [redacted]	Address: [redacted]
City, State ZIP: [redacted] New Jersey [redacted]	City, State, Zip: [redacted]
Member Phone:	

Drug Name: SUBSYS 100 MCG SPRAY ☐ Expedited/Urgent

Directions:

Please attach any pertinent medical history or information for this patient that may support approval. Please answer the following questions and sign:

Q1. Is the drug being requested for initial therapy or continuing therapy?
☒ Initial therapy ☐ Continuing therapy

Q2. What is the patient's diagnosis?
162.9 - Malignant Neoplasm Bronchus+Neoplasm / 338.3 Breakthrough Cancer Pain

Q3. Does the member reside in a Long Term Care Facility or at home?
☐ Long Term Care Facility
☒ Home residence

Q4. What is the anticipated duration of therapy?
☐ Less than a month
☐ One to three months
☐ Three months to one year
☒ Lifetime

Q5. Is brand name medically necessary for this patient? If so, please provide details
☒ Yes ☐ No Pt cannot take generic Actiq due to sugar content - Pt is diabetic

Q6. Please list any other medications in the same therapeutic class the patient has tried:
Dilaudid, cannot take Actiq due to sugar content - pt is diabetic, Percocet, morphine ER

Q7. Are formulary alternatives contraindicated or not appropriate for this patient? Please provide details: Yes - Pt is diabetic, cannot take Actiq, pt has tried + failed all formulary alternatives

[redacted] 3/15/13

Physician Signature Date

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1 of 2

[redacted]

178. EnvisionRx ultimately approved that prior authorization request, and the patient began taking Subsys soon thereafter.

179. This misconduct is not isolated. As set forth in the Affidavit of a former IRC employee, Patty Nixon, IRC employees routinely altered patients' electronic charts to reflect diagnoses that included BTCP and dysphagia. Indeed, as Nixon affirmed, IRC employees "were mandated to follow Insys 'best practices,' which included that the unit alter documents and mislead and lie to insurers and PBMs regarding the medical conditions of patients for whom Insys was seeking approval and payment for the use of Subsys." Likewise, another Insys "best practice" was for IRC employees "to lead insurers and PBMs to believe that [they] were calling for prior authorization from the office of the prescribing physicians as if [they] were employees of the various prescribing physicians' offices throughout the country."

180. These examples confirm that Insys used its IRC, through telephonic prior authorization calls and through IRC paperwork, to falsify diagnoses and treatment histories to obtain approval for Subsys.

181. And, the IRC was successful. IRC personnel obtained prior authorizations from insurers and PBMs at a very high rate. Yet, even based on Insys IRC documents—which are inherently unreliable—fewer than thirty percent of New Jersey patients who went through the IRC process had a current or past cancer diagnosis. More importantly, Insys IRC documents reflect that only five percent of those New Jersey patients had BTCP—a figure that is likely inflated, as Insys's records included supporting healthcare provider records for only half of those patients.

182. The SHBP and SEHBP were also defrauded by the IRC scheme. At least fifty-nine of the New Jersey IRC records were for SHBP/SEHBP members. Of those, fewer than forty percent had a past or present cancer diagnosis. Only one had a clear BTCP diagnosis in doctor records, and only twelve percent had an indication of BTCP in an Insys-produced IRC

document. Moreover, at least eight SHBP/SEHBP members received prior authorizations for an off-label Subsys prescription, notwithstanding the plans' express restrictions against off-label use applicable to those individuals.

183. Further discovery in this matter will reveal the full extent of Insys's insurance fraud involving New Jersey residents, as well as the State's health benefits plans and the Workers' Compensation Program.

iii. Insys Created a Pay Structure for IRC Staff That Rewarded Fraudulent Behavior With Substantial Bonuses.

184. Insys provided substantial financial incentives to IRC staff to ensure that they engaged in the fraud vital to the success of Insys's enterprise.

185. Specifically, Insys paid its IRC staffers based on their ability to meet individual and group quotas for Subsys prior authorization approvals. Once the minimum group quota was satisfied—which former Prior Authorization Specialist, Nixon, referred to as the "gate threshold," a bonus per prior authorization approval accrued for the team. To qualify to receive his or her share of the group bonus, however, an IRC staffer would have to meet his or her individual quota too. Any individual staffer who exceeded thirty approvals per week would accrue an additional bonus per each successful approval secured.

186. Because the majority of opt-in forms that the IRC received were for off-label Subsys prescriptions, and because most insurers and PBMs would not authorize payment for Subsys without an appropriate diagnosis, the IRC's incentive compensation structure—like the incentive compensation scheme Insys established for its sales force—provided a strong incentive for each IRC staffer to commit the fraud that Insys required.

VI. DESPITE INSYS'S PUBLIC ACKNOWLEDGMENTS OF ITS WRONGDOING AND PROMISES TO RECTIFY ITS PRIOR GROSS MISCONDUCT, INSYS HAS NOT BROKEN TIES WITH ITS BAD ACTORS, INCLUDING ITS FOUNDER.

187. During all relevant times, Insys—a company that sells a product fifty times stronger than heroin—purposefully maintained little or no supervision over its sales force, except to push the company's illicit core agenda. To the extent the company maintained any compliance, it wholly failed to monitor its executives or sales force to ensure that increased sales were not coming at the expense of the law or patient safety.

188. In light of its gross misconduct, Insys now finds itself at the center of significant controversy and heightened governmental scrutiny.

189. To date, at least eighteen Insys-connected individuals, including high-ranking Insys executives and corporate officials, sales representatives, and prescribers, have been indicted on, convicted of, and/or pled guilty to several serious criminal offenses in connection with Insys's enterprise. And three New Jersey doctors have had their licenses suspended or revoked due to indiscriminate and dangerous Subsys prescribing.

190. In particular, in December 2016, the Department of Justice charged six high-level executives, including Michael Babich, the former CEO and President of Insys and a longtime colleague of Insys founder and then-Board Chairman John Kapoor; Alec Burlakoff, the former Vice President of Sales; and Michael Gurry, the former Vice President of Managed Markets, with among other things, conspiring to bribe practitioners in various states.

191. Publicly, Insys now acknowledges "certain mistakes and unacceptable actions of former Insys employees," claiming that those actions are "not indicative of the people that are currently employed at Insys" and pointing to the fact that "over 90% of the 250 field-based sales staff employed prior to 2014 are no longer with the organization."

192. Plaintiffs' investigation, however, demonstrates otherwise. For one, Kapoor—who federal authorities have identified as an unindicted co-conspirator in their criminal case—remains a member of the Board of Directors.

193. In addition, in New Jersey, one of Insys's top sales personnel, Susan Beisler, who was nicknamed "Subsys Sue," not only remains with the company, but on May 2, 2016, was promoted from a sales representative role to District Sales Manager of the New Jersey district. Significantly, Beisler was promoted only after emailing Kapoor directly from her personal email account, begging him to make it happen. When first applying for the position, Beisler name-dropped Kapoor to then-COO Brennan, stating: "Dr. Kapoor has known me for quite a long time and I believe he can give you insight on my character and integrity." Beisler then complained to Kapoor about, among many other things, the fact that "[f]or some reason, [she] ha[s] always been overlooked for promotions, although [she] ha[s] extensive background in training and management." After laying the groundwork, Beisler explicitly asked Kapoor for his help: "[P]lease don't forget to speak to Dan [Brennan] for me? He has not responded to my request to interview next Monday."

194. During the course of a five-hour investigatory interview conducted by Plaintiffs, Beisler invoked her Fifth Amendment right against self-incrimination more than 400 times.

VII. INSYS CAUSED THE SUBMISSION OF FALSE CLAIMS TO SHBP/SEHBP AND THE WORKERS' COMPENSATION PROGRAM THROUGH ITS ILLICIT, OFF-LABEL MARKETING SCHEME.

195. Throughout the relevant time period, Insys knowingly caused the submission of false claims for reimbursement of Subsys to SHBP/SEHBP and the Workers' Compensation Program. As alleged in detail above, Insys, through its sales force, marketed Subsys in a false and deceptive way by, among other things, promoting the drug for a dosing regimen (*e.g.,* initial prescriptions above the 100 mcg dose) and patient population (non-BTCP patients) not indicated

on the label nor approved by the FDA as safe and effective for treatment of patients. This conduct constituted impermissible and misleading off-label promotion.

196. As a result of Insys's fraudulent conduct, Insys caused false claims to be submitted to New Jersey's SHBP/SEHBP and its Workers' Compensation Program for reimbursement. Each of the claims for Subsys to these State programs included an express and/or implied certification of compliance with federal and State law, regulations and contracts. These certifications were false because Subsys was not "medically necessary" for many of the patients it was prescribed for, and, in fact, was dangerous for those patients. Accordingly, the associated claims are not eligible for reimbursement.

197. Insys also created false records, such as fraudulent LMNs and fraudulent IRC forms, in order to obtain reimbursement for its false claims.

198. While the cost of providing Subsys for on-label uses is covered by these State programs, the cost of off-label prescriptions is not. Since Insys promoted Subsys off-label and in a misleading manner, and was thus not "medically necessary" for the treatment of some patients, claims for prescriptions caused by this misconduct are not reimbursable.

199. Knowingly submitting or causing the submission of claims for prescription drugs, which are not reimbursable, creates liability under the FCA. Thus, these claims to the State of New Jersey for reimbursement caused to be submitted by Insys's unlawful conduct constitute violations of the FCA.

COUNT I

VIOLATIONS OF THE NEW JERSEY CONSUMER FRAUD ACT (UNCONSCIONABLE COMMERCIAL PRACTICES AND DECEPTION)

200. Plaintiffs repeat and reallege the General Allegations above, as if fully set forth verbatim herein.

201. The CFA, N.J.S.A. 56:8-2, prohibits:

> The act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing[] concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise . . . .

202. The CFA defines "advertisement" as:

> [T]he attempt directly or indirectly by publication, dissemination, solicitation, indorsement or circulation or in any other way to induce directly or indirectly any person to enter or not enter into any obligation or acquire any title or interest in any merchandise or to increase the consumption thereof . . . .
>
> [N.J.S.A. 56:8-1(a).]

203. The CFA defines "merchandise" as including "any objects, wares, goods, commodities, services or anything offered, directly or indirectly to the public for sale." N.J.S.A. 56:8-1(c).

204. The CFA defines "sale" as "any sale, rental or distribution, offer for sale, rental or distribution or attempt directly or indirectly to sell, rent or distribute." N.J.S.A. 56:8-1(e).

205. Defendant is a "person" as defined by the CFA and has advertised, offered for sale, and sold "merchandise" also as defined by the CFA.

206. Pharmaceutical manufacturers are required to comply with the provisions of the CFA.

207. In its advertisement, offer for sale, and sale of Subsys, since at least 2012, Defendant has engaged in the use of unconscionable commercial practices and deception, including, but not limited to, the following:

(a) Paying kickbacks to healthcare providers disguised as "speaker's fees" to induce the providers to prescribe Subsys to patients off-label, thus endangering the health and safety of New Jersey residents who were prescribed Subsys off-label and increasing their medical expenses;

(b) Inducing healthcare providers to prescribe Subsys off-label for conditions and in a manner as to which it has not been determined to be either safe or effective by providing free office assistance;

(c) Representing to the public that Subsys was safe and effective to treat off-label indications as to which Subsys's safety and efficacy has not been established;

(d) Failing to adequately advise consumers of the substantial risk of dependency, addiction, respiratory depression, and death associated with using Subsys;

(e) Employing a base salary and incentive compensation structure for sales representatives that encouraged the unlawful off-label promotion of Subsys, thus endangering the health and safety of New Jersey residents who were prescribed Subsys off-label and increasing their medical expenses;

(f) Providing gifts and other things of value to prescribers to induce them to prescribe Subsys off-label for conditions and in a manner as to which it has not been determined to be either safe or effective;

(g) Targeting Subsys marketing efforts at high volume ROO prescribers who did not typically treat patients with BTCP, thus endangering the health and safety of New Jersey residents who were prescribed Subsys off-label and increasing their medical expenses;

(h) Targeting Subsys marketing at prescribers in specialty practice areas who typically did not treat patients with BTCP, thus endangering the health and safety of New Jersey residents and increasing their medical expenses;

(i) Promoting Subsys through the use of deceptive marketing and other practices that were designed to increase the off-label use of Subsys, thus endangering the health and safety of New Jersey residents who were prescribed Subsys off-label and increasing their medical expenses;

(j) Encouraging prescribers to begin patients on an inappropriate starting dosage of Subsys, i.e., greater than the FDA-mandated initial starting dose of 100 mcg, thus endangering the health and safety of New Jersey residents who were prescribed Subsys off-label and increasing their medical expenses;

(k) Encouraging prescribers to increase patients' dosages of Subsys solely for Insys's economic benefit and without regard to patient welfare;

(l) Encouraging prescribers to do off-label one-to-one strength switches of patients from high doses of Actiq or Fentora to high doses of Subsys solely for Insys's economic benefit and without regard to FDA prohibitions or to patient welfare;

(m) Submitting or causing to be submitted false diagnoses of, for example and without limitation, cancer and dysphagia, to PBMs and insurers to secure insurance coverage for off-label Subsys prescriptions, thus endangering the health and safety of New Jersey residents who were prescribed Subsys off-label and potentially subjecting them to claims disputes with their carriers;

(n) Concealing the telephone number of the Insys IRC from PBMs and insurers so that those entities would not be aware that Insys IRC employees were calling directly from Insys and not from some other location in an attempt to increase insurance reimbursement approvals for Subsys;

(o) Obtaining prior authorization for insurance coverage for off-label Subsys prescriptions by misleading insurers and PBMs that Insys's IRC employees were affiliated with a particular prescriber's office or calling from such office;

(p) Creating a base salary and incentive compensation structure, with inadequate compliance procedures and systems, so as to promote the likelihood of non-compliant, off-label marketing of Subsys by Insys sales representatives;

(q) Incentivizing sales representatives to seek increases in patients' dosages of Subsys so as to increase the sales representatives' bonus compensation without regard to patient welfare and safety or the cost to patients; and

(r) Hiring prescribers' relatives and/or friends so as to induce prescribers to prescribe Subsys off-label, thus endangering the health and safety of New Jersey residents who were prescribed Subsys off-label and increasing their medical expenses.

208. Each unconscionable commercial practice and/or act of deception by Defendant constitutes a separate violation under the CFA, N.J.S.A. 56:8-2.

COUNT II

VIOLATIONS OF THE NEW JERSEY CONSUMER FRAUD ACT (FALSE PROMISES AND MISREPRESENTATIONS)

209. Plaintiffs repeat and reallege the General Allegations above, and the allegations of all preceding Counts, as if fully set forth verbatim herein.

210. In its advertisement, offer for sale, and sale of Subsys, since at least 2012, Defendant has made false promises and misrepresentations, including, but not limited to, the following:

(a) Misrepresenting that consumers could safely start on Subsys at an initial dose exceeding 100 mcg, thus endangering the health and safety of New Jersey residents who were initially prescribed Subsys above 100 mcg and increasing their medical expenses;

(b) Misrepresenting that Subsys was safe and effective for the treatment of chronic pain beyond BTCP, thus endangering the health and safety of New Jersey residents who were prescribed Subsys off-label and increasing their medical expenses;

(c) Misrepresenting that healthcare providers not otherwise knowledgeable and experienced in the administration of Schedule II opioids could safely and appropriately prescribe Subsys, thus endangering the health and safety of New Jersey residents who were prescribed Subsys;

(d) Misrepresenting that healthcare providers prescribing Subys were doing so based on their unbiased, independent clinical judgment, when in fact, that clinical judgment had been co-opted based on Insys's unlawful payment of kickbacks to prescribers;

(e) Misrepresenting to insurers and PBMs that Insys's IRC employees were affiliated with a particular prescriber's office or calling from such an office when seeking prior authorizations for insurance coverage for off-label Subsys prescriptions;

(f) Misrepresenting to insurers and PBMs in telephone conversations that particular patients for whom IRC employees were seeking prior

authorizations for insurance coverage for off-label Subsys prescriptions had an active cancer diagnosis; and

(g) Misrepresenting to insurers and PBMs in telephone conversations that particular patients for whom IRC employees were seeking prior authorizations for insurance coverage for off-label Subsys prescriptions had tried and failed certain other pain relief medication prior to obtaining a prescription for Subsys.

211. Each false promise and misrepresentation constitutes a violation of the CFA, N.J.S.A. 56:8-2.

COUNT III

VIOLATIONS OF THE NEW JERSEY CONSUMER FRAUD ACT (KNOWING OMISSIONS OF MATERIAL FACTS)

212. Plaintiffs repeat and reallege the General Allegations above, and the allegations of all preceding Counts, as if fully set forth verbatim herein.

213. In its advertisement, offer for sale, and sale of Subsys, since 2012, Defendant has knowingly made omissions of material facts, including, but not limited to the following:

(a) Failing to adequately disclose to consumers the severe risks of dependency, addiction, respiratory depression, and death associated with taking Subsys for an off-label indication;

(b) Failing to disclose to consumers that Subsys had not been determined to be safe and effective in the treatment of conditions other than BTCP;

(c) Failing to disclose to consumers that Insys was paying prescribers illegal kickbacks to induce them to prescribe Subsys off-label and without regard to the appropriateness of treatment with Subsys for a given patient's condition;

(d) Failing to disclose to consumers that Insys was providing free office assistance to prescribers to induce them to prescribe Subsys for off-label indications; and

(e) Failing to disclose to consumers that Insys's IRC misrepresented to insurers and PBMs patients' diagnoses and treatment histories to obtain approvals for insurance coverage of off-label Subsys prescriptions.

214. Each knowing omission by Defendants constitutes a separate violation under the CFA, N.J.S.A. 56:8-2.

COUNT IV

VIOLATION OF THE NEW JERSEY FALSE CLAIMS ACT

215. Plaintiffs repeat and reallege the General Allegations above, and the allegations of all preceding Counts, as if fully set forth verbatim herein.

216. The FCA, which was enacted in 2008, provides in pertinent part as follows:

> A person shall be jointly and severally liable to the State for a civil penalty of not less than and not more than the civil penalty allowed under the federal False Claims Act . . . for each false or fraudulent claim, plus three times the amount of damages which the State sustains, if the person commits any of the following acts:
>
> a. Knowingly presents or causes to be presented to an employee, officer or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval;
>
> b. Knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State;
>
> [N.J.S.A. 2A:32C-3.]

217. For purposes of the NJFCA, the terms "knowing" and "knowingly" mean that a person, with respect to information: "(1) has actual knowledge of the information; or (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information. No proof of specific intent to defraud is required." N.J.S.A. 2A:32C-2.

218. The "State" is defined in the NJFCA as "any of the principal departments in the Executive Branch of State government, and any division, board, bureau, office, commission or

other instrumentality within or created by such department; and any independent State authority, commission, instrumentality or agency." N.J.S.A. 2A:32C-2.

219. The Division of Pensions and Benefits in the New Jersey Department of the Treasury is a Department of the Executive Branch of the State government for purposes of the New Jersey False Claims Act, and administers the New Jersey State Health Benefits Program and the New Jersey School Employees' Health Benefits Program, which are self-funded by the State.

220. The Division of Risk Management in the New Jersey Department of the Treasury is a Department of the Executive Branch of State government for purposes of the New Jersey False Claims Act, and administers the State's Workers' Compensation Program for State employees.

221. As set forth in this Complaint, throughout the relevant time period, Insys engaged in fraudulent conduct, including, without limitation, insurance fraud, a kickback scheme, and aggressive off-label and misleading marketing of Subsys. Insys violated the New Jersey False Claims Act by:

a. knowingly presenting or causing to be presented to an agent or contractor of the State, false or fraudulent claims for payment or approval; and

b. knowingly making, using, and causing to be made or used false records to get false claims paid or approved by the State, by, including, without limitation, creating false and fraudulent patient medical histories and diagnoses through its IRC process including in prior authorization forms and other prior authorization communications and by providing prescribers with false letters of medical necessity.

222. Insys knowingly caused the submission of false claims for reimbursement of Subsys to SHBP/SEHBP and the Workers' Compensation Program through its illicit, off-label marketing scheme by promoting Subsys for, among other things, an improper dosing regimen and patient population in direct contravention of its FDA-approved label.

223. Each of the claims for Subsys to these State programs included an express and/or implied certification of compliance with federal and State law, regulations and contracts. These certifications were false because in many cases, Subsys was not "medically necessary" for the patients it was prescribed for, and, in fact, was dangerous for those patients. Accordingly, the associated claims are not eligible for reimbursement.

224. Knowingly submitting or causing the submission of claims for prescription drugs, which are not reimbursable, creates liability under the FCA. Thus, these claims to the State of New Jersey for reimbursement caused to be submitted by Insys's unlawful conduct constitute violations of the FCA.

225. Each false claim submitted for payment or approval or caused to be submitted for payment or approval by Defendant, as well as each false record or statement made, used or caused to be made or used to get a claim paid by Defendant constitutes a separate violation under the FCA, N.J.S.A. 2A:32C-1, et seq.

PRAYER FOR RELIEF

WHEREFORE, based upon the foregoing allegations, Plaintiffs respectfully request that the Court enter judgment against Defendant:

(a) Finding that the acts and omissions of Defendant constitute multiple instances of unlawful practices in violation of the CFA;

(b) Permanently enjoining Defendant, its officers, directors, agents, employees, and all persons acting on its behalf and/or under its authority, from engaging in any acts or practices in violation of the CFA, as authorized by N.J.S.A. 56:8-8;

(c) Disgorging Defendant of all profits that resulted from its unlawful conduct in New Jersey, as authorized by N.J.S.A. 56:8-8;

(d) Directing Defendant to pay the maximum statutory civil penalties for each and every violation of the CFA, in accordance with N.J.S.A. 56:8-13, and the FCA, in accordance with N.J.S.A. 2A:32C-3;

(e) Assessing three times the State's actual damages for Defendant's violations of the False Claims Act in accordance with N.J.S.A. 2A:32C-3;

(f) Directing Defendant to pay costs and fees, including attorneys' fees, for the use of the State of New Jersey, as authorized by the CFA, N.J.S.A. 56: 8-11 and 56:8-19, and the FCA, N.J.S.A. 2A:32C-8; and

(g) Granting such other relief as the interests of justice may require.

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Dated: October 5, 2017
Newark, New Jersey