

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

THE PEOPLE OF THE STATE OF NEW YORK, :
by ERIC T. SCHNEIDERMAN, Attorney General :
of the State of New York, :

Plaintiff :

v. :

INSYS THERAPEUTICS, INC., :

Defendant :
----- X

COMPLAINT

Index No.:

Plaintiff, The People of the State of New York, by its attorney, ERIC T.

SCHNEIDERMAN, Attorney General of the State of New York, respectfully alleges, upon information and belief:

I. Introduction

1. This lawsuit is a challenge to the years-long practice by Insys Therapeutics, Inc. (“Insys”) of deceptively and illegally marketing Subsys, an extremely powerful and addictive opioid. Insys marketed Subsys with no regard to the health and safety of patients, nor to the grave risks of addiction and death posed by opioids.

2. Insys’ pattern of deceptive and unlawful conduct included targeting health care providers who should not have been prescribing the drug and encouraging the drug’s use for unapproved uses like mild or non-cancer-related pain; misrepresenting safe dosage amounts so that providers would prescribe higher (and more profitable) doses; lying to health plans in order to evade the authorization process; and bribing health care providers who prescribed the drug by paying them thousands of dollars in connection with sham “speaker” programs.

3. This conduct contributed to the over-prescription and overuse of this powerful opioid drug. New York, like states across the nation, is suffering from an opioid epidemic of

crisis proportions. Opioid prescriptions have grown ten-fold over the past 20 years in the United States. In 2014, 11 million opioid prescriptions were written in New York State alone.

4. Prescription opioids are highly addictive and their users are susceptible to overdose and death. In New York in 2016, there were 3,638 deaths from all drug overdoses. Of those total overdose deaths, 3,009 (82%) were from opioids (including heroin), and 2,337 (64%) were specifically from opioid pain relievers.

5. New York now logs more treatment facility admissions for opioids than it does for alcohol abuse.

6. Opioid overdose deaths are one reason that U.S. life expectancy declined in 2015 for the first time in decades. In 2016, drug overdoses -- of which opioid overdoses rose to more than 60% -- caused more deaths in the United States than gun violence or car crashes, and took more lives than HIV/AIDS at the height of that epidemic.

7. The Food and Drug Administration (FDA) approved Subsys in 2012 only for the treatment of breakthrough cancer pain in patients who are already receiving and tolerant to opioid therapy. Subsys is a fast-acting opioid fentanyl pain reliever that is one hundred times more potent than morphine.

8. Insys promoted Subsys in New York through several deceptive and illegal schemes. First, Insys hired a force of sales representatives tasked with making sales calls to, or “detailing,” a wide range of health care providers in various specialties, including medical doctors, nurse practitioners, and physician assistants (collectively referred to as “providers”). With no regard for the health or safety of patients, Insys directed its sales representatives to urge providers to prescribe Subsys in high doses to a wide range of patients, in direct contradiction to the FDA’s approved narrow indication for the drug. The higher the strength

of Subsys that was prescribed, the higher the compensation that Insys paid to its sales representatives.

9. Second, Insys created a specialized business unit devoted to pushing these prescriptions through the insurance prior authorization process. Health insurers require patients to obtain prior authorization before covering the cost of addictive opioids, like Subsys, in order to verify that the patients meet the approved indication of the drug. Individuals from Insys' prior authorization unit posed as employees of the providers, and lied to health insurers about patients' medical conditions in order to get Subsys prescriptions approved.

10. Third, Insys recruited and rewarded high-volume prescribers by paying them thousands of dollars in "speaker" fees to lead a "speaking program" at a high-end restaurant or bar with other providers and their staff members. Insys represented the dinners as educational opportunities for new prescribers, but they were nothing more than bribes and kickbacks to the "speaker" providers, as an incentive to those providers to expand or continue prescribing Subsys. Patients knew nothing of these arrangements.

11. In all of these marketing schemes, Insys led a campaign to downplay the risks of addiction. Insys even targeted "pill mills," providers known to Insys as prescribing high volumes of opioids without regard to medical necessity.

12. Insys' illegal and deceptive acts and practices contributed to the drug's over-prescription and overuse, and ultimately to patient deaths: the FDA's Adverse Event Reporting System (FAERS) – a nationwide database of undesirable events associated with the use of a medical product -- has recorded more than 750 adverse events involving Subsys, three-quarters of which resulted in death.

II. Jurisdiction and Parties

13. Plaintiff, the People of the State of New York, by Attorney General Eric T. Schneiderman, brings this action pursuant to Executive Law § 63 and General Business Law (“GBL”) Article 22-A. Eric T. Schneiderman is the Attorney General of the State of New York and is authorized to: institute all actions and proceedings in which the State is interested, N.Y. Executive Law § 63(1); seek an order that enjoins repeated or persistent fraudulent or illegal business acts or practices and awards damages and restitution for such acts, N.Y. Executive Law § 63(12); and bring an action to enjoin deceptive acts or practices in the conduct of business and to obtain restitution and civil penalties, including additional civil penalties for fraud perpetrated against the elderly. GBL §§ 349, 349-c, 350, 350-d.

14. Insys Therapeutics, Inc. is a publicly traded Delaware corporation with its principal place of business in Chandler, Arizona. Insys is a pharmaceutical company engaged in the manufacture, marketing and sale of specialty drugs, including Subsys. Until recently, Subsys was Insys’ only drug.

15. Insys regularly conducts business within the State of New York and derives substantial revenues from goods sold and/or consumed in New York.

16. The Attorney General provided Insys with the pre-litigation notice required by GBL §§ 349(c) and 350-c.

III. Insys promoted Subsys in a repeated and persistent illegal and deceptive manner.

A. Insys misrepresented safe and effective uses of Subsys by marketing the drug to providers who the FDA did not intend to prescribe the drug, and by encouraging its use for non- “breakthrough” pain and non-cancer-related pain.

17. Subsys is a fentanyl spray that is applied under the tongue so that it absorbs quickly into the bloodstream. Subsys is delivered in single dose spray units, and a patient

should take no more than four doses per day. A 30-unit prescription ranges in cost from approximately \$700 for the lowest strength, to more than \$3500 for the highest strength.

18. In 2012, the FDA approved Subsys for the limited purpose of alleviating intense “breakthrough” flares of cancer pain in patients “who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.”

19. The FDA’s approval sets out that 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.”

20. The FDA label warns that fatal respiratory depression can occur with the use of Subsys.

21. Despite the fact that other uses and indications for Subsys were not approved, safe, or effective, Insys targeted physicians who did not treat cancer patients and promoted Subsys for uses much broader than those approved by the FDA.

22. In New York and elsewhere, Insys supplied each sales representative with a list of providers to target. Many providers on the list were not oncologists or pain management specialists who treated cancer pain, yet Insys did nothing to remove inappropriate providers from the call lists prior to giving them to sales representatives.

23. Insys knowingly focused on these providers, who were not oncologists or pain management specialists. For instance, a sales representative reported to Insys that a particular New York provider did not treat cancer pain, but asserted that she would nevertheless detail the provider in the future, and did so dozens of times after that report. Another sales presentation focused on four New York providers whom Insys hoped would start prescribing

Subsys, and the presentation explicitly acknowledged that one of the providers did *not* treat breakthrough cancer pain.

24. Consistent with Insys' targeting of providers who were not oncologists or pain management specialists, Insys marketed Subsys to New York providers in an illegal and deceptive manner for unsafe and ineffective purposes. Insys marketed Subsys as appropriate for patients with even mild, non-cancer pain. For example, Insys used a sales presentation for providers that specifically advised that the definition of "breakthrough" cancer pain includes mild pain. However, the true definition of breakthrough cancer pain, as set out in the controlling study, was cancer pain having an intensity of "severe" or "excruciating."

25. Insys similarly trained its New York sales staff that breakthrough pain included flares of mild pain, contrary to the study described above.

26. Insys' training materials for its sales representatives in New York included references to "breakthrough" pain occurring as a result of "neuropathic, musculoskeletal, visceral and postoperative syndromes," as well as from back pain. Insys included these topics in its training so that its sales force would widen the scope of potential sales targets.

27. Insys' directives to broaden both the prescriber and patient base were implemented in New York. One New York sales presentation made clear the goal was to have Subsys as a provider's "main 'go-to' medication for *all* of his patients suffering from *breakthrough pain*," not only cancer patients with breakthrough cancer pain. (Emphasis supplied).

B. Insys misrepresented safe and effective dosage amounts by encouraging providers to prescribe the highest strength of Subsys, notwithstanding medical appropriateness.

28. Insys sells Subsys in a wide range of dosage strengths, from 100 micrograms (mcg) to 1600 mcg. Based on a study involving cancer patients, the FDA-approved Subsys label directed providers to start Subsys at 100 mcg and only then adjust the dosage upward in small increments, if necessary, to achieve a dose at which the patient's "breakthrough" cancer pain is relieved.

29. Insys taught and encouraged its sales force in New York and throughout the nation to push providers to prescribe higher strengths of Subsys than medically necessary, misrepresenting appropriate dosage parameters, and disregarding the fact that higher strengths could be fatal to patients who have not first taken the medicine at lower doses. The sales force in turn relayed this message to providers.

30. Insys fueled this dangerous and misleading march for high dose prescriptions by the manner in which it set up its employee compensation structure. In an email from the COO to the CEO and other top management of Insys, Insys acknowledged that it hired sales representatives with no former experience in drug detailing and paid them a base salary "way outside the norm," and "barely above minimum wage." Insys instead offered sales representatives significant bonuses based not only on net sales, but also on the strength of the prescriptions written -- the higher the strength of Subsys, the higher the bonus the sales representatives received, contrary to any appropriate sales incentive framework.

31. In order to make the incentive as explicit as possible, the compensation presentation to its sales staff included a slide titled "Don't forget the Doses" with the equation: "Higher Doses = Higher Payouts!"

32. Insys pushed these high-strength prescriptions because the company made far more money from higher strengths. In 2013, the price of the highest strength of Subsys was at least five times higher than the lowest strength

33. Insys relentlessly pressed sales staff to push for higher-dose prescriptions. Insys emailed “low strength” reports to its sales force any time a provider was prescribing a dose of 400 mcg or lower, which required the sales representatives to report to management and “work with” the providers to increase the strength. Even the Insys designee and vice president of marketing, Ariyapadi Krishnaraj, testifying on behalf of Insys at an investigatory subpoena hearing,¹ admitted that it was inappropriate to encourage these increases indiscriminately for any patient taking 400 mcg of Subsys or less.

34. Putting patients in peril, Insys even characterized patients whose providers prescribed lower doses of Subsys as “low hanging fruit,” whose doses could easily be doubled.

35. Insys made it clear to its sales force that they needed to get providers to prescribe at least one prescription per day, and if the sales representatives did not meet this goal, their jobs would be in “extreme risk.”

C. Insys lied to insurance companies in order to secure prior authorization, getting patients hooked on the drug in the process.

36. Because Subsys is a very dangerous and expensive drug, health insurers require patients to obtain prior authorization before covering its cost. Before granting prior authorization, these health insurers set out a list of criteria that the patient must meet,

¹ As part of its investigation into Insys, the Attorney General issued subpoenas for documents and sworn testimony, as provided by the New York Executive Law.

including that the patient has a diagnosis of cancer, is opioid tolerant, and has tried alternate medications.

37. In order to secure more authorization approvals, Insys established within the company the Insys Reimbursement Center (IRC), later called the Patient Services Center, an internal unit dedicated to obtaining prior authorizations directly from insurers. The IRC called the health insurers to obtain approval for Subsys prescriptions written by New York and other prescribers.

38. During these calls, the Insys IRC employees misled the insurance companies as to patient diagnoses in an attempt to get the insurance companies to believe that patients had an approved diagnosis of “breakthrough” cancer pain when they did not.

39. This was not the work of rogue employees. Insys specifically instructed its employees to misdirect and mislead the health insurance companies. In an FAQ provided to its employees, Insys directs its IRC employees to use the following scripted statement in conversations with health insurers whenever the patient has breakthrough pain *of any kind*, not just breakthrough cancer pain: "The physician is aware that the medication is intended for the management of breakthrough pain in cancer patients. The physician is treating breakthrough pain."

40. Insys also developed its own “opt-in” form to provide health insurers with patient information to support a prior authorization approval.

41. Included in the opt-in form was a question about the patient’s tolerance of opioids. The directions on the form instructed Insys employees that the box indicating opioid tolerance was required to be checked. In emails to sales staff, Insys management would also

remind staff to check the box. This directive existed despite the fact that sales representatives did not know whether the patients were in fact opioid tolerant.

42. During the prior authorization process, Insys IRC employees also lied by purporting to be employed by a provider, and asserting that they were calling from the doctor's office.

43. While authorizations were pending, Insys issued vouchers to patients to obtain Subsys, which allowed the patients to obtain Subsys at the pharmacy at no cost. Even when the health insurer refused to grant authorization – because, for example, it learned that the patient did not have cancer pain – Insys gave Subsys vouchers to patients for the duration of the prescription. As a result, patients were taking, and becoming dependent on, Subsys regardless of the health insurer's determination, and often for non-cancer pain.

44. And although federal anti-kickback laws forbid Insys from giving these Subsys vouchers to patients insured by governmental plans, such as Medicaid and Medicare, Insys ordered that vouchers be given out to all patients. Insys promoted Subsys for Medicare patients, yet instructed staff that vouchers should be used for all insurance: "Make sure vouchers are ALWAYS utilized! No matter what kind of insurance, I dont care, voucher them. Our future completely relies on new pts, so in no way shape or form are we to allow a Subsys candidate to be put on another product."

D. Insys downplayed the risk of addictiveness of Subsys and marketed to pill mills.

45. Insys' business plan for Subsys acknowledged the growing rate of opioid abuse, addiction, diversion and deaths, as well as the growing concern of irresponsible opioid prescribing. Despite this evolving epidemic and the devastating impact of opioid addiction, Insys downplayed and minimized the risk of addiction. Insys' training materials included the

dismissive assertion that “some clinicians incorrectly assume that exposure to an addictive drug may result in addiction.”

46. Insys also trained its sales representatives to distinguish addiction from “pseudoaddiction,” a purported condition in which patients exhibit drug-seeking behavior that resembles, but is not the same as, addiction. In one Insys presentation to its sales force about long-term opioid therapy, Insys introduced the concept of pseudoaddiction in the context of long-term opioid treatment in cancer survivors. The presentation describes pseudoaddiction as “behaviors that occur when pain is undertreated and patients are focused on obtaining pain relief, and can be misinterpreted by the clinician as ‘drug-seeking’.” The concept of pseudoaddiction was also included in presentations to prescribers.

47. The “pseudoaddiction” concept has never been empirically validated nor widely used by providers. The concept has even been rejected by a pain specialist who was well compensated by Insys. A New York Subsys speaker testified at an investigatory subpoena hearing that he does not consider “pseudoaddiction” a viable term even though drug companies have used the term in their slide decks. “It’s a gray area. I don’t really like the term. I don’t use it because I think it’s a gray area between tolerance and possibly someone who may be an addict.”

48. In short, Insys engaged in a practice of encouraging prescribers to give addicted patients more opioids, regardless of --- or even because of -- their drug seeking behavior.

49. These addiction risks were heightened with immediate action “rapid onset opioids” such as Subsys. In an internal Insys marketing plan, Insys quoted a study that

warned that rapid-onset opioids like Subsys have “enhanced risks for iatrogenic addiction,” which is addiction caused by medical treatment. Specifically, the article sets forth:

Three prescribing patterns potentially initiate addiction and are likened to the mechanisms by which patients become addicted to heroin and tobacco. These mechanisms include rapid onset, cycles of abrupt peak and trough, and high magnitude changes.... **Clinicians must understand the enhanced risks associated with rapid-onset opioids characterized by sublingually-delivered agents..., as these opioids similarly result in presentation of abrupt dopamine surges to the nucleus accumbens, with enhanced risks for iatrogenic addiction.**” (Emphasis supplied).

Insys failed to share this information with its prescribers.

50. Insys also, without basis, trained its sales personnel that the delivery system for Subsys reduced its risk of abuse. Notes to an Insys training presentation stated that Subsys was “[d]elivered in single-unit doses **which reduces the risk of abuse.**” (Emphasis supplied).

51. In addition to misrepresenting and downplaying the risks of Subsys, Insys showed equal disregard for the kinds of providers it detailed. For example, providers on Insys’ call lists had been previously arrested and charged with crimes concerning the illegal prescribing of opioids. Shockingly, Insys sales representatives continued to visit these providers’ offices even after their arrests.

52. An Insys sales representative even tried to recruit to its speaker program a physician assistant in New York -- who wrote more than \$200,000 worth of prescriptions for Subsys -- only a few days before he was arrested. The provider later pled guilty to illegal distribution of opioids.

53. Insys had no policy in place whereby Insys sales representatives would cease detailing these or other providers. Quite the opposite was true; Insys management repeatedly directed its sales team to visit its highest prescribers and “move in” to their offices. The message could not be clearer: “DON’T LEAVE THE \$\$\$\$ on the table.”

IV. Insys engaged in repeated and persistent illegal and deceptive conduct through its sham “speaker” programs.

54. Insys also paid providers to induce them to prescribe more Subsys.

55. Patients -- who enjoyed a fiduciary relationship with their physicians – were not aware of, and did not consent to, these financial arrangements. Patients were therefore prescribed a dangerous, potent, and fast-acting opioid based on undisclosed and inappropriate incentives that Insys offered prescribers.

56. Specifically, Insys arranged and funded “speaker” programs: dinners at high-end restaurants and bars where Insys represented that a “speaker” provider would ostensibly educate other providers as to the benefits of Subsys. In fact, the events were nothing more than bribes and kickbacks to the “speaker” providers who prescribed Subsys, as an incentive to those providers to prescribe increased amounts of Subsys.

57. For each speaker event, Insys paid approximately \$3,000 to \$5,000 to the provider whom Insys had selected to speak at the dinner. Insys paid some physicians well over a dozen times per year to be speakers at these dinners.

58. Time and time again, Insys executives used the words “return on investment” (or “ROI”) in internal discussions of doctors to select for its speaker programs. Insys chose speakers based only on the expectation that the providers would prescribe more Subsys as a “return on investment.” For example, Insys sent an email to New York sales representatives that contained the volume of prescriptions written by New York providers, and asked:

Where is the ROI??!!! All prescribers from this team that are on this list are Insys speakers. We invest a lot of time, \$, blood, sweat, and tears on "our guys" and help spreading the word on treating BTCP. We hire only the best of the best to be apart [sic] of our speaker bureau and dropping script counts is what we get in return?

59. In one analysis of a speaker's value, the sales representative noted that she had spent a large amount of money on a particular New York doctor and always gets "a return on investment." She reported that "as soon as speaker programs were presented he began finding new patients."

60. Another sales representative gave a slide presentation about a nurse practitioner where the representative explained that she "couldn't possibly justify giving [the nurse practitioner speaker] programs without at least one new rx of Subsys weekly."

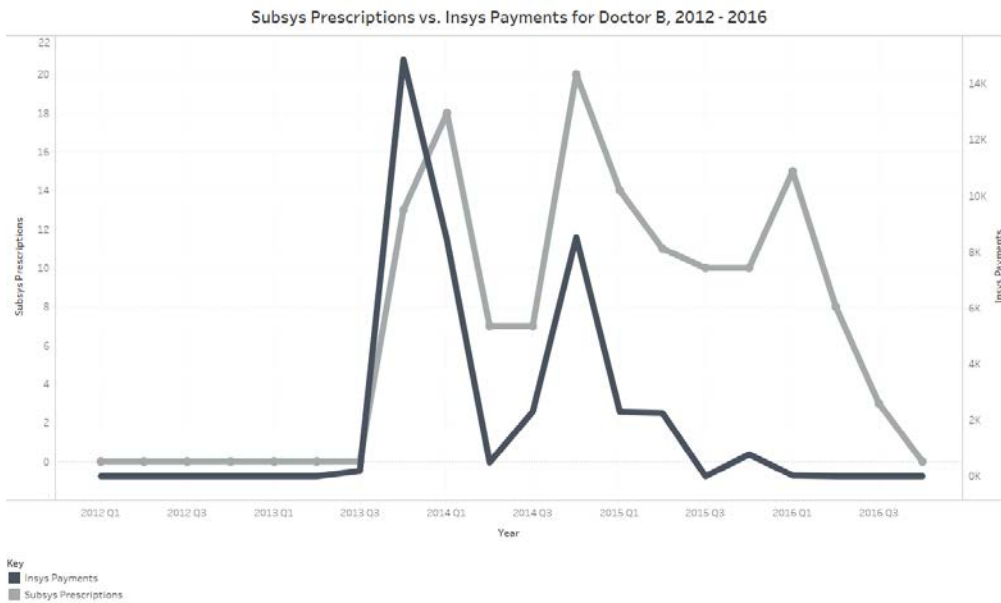
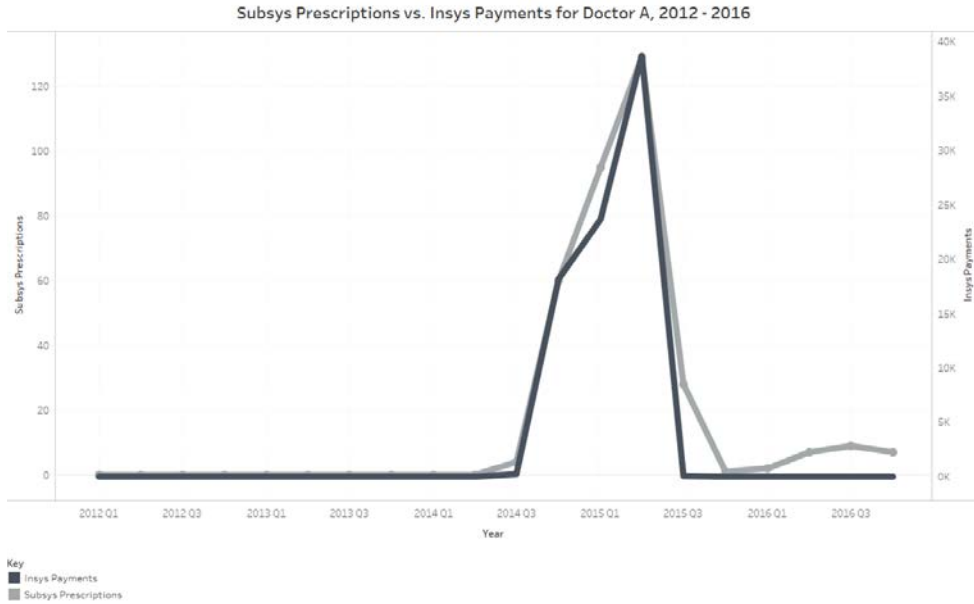
61. The Insys designee testifying on behalf of Insys at an investigatory subpoena hearing could not defend these conversations, admitting that speaking of "ROI" in the context of a speaker is "not right."

62. The pressure for arranging a quid pro quo was extreme. Insys told representatives that their jobs were at risk if they did not take advantage of "relationships" and ask the providers to write prescriptions; "Your providers owe it to you...!"

63. The CEO of Insys even instructed the sales managers to make sure their sales representatives understood the "important nature of having one of their top targets as a speaker. It can pay big dividends for them."

64. Insys achieved its goal of a return on investment. From the time of the launch of the speaker program in 2012 to the present, Insys paid its top five prescribers in New York close to \$1 million dollars, and those prescribers in turn generated more than \$20 million dollars in net sales for Insys. Indeed, a strong correlation exists between Insys' payments to speakers and the number of Subsys prescriptions written by those providers – as the amount of payments increased, so did the number of prescriptions. For example, these charts reflecting

the number of prescriptions of two of the top prescribers in New York show clearly that relationship:



65. There were additional indications that Insys scheduled speaker programs to line prescriber pockets and incentivize more prescriptions, and not for the stated purpose of educating potential legitimate prescribers about Subsys. For at least some of the programs,

many if not all of the attendees were fellow Insys staff and other individuals who did not have prescription-writing authority.

66. Moreover, repeat attendees were a common occurrence; several individuals attended the dinners on more than one occasion. One sales representative, for example, testified that an individual had attended a Subsys speaker dinner three times in nine days. Indeed, repeat attendees were to be expected, in light of the fact that Insys set unrealistic quotas for the speaker presentations, instructing sales representatives that they should have one speaker program per week for each of their providers.

67. The true Insys ethos, as it relates to the speaker programs, is revealed in a text message between the Insys Director of Sales and a provider speaker. In it, the executive threatened a provider who agreed to speak for a competitor's product: "We work on loyalty here pal. Waxh your fuckn back and grow a set of eyes in the back of your head..."

FIRST CAUSE OF ACTION
DECEPTIVE ACTS AND PRACTICES

68. Plaintiff realleges and incorporates by reference each and every allegation in Paragraphs 1 through 67 above as if the same were fully set forth herein.

69. GBL § 349 provides that "[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in [New York] are ... unlawful."

70. By engaging in the acts and practices described above, Insys has engaged in and continues to engage in deceptive business practices in violation of GBL § 349.

SECOND CAUSE OF ACTION
REPEATED AND PERSISTENT FRAUD

71. Plaintiff realleges and incorporates by reference each and every allegation in Paragraphs 1 through 67 above as if the same were fully set forth herein.

72. Executive Law § 63(12) makes “repeated fraudulent or illegal acts or otherwise demonstrate persistent fraud or illegality in the carrying on, conducting or transaction of business,” actionable by the Attorney General.

73. By engaging in the acts and practices described above, Insys has engaged in and continues to engage in repeated fraudulent acts or persistent fraud in violation of Executive Law § 63(12).

THIRD CAUSE OF ACTION
REPEATED AND PERSISTENT ILLEGALITY

74. Plaintiff realleges and incorporates by reference each and every allegation in Paragraphs 1 through 67 above as if the same were fully set forth herein.

75. Executive Law § 63(12) makes “repeated fraudulent or illegal acts or otherwise demonstrate persistent fraud or illegality in the carrying on, conducting or transaction of business,” actionable by the Attorney General.

76. By engaging in the acts and practices described above, which include violations of GBL §§ 349 and 350, Insys has engaged in and continues to engage in repeated illegal acts or persistent illegality in violation of Executive Law § 63(12).

FOURTH CAUSE OF ACTION
REPEATED AND PERSISTENT ILLEGALITY
COMMERCIAL BRIBING

77. Plaintiff realleges and incorporates by reference each and every allegation in Paragraphs 1 through 67 above as if the same were fully set forth herein.

78. Penal Law § 180.00 provides that “A person is guilty of commercial bribing in the second degree when he confers, or offers or agrees to confer, any benefit upon any employee, agent or fiduciary without the consent of the latter's employer or principal, with intent to influence his conduct in relation to his employer's or principal's affairs.”

79. By engaging in the acts and practices described above, Insys has engaged in commercial bribing in the second degree in violation of New York Penal Law § 180.00. Specifically, Insys paid providers, each of whom is a fiduciary to his/her patients, without patient consent and with the intent to encourage the providers to prescribe Subsys to patients.

80. Defendants' violations of Penal Law § 180.00 constitute repeated and persistent illegal conduct in violation of Executive Law § 63(12).

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, the People of the State of New York, respectfully requests that a judgment and order be entered that:

- A. Permanently enjoins Insys from engaging in the deceptive, fraudulent and unlawful practices alleged herein;
- B. Directs Insys to disgorge all amounts obtained in connection with or as a result of the violations of law alleged herein;
- C. Directs Insys to pay a civil penalty of \$5,000 to the State of New York pursuant to GBL § 350-d for each instance of a deceptive or unlawful act or practice that violates GBL Article 22-A;
- D. Directs Insys to pay an additional civil penalty of \$10,000 to the State of New York pursuant to GBL § 349-c for fraud committed against the elderly;

- E. Directs Insys to pay restitution and damages to the State of New York based on Insys' fraudulent, deceptive and illegal practices;
- F. Awards State of New York's costs; and
- G. Grants all other relief that is just and proper.

Dated: New York, New York
February 1, 2018

Respectfully submitted,

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