IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT - CHANCERY DIVISION

THE PEOPLE OF THE STATE OF ILLINOIS,	)	2016CH11216 CALENDAR/ROOM 05 TIME 00:00 Injunction
Plaintiff,	)	
-vs-	)	No.
INSYS THERAPEUTICS, INC.	)	
Defendant.	)	

COMPLAINT FOR INJUNCTIVE AND OTHER RELIEF

Now comes the Plaintiff, THE PEOPLE OF THE STATE OF ILLINOIS, by LISA MADIGAN, THE ATTORNEY GENERAL OF THE STATE OF ILLINOIS, and brings this action against INSYS THERAPEUTICS, INC. for violations of the Illinois Consumer Fraud and Deceptive Business Practices Act ("Consumer Fraud Act"), 815 ILCS 505/1 *et seq.* and states as follows:

Investigation by THE ATTORNEY GENERAL OF THE STATE OF ILLINOIS has revealed that INSYS THERAPEUTICS, INC. has sold and is continuing to sell its main drug, Subsys - a form of the prescription opioid drug fentanyl - in Illinois through aggressive targeting of high-volume opioid drug prescribers in this State. It has done so without regard to the suitability of the patient population for the approved use of Subsys (breakthrough pain in adult cancer patients). And, it has done so while misrepresenting to those patients and prescribers what the approved use and dosage parameters are for Subsys.

Insys' conduct of pushing higher sales volumes and dosages of its form of a highly-addictive and powerful prescription opioid drug, which can cause addiction and death if not used appropriately, is a violation of Illinois law and has placed the citizens of Illinois in harm's way.

PUBLIC INTEREST

1. The State of Illinois and its citizens are and will be adversely impacted by Defendant's unfair and deceptive practices as alleged in this Complaint. Therefore, pursuant to 815 ILCS 505/7(a), THE ATTORNEY GENERAL OF THE STATE OF ILLINOIS brings this action in the public interest of the citizens of the State of Illinois.

JURISDICTION AND VENUE

2. This action is brought for and on behalf of THE PEOPLE OF THE STATE OF ILLINOIS, by LISA MADIGAN, THE ATTORNEY GENERAL OF THE STATE OF ILLINOIS, pursuant to the provisions of the Consumer Fraud Act and her common law authority as THE ATTORNEY GENERAL OF THE STATE OF ILLINOIS to represent THE PEOPLE OF THE STATE OF ILLINOIS.

3. Venue for this action properly lies in Cook County, Illinois, pursuant to section 2-101 of the Illinois Code of Civil Procedure, 735 ILCS 5/2-101, in that some of the activities complained of herein out of which this action arose occurred in Cook County.

PARTIES

THE PEOPLE OF THE STATE OF ILLINOIS

4. Plaintiff, THE PEOPLE OF THE STATE OF ILLINOIS, by LISA MADIGAN, THE ATTORNEY GENERAL OF THE STATE OF ILLINOIS, is charged with enforcement of the Consumer Fraud Act.

INSYS THERAPEUTICS, INC.

5. Defendant INSYS THERAPEUTICS, INC. ("Insys") is a Delaware corporation headquartered in Chandler, Arizona.

6. From January of 2012 until March of 2015, the time period for the allegations contained

in this Complaint, Subsys was the main product and one of two products Insys marketed in Illinois.

TRADE AND COMMERCE

7. Subsection 1(f) of the Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1(f), defines "trade" and "commerce" as follows:

> The terms 'trade' and 'commerce' mean the advertising, offering for sale, sale, or distribution of any services and any property, tangible or intangible, real, personal, or mixed, and any other article, commodity, or thing of value wherever situated, and shall include any trade or commerce directly or indirectly affecting the people of this State.

8. Since at least April of 2012, Insys engaged in trade and commerce in Illinois by marketing, selling, and promoting the Schedule II opioid drug Subsys.

9. Insys' sales representatives promoted Subsys directly to Illinois prescribers by calling on them at their offices.

BACKGROUND

The Opioid Drug Abuse Public Health Epidemic in the United States

10. Opioid drug abuse is a growing public health epidemic in the United States. According to the Center for Disease Control, from 2000 to 2014 nearly half a million people in the United States died from drug overdoses – the majority of those deaths involved either a prescription or illegal opioid drug. Approximately 78 Americans die every day from an opioid drug overdose.

11. Opioids are a class of narcotic pain relieving drugs.

12. Oxycodone, hydrocodone, codeine, morphine, and fentanyl are all examples of prescription opioid drugs.

13. Heroin is an illegal opioid.

14. Prescription opioids are gateway drugs to heroin. After using prescription opioids, some people turn to heroin because it is cheaper and easier to obtain.

15. According to some studies, nearly half of young people who inject heroin reported abusing prescription opioids before starting to use heroin.

16. Opioids reduce the intensity of pain signals reaching the brain, but they also have serious side effects, including respiratory depression and death.

17. Prescription opioid drugs are a driving factor in the increase of opioid overdose deaths. According to the Center for Disease Control, from 1999-2014, both the amount of prescription opioid drugs sold in the U.S. and the rate of overdose deaths involving prescription opioid drugs in the U.S. nearly quadrupled, yet there has not been an overall change in the amount of pain that Americans report.

18. Subsys is a prescription opioid drug consisting of the powerful and highly addictive narcotic, fentanyl, administered through a sub-lingual (under the tongue) spray, which gives Subsys a rapid onset.

19. Subsys is classified as a Schedule II controlled substance, which means it has a high potential for abuse and addiction.

20. In its December 4, 2015 press release, Insys reported that 244 patients have died while taking Subsys since it launched in 2012.

21. Three of those deaths were due to Subsys overdoses.

22. Insys categorized 83 deaths as due to "unknown causes."

Overview of FDA Prescription Drug Regulation

23. To ensure that prescription drugs sold in the United States are safe and effective, the Food Drug and Cosmetic Act ("FDCA") requires drug manufacturers to submit a new drug application

("NDA") for all prescription drugs sold in the United States.

24. The NDA must include clinical trials sufficient to prove to the U.S. Food and Drug Administration ("FDA") that the drug is safe and effective for each and every indication (use) for which the drug is sold.

25. If a manufacturer wants to market a drug for an indication not initially approved by the FDA, the company must submit a supplemental new drug application ("sNDA") that demonstrates to the FDA that the drug is safe and effective for the new indication.

26. Although prescribers may use their own professional judgment to prescribe drugs for uses the FDA has not determined to be safe and effective ("off-label prescribing"), the FDCA makes it unlawful for companies to market drugs for indications the FDA has not approved ("off-label marketing").

27. The ban on off-label marketing is intended to prohibit pharmaceutical companies from misleading prescribers and patients about uses of the product that have not been approved by the FDA and may not have been appropriately studied to determine whether the benefits of the use outweigh the risks.

Pharmaceutical Marketing Practices

28. Because pharmaceutical companies have an interest in increasing sales, which could conflict with a patient's best interest, some physician offices and hospitals have a policy of either prohibiting sales representatives from entering their facility all together, or significantly limiting their interaction with prescribers and staff.

29. In places that do allow pharmaceutical sales representatives to market their products, sales representatives typically spend short periods of time marketing to several different prescribers throughout the day.

30. In most instances, when sales representatives are marketing a drug rather than a medical device, they do not interact directly with patients.

FDA Approval of Subsys

31. In January of 2012, FDA approved Subsys "... for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain" per the Subsys label.

32. This means that patients who take Subsys must already be taking a different, long-acting opioid to manage their pain.

33. Subsys is one of a class of drugs described as Transmucosal Immediate-Release Fentanyl ("TIRF").

34. To reduce the risk of abuse, misuse, and diversion of opioids, FDA instituted a Risk Evaluation and Mitigation Strategy ("REMS") for Subsys and other TIRF products to ensure that the benefit of the drugs outweigh their risk. The purpose of this REMS, according to a December 29, 2011 FDA press release, was to educate "... prescribers, pharmacists, and patients on the potential for misuse, abuse, addiction, and overdose..." for this class of drugs.

35. Prescribers must enroll in the TIRF REMS program before writing a prescription for Subsys.

Prior Authorization Required by Insurance

36. In most instances, prescribers must also submit Subsys prescriptions for prior authorization to insurance companies due largely to its high cost.

37. Prior authorization is a process insurance companies use to determine whether they will cover a drug prior to the patient filling the prescription.

38. Depending on a patient's dosage and frequency of usage, a month's supply of Subsys

could cost thousands of dollars.

39. One patient, who did not have cancer, told an Illinois Subsys sales representative that he obtained a second mortgage on his home to pay approximately $8,000 a month for Subsys after his insurance company refused to pay for it.

40. As part of the prior authorization process, insurance companies may request portions of a patient's medical records and/or a letter of medical necessity from the prescriber stating why a patient needs the drug being requested.

41. To alleviate some of the administrative burden on prescribers, Insys created the Insys Reimbursement Center (IRC).

42. The goal of the IRC was to facilitate the prior authorization process and act as an intermediary between the prescriber and the patient's insurance company.

43. The IRC also processed vouchers that Insys gave patients so patients could fill their Subsys prescriptions without any out of pocket cost during the prior authorization process.

DEFENDANT'S UNFAIR AND DECEPTIVE BUSINESS PRACTICES

Insys Heavily Marketed to High-Volume Prescribers Without Regard to Whether the Prescribers Treated Cancer Pain

44. The Indications and Usage section of the FDA-approved label states, "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."

45. Rather than focusing on oncologists and/or pain specialists who treat cancer pain, Insys instead directed its promotion and marketing in Illinois to high-volume opioid prescribers who are not oncologists or pain specialists who treat cancer.

46. Insys categorized prescribers into deciles (D1-D10) according to the number of rapid

onset opioids (ROOs) he/she prescribed.

47. The lowest volume ROO prescribers were in the first decile and the highest volume ROO prescribers were in the tenth decile.

48. Each sales representative had an assigned list of prescribers to call on, which included a range of low and high-volume ROO prescribers.

49. Insys instructed sales representatives to call on high-volume ROO prescribers much more frequently than low volume prescribers.

50. Insys instructed sales representatives to call on the highest volume ROO prescribers at least three times a week, and the lowest volume ROO prescribers only twice a month.

51. Some Illinois sales representatives visited their high-volume prescriber(s) nearly every day.

52. Insys encouraged sales representatives to secure the majority of their sales from one or two high-volume prescribers.

53. In a May 1, 2013 email, Alec Burlakoff, the former Vice President of Sales for Insys, told the Sales Department to follow a simple formula to be successful: " – pick an office that your gut tells you is worth going after – pack your bags – move in – don't leave until you have seen the Subsys prescription you need on a daily basis 'with your own two eyes'!"

54. From April of 2012 until March of 2015, Insys sold $11,958,654 of Subsys in Illinois.

55. Approximately 94% of those sales can be attributed to Illinois' top ten Subsys prescribers.

56. The highest volume Subsys prescriber in Illinois, by far, was Dr. Paul Madison.

57. Dr. Madison prescribed approximately 58% of the Subsys prescriptions in Illinois.

58. Dr. Madison is not an oncologist, and he treats few, if any, cancer patients.

59. Over 95% of the Subsys prescriptions written by Dr. Madison were for patients that did

not have cancer.

60. The vast majority of Dr. Madison's Subsys prescriptions related to back pain, neck pain, and/or other types of chronic pain.

61. Illinois sales representatives observed patients in Dr. Madison's office exhibiting drug seeking attributes and behavior.

62. An Illinois sales representative expressed concerns about Dr. Madison to the sales representative's supervisor and then Insys CEO, Michael Babich, in an email on August 19, 2012.

63. In the August 19, 2012 email, the Illinois sales representative states:

> **Dr. Madison runs a very shady pill mill** and only accepts cash. He sees very few insured patients but does write some Fentora. He is extremely moody, lazy and inattentive. **He basically just shows up to sign his name on the prescription pad, if he shows up at all.** I have been working more with his MA who is the one that knows what is going on in his office. He has agreed to try and help me out but I know he is afraid of Dr. Madison's outbursts and is reluctant to input. I think that being in the office at the right time, when the right patient walks in, on a day Dr. Madison is in a good mood is the only way I will get him to write. This is the reason I call on him frequently.

(emphasis added)

64. The same Illinois sales representative sent an email to another supervisor on October 3, 2012 in which the Illinois sales representative states, "[Dr. Madison] did call me personally though later in the afternoon to tell me it is his Illinois office that is really under the eye of the DEA and that he planned on getting patients started on Subsys in Indiana."

65. The supervisor responded, "I am very confident that Dr. Madison will be your 'go to physician.' Stick with him."

66. Dr. Madison was indicted in December of 2012 on federal false claims charges for

allegedly billing insurers for procedures that were never performed.

67. Illinois sales representatives who called on Dr. Madison admitted they knew of Dr. Madison's 2012 indictment, yet they continued to call on Dr. Madison.

68. In April of 2014, the Illinois Department of Financial and Professional Regulation ("IDFPR") reprimanded Dr. Madison for prescribing controlled substances without an Illinois Controlled Substance License.

69. Despite the fact that Insys knew Dr. Madison did not routinely treat cancer patients and was possibly running a "pill mill," Insys continued marketing to Dr. Madison and even paid him $84,400 to promote Subsys at 46 "speaking" events in Illinois.

70. Dr. Madison was not the only problematic prescriber in Insys' top 10 Subsys prescribers.

71. In 2014, IDFPR fined and reprimanded another Subsys prescriber for, according to IDFPR's website, prescribing "... a controlled substance to an established patient without examining the patient at the proper frequency he typically maintained" and failing to "... properly document his examinations of the patient."

72. IDFPR is currently in the process of disciplining yet another one of the top ten Illinois Subsys prescribers for, among other things, failing to appropriately assess and monitor a patient taking a prescription opioid drug.

Insys Used its "Insys Speaker Program" to Pay High-Volume Prescribers to Prescribe Subsys

73. Insys represented that it paid Illinois prescribers to promote Subsys to other Illinois prescribers as part of the Insys Speaker Program (ISP).

74. In reality, ISP events in Illinois functioned more as social gatherings, and the Speaker Program was a sham created so Insys could pay the Illinois "speaker" prescribers to prescribe

Subsys.

75. Almost all of the Illinois ISP events took place at upscale restaurants in the Chicago area.

76. In addition to their meal, Illinois speakers received a speaker honorarium ranging from $700-$5,100 per ISP event.

77. "Speakers" discussed Subsys very little, if at all, during the ISP.

78. At these events, top Subsys prescribers, such as Dr. Madison, were allowed to order as much food and alcohol as they wanted.

79. From November of 2012 until June of 2015, Dr. Madison "spoke" at approximately 46 ISP events in the Chicago area.

80. He received $84,400 from Subsys in speaker honoraria during that time.

81. Sometimes Dr. Madison hosted multiple ISP events in a week.

82. All of Dr. Madison's Illinois ISP events had the same program title, "Advancements in the Treatment of Breakthrough Pain in Cancer Patients," yet Dr. Madison had little to no experience in treating breakthrough pain in cancer patients.

83. During these events, Dr. Madison either did not speak about Subsys at all or did so briefly in a very conclusory fashion at the beginning of dinner.

84. In at least two instances, on April 5, 2013 and June 21, 2013, Insys paid Dr. Madison $1,600 per event to "speak" at Illinois ISP events, yet the only attendees were Dr. Madison and an Illinois sales representative.

85. Even when prescribers did attend Dr. Madison's ISP events, they were not prescribers that specialized in treating cancer-related pain.

86. Some prescribers specialized in neurology, obstetrics and gynecology, urology, and plastic surgery.

87. In a March 19, 2015 text message conversation, one Illinois sales representative who regularly markets to Dr. Madison asks another Illinois sales representative whether he knows a prescriber he could invite to an ISP event hosted by Dr. Madison that evening.

88. The Illinois sales representative who regularly marketed to Dr. Madison advised the other Illinois sales representative to, "... make the judgment to see if the doc will learn/benefit. If ur doc is very conservative, might not be a good match."

89. Many attendees that attended Dr. Madison's Illinois ISP events were friends of Dr. Madison and attended more than one of his Illinois ISP events.

90. One Illinois physician assistant attended at least nine ISP events hosted by Dr. Madison and never wrote a single Subsys prescription.

Insys Marketed Subsys Off-Label to Treat Non Cancer-Related Breakthrough Pain

91. While aggressively marketing to Illinois prescribers who saw few, if any, cancer patients, Insys marketed Subsys to treat breakthrough pain rather than breakthrough cancer pain to broaden Subsys' limited indication.

92. Insys trained Illinois sales representatives to use the phrase "breakthrough pain," rather than "breakthrough cancer pain," when marketing to prescribers in Illinois in order to capture a larger patient population.

93. Insys created and distributed in Illinois a Breakthrough Pain Tracker that patients could use as a journal to record and rate their pain.

94. The Breakthrough Pain Tracker defines breakthrough pain without any reference to cancer.

95. The word cancer does not appear at all in the Breakthrough Pain Tracker.

Insys Marketed Subsys for Patients Taking Competing Prescription Opioid Drugs Regardless of Whether Patients Had Breakthrough Cancer Pain

96. Insys' primary objective was to capture the existing ROO market regardless of whether patients had breakthrough cancer pain.

97. Insys instituted a marketing initiative known as the Switch Program to further that goal.

98. As part of the Switch Program, Insys instructed its Illinois sales representatives to target prescribers that prescribed competing opioid drugs and offered their patients free product if they switched to Subsys.

99. Marketing for the Switch Program by Illinois Insys sales representatives was not limited to patients with breakthrough cancer pain. Instead, Insys marketed this free product program to any patient, regardless of whether the patient was taking a competing opioid for breakthrough cancer pain.

100. A significant number of the prescriptions written in Illinois as part of the Switch Program were for off-label uses.

101. In addition to targeting prescribers, Insys instructed its representatives to aggressively target individual patients on competing prescription opioid drugs who could potentially switch to Subsys regardless of whether the patient had breakthrough cancer pain.

102. In an October 15, 2012 email, an Insys supervisor tells an Illinois sales representative to report back to the supervisor "...the exact day and time [a potential switch patient] is scheduled back for his or her next visit."

103. The Insys supervisor then instructs the Illinois sales representatives to "...be in the office/when the patient is coming in (with coffee/bagels, etc.)" to ensure the patient is prescribed Subsys.

104. The Insys supervisor warns the Illinois sales representative, "If you do not carry through with these actions you will most likely lose the potential 'switch' patient."

Insys Sales Representatives Inserted Themselves Into the Prior Authorization and Prescription-Writing Process, Including for Off-Label Purposes

105. The role of the Illinois sales representative did not end when he/she called on an Illinois prescriber, or even when the Illinois prescriber wrote a Subsys prescription.

106. Despite Insys having dedicated reimbursement personnel at their main office, Illinois sales representatives played a large role in the insurance prior authorization process.

107. Illinois Insys sales representatives completed, or helped to complete, insurance prior authorization forms, including providing template letters of medical necessity.

108. Illinois Insys sales representatives also frequently distributed template letters of medical necessity to Illinois prescribers even though Insys' own Director of Drug Safety and Medical Information refused to provide such a template letter to a provider stating, "...in today's regulatory climate, that would be problematic."

109. Illinois Insys sales representatives even communicated directly with patients.

110. Sometimes, patients contacted Illinois sales representatives directly to request a Subsys refill.

111. In other instances, patients contacted Illinois sales representatives to obtain vouchers for Subsys with no out-of-pocket cost during the prior authorization process.

112. In an April 23, 2015 text message conversation between an Illinois sales representative and a patient relating to a voucher for Subsys, the Illinois sales representative says, "Yeah, give [the pharmacy] a call and see if u can set up pick up time. They should have received the voucher already. Dnt tell them we communicate... Technically I'm not suppose to. I'm still waiting for

them to get back to me."

113. Insys created multiple versions of its Subsys prior authorization form.

114. Some versions of the Subsys prior authorization form listed preprinted diagnoses that prescribers could circle or check.

115. One Insys-created prior authorization form distributed in Illinois contained eleven preprinted diagnoses. Only two preprinted diagnoses (cancer and neoplasm related pain) relate to an on-label use of Subsys. The remaining nine preprinted diagnoses relate to off-label uses.

116. Insys processed prior authorization forms for patients diagnosed with migraines, even though Subsys is contraindicated (should never be used) to treat a headache/migraine according to the FDA approved Subsys label.

117. Because the Illinois sales representatives were so involved in the entire prescription process, including talking to individual patients and assisting with prior authorization forms, they knew certain prescribers saw very few, if any, cancer patients.

118. Despite this knowledge, Insys continued marketing to these prescribers, knowing the prescribers were writing Subsys mostly, if not exclusively, for off-label, and even expressly contraindicated, uses.

Insys Deceptively Represented That the "Effective Dose" of Subsys Was Between 600 Mcg and 1600 Mcg in Order to Promote High Dose Use of Subsys.

119. To help protect against Subsys' potentially fatal side effects, and to reduce the risk of misuse and abuse, the FDA determined that prescribers should use the lowest possible dose of Subsys that adequately treats a patient's symptoms.

120. The FDA requires that most patients start by taking 100 micrograms (mcg) of Subsys and then incrementally increase or decrease dosage to a dosage that provides adequate pain relief and

minimizes side effects. This process is called medication titration.

121. Although patients benefit from using the lowest possible dose, Insys earns more money when a higher dose is prescribed since the higher doses are more expensive.

122. Insys sales representatives also make more money on higher doses, because their commission is a percentage of the overall sale amount rather than a flat commission per prescription.

123. As part of a February 5, 2013 Board of Directors Meeting in Chandler, Arizona, Insys identified the 100 mcg starting dose of Subsys and its titration schedule as a strategic challenge.

124. To overcome this challenge, Insys created a strategy to "facilitate titration" by focusing on the "effective dose."

125. Insys uses the phrase "effective dose" to mean high doses of Subsys, even though, the truly effective dose is the lowest possible dose that effectively manages a patient's pain.

126. To support its "effective dose" strategy, Insys emphasized, in its marketing materials, that "3 out of 4 patients found an effective dose between 600 mcg and 1600 mcg."

127. Sales representatives in Illinois represented to prescribers that most patients find an effective dose between 600 mcg and 1600 mcg.

128. Even if it were true that "most patients" need between 600 mcg and 1600 mcg of Subsys to effectively manage their pain, not all patients will need such a high dose of Subsys.

129. Through its effective dose strategy, Insys represented to prescribers that patients should receive 600 mcg to 1600mcg of Subsys to effectively manage their pain rather than focusing on finding the lowest possible dose to manage a patients pain, per the FDA-approved Subsys label.

130. Insys' push to facilitate titration to higher doses did not end with sales representatives marketing to prescribers.

131. Insys trained its Illinois sales representatives to insert themselves into the prescriber-patient relationship by asking prescribers about their titration plan for each specific patient.

132. When a prescriber prescribed 400 mcg or less, Insys tracked and reported such events daily, and instructed the sales representative to work with the prescriber to "titrate" the patients to higher doses.

133. In a November 9, 2012 email, the Director of Sales Operations states, "It is imperative that you work with your writers to titrate patients to their effective dose."

134. If a prescriber wrote a Subsys prescription for 200 mcg or less, the Director of Sales Operations instructed that prescriber's assigned sales representative to "... report back to your manager within 24 hours on WHY the low dose was used and HOW the doctor plans to titrate the patient to effective dose."

135. Insys deceptively represented to prescribers that patients should be on a higher dose of Subsys because lower doses were not effective, contradicting the FDA mandated purpose of titration: finding the lowest possible effective dose.

APPLICABLE STATUTES

136. Section 2 of the Consumer Fraud Act, 815 ILCS 505/2, provides:

> Unfair methods of competition and unfair or deceptive acts or practices, including but not limited to the use or employment of any deception, fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission of such material fact, or the use or employment of any practice describe d in section 2 of the 'Uniform Deceptive Trade Practices Act', approved August 5, 1965, in the conduct of any trade or commerce are hereby declared unlawful whether any person has in fact been misled, deceived or damaged thereby.

VIOLATIONS

Count I: Consumer Fraud and Deceptive Business Practices Act

137. The Plaintiff repeats and realleges Paragraphs 1-136 herein and incorporates each by reference herein.

138. Defendant INSYS THERAPEUTICS, INC., while engaged in the course of trade or commerce, has engaged in conduct that constitutes unfair and/or deceptive acts declared unlawful under section 2 of the Consumer Fraud Act, 815 ILCS 505/2, with the intent that consumers and/or prescribers rely upon the deceptive conduct, by:

a. engaging in the unfair and deceptive act of targeting Subsys promotion at prescribers who do not routinely treat cancer patients;

b. engaging in the unfair and deceptive act of targeting Subsys promotion at high-volume opioid prescribers who do not routinely treat cancer patients;

c. engaging in the deceptive and/or unfair act of paying prescribers to prescribe Subsys under a sham speaker program;

d. engaging in the deceptive act of marketing Subsys for breakthrough pain not associated with cancer, when in fact, Subsys is not approved for such use;

e. representing, expressly or by implication, that Subsys should be used for the treatment of breakthrough pain rather than breakthrough cancer pain, when in fact, this has not been adequately substantiated;

f. representing, expressly or by implication, that Subsys is safe and effective for the treatment of migraines, when in fact, Subsys is contraindicated in the treatment of headaches/migraines;

g. representing, expressly or by implication, that any consumer currently taking a

competing prescription opioid drug should switch to Subsys, when in fact, not every consumer taking a competing prescription opioid drug has breakthrough cancer pain;

h. deceptively representing to prescribers that patients should be on a higher dose of Subsys because lower doses were not effective; and

i. engaging in the unfair act of marketing Subsys at higher doses, contrary to both the FDA mandated titration schedule designed to protect consumers and the public policy of combating prescription opioid drug addiction.

REMEDIES

139. Section 7 of the Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/7, provides:

> (a) Whenever the Attorney General has reason to believe that any person is using, has used, or is about to use any method, act or practice declared by the Act to be unlawful, and that proceedings would be in the public interest, he may bring an action in the name of the State against such person to restrain by preliminary or permanent injunction the use of such method, act or practice. The Court, in its discretion, may exercise all powers necessary, including but not limited to: injunction, revocation, forfeiture or suspension of any license, charter, franchise, certificate or other evidence of authority of any person to do business in this State; appointment of a receiver; dissolution of domestic corporations or association suspension or termination of the right of foreign corporations or associations to do business in this State; and restitution.
>
> (b) In addition to the remedies provided herein, the Attorney General may request and this Court may impose a civil penalty in a sum not to exceed $50,000 against any person found by the Court to have engaged in any method, act or practice declared unlawful under this Act. In the event the court finds the method, act or practice to have been entered into with intent to defraud, the court has the authority to impose a civil penalty in a sum not to exceed $50,000 per violation.

140. Section 10 of the Consumer Fraud Act, 815 ILCS 505/10, provides that "[i]n any action brought under the provisions of this Act, the Attorney General is entitled to recover costs for the use of this State."

PRAYER FOR RELIEF

WHEREFORE, the plaintiff prays that this honorable Court enter an Order:

A. Finding that Defendant INSYS THERAPEUTICS, INC. violated Section 2 of the Consumer Fraud Act, 815 ILCS 505/2, by engaging in unlawful acts and practices including, but not limited to, the unlawful acts and practices alleged herein;

B. Permanently enjoining the Defendant from engaging in trade or commerce in the State of Illinois;

C. Permanently enjoining the Defendant from engaging in in the unfair and/or deceptive acts or practices described herein;

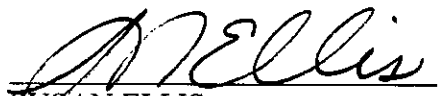
D. Assessing a civil penalty in the amount of Fifty Thousand Dollars ($50,000) if the Court finds the Defendant has engaged in methods, acts or practices declared unlawful by the Act without the intent to defraud. If the Court finds the Defendant has engaged in methods, acts, or practices declared unlawful by the Act with the intent to defraud, then assessing a statutory civil penalty of Fifty Thousand Dollars ($50,000), all as provided in section 7 of the Consumer Fraud Act, 815 ILCS 505/7;

E. Requiring the Defendant to pay all costs for the prosecution and investigation of this action, as provided by Section 10 of the Consumer Fraud Act, 815 ILCS 505/10; and

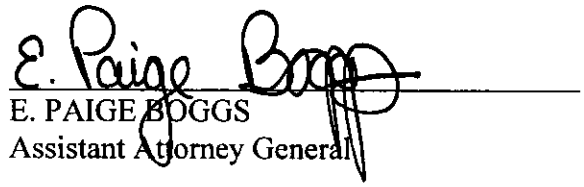
F. Providing such other and further equitable relief as justice and equity may require.

Respectfully submitted,

THE PEOPLE OF THE STATE OF ILLINOIS,
By LISA MADIGAN,
ATTORNEY GENERAL OF ILLINOIS

BY: 

SUSAN ELLIS
Consumer Fraud Bureau, Chief



E. PAIGE BOGGS
Assistant Attorney General

Attorney No. 99000

LISA MADIGAN
Attorney General of Illinois

SUSAN ELLIS
Chief, Consumer Fraud Bureau

VAISHALI RAO
Supervising Attorney

E. PAIGE BOGGS
Assistant Attorney General
Consumer Fraud Bureau
100 West Randolph St., 12th Floor
Chicago, Illinois 60601
(312) 814-1528
EBoggs@atg.state.il.us