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UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS JUN -5 PM 3:36

UNITED STATES OF AMERICA)	
)	Criminal No. U.S. DISTRICT COURT
v.)	DISTRICT OF MASS.
)	19cr10191
)	Violations:
INSYS THERAPEUTICS, INC.,)	
INSYS PHARMA, INC.,)	<u>Counts One-Five:</u> Mail Fraud
)	(18 U.S.C. §§ 1341)
)	
Defendants)	<u>Forfeiture Allegation:</u>
)	(18 U.S.C. § 981(a)(1)(C) and
)	28 U.S.C. § 2461(c))

INFORMATION

General Allegations

At all times relevant to this Information:

1. Defendants Insys Therapeutics, Inc. and Insys Pharma, Inc. (collectively, “Defendants”) are both Delaware corporations that maintain a principal place of business in Chandler, Arizona. At all times relevant to the Information, Insys Pharma, Inc. was a wholly-owned subsidiary of Insys Therapeutics, Inc., and was its main operating subsidiary.

2. Defendants developed and own a drug called SUBSYS® (hereafter “Subsys”), a spray formulation of fentanyl to be applied under a patient’s tongue (also called a sublingual spray). Fentanyl, a Schedule II controlled substance, and analogues of fentanyl were among the most potent opioids available for human use. The United States Food and Drug Administration (“FDA”) approved Subsys in or about January 2012 for the management of breakthrough pain in cancer patients 18 years of age or older who were already receiving and were tolerant to opioid therapy for their underlying persistent cancer pain. Subsys is in a category of drugs called Transmucosal Immediate Release Fentanyl (“TIRF”) products, which includes other fentanyl-based rapid onset opioids that competed with Subsys.

3. From in or about March 2012 to the present, Defendants marketed and sold Subsys in interstate commerce, including in the District of Massachusetts.

4. Subsys could only be prescribed by a licensed medical practitioner who was registered with the United States Drug Enforcement Administration (“DEA”) and able to prescribe opioids in the usual course of professional practice for a legitimate medical purpose.

5. Market demand for Subsys was driven by practitioners who wrote prescriptions for their patients. Practitioners willing to write prescriptions for Subsys had a large number of competing medications from which to choose. In addition to other brand name TIRF drugs, practitioners could also prescribe a generic TIRF medicine.

6. Subsys, like many of its competitors, was expensive. Depending upon the dosage and number of units prescribed, a prescription for Subsys usually cost thousands of dollars per month. Most patients relied on commercial insurance and/or publicly funded insurance, including Medicare and Medicaid, to subsidize the cost of taking Subsys.

7. Insurers and their agents, including pharmacy benefit managers or PBMs, (hereinafter “insurers”) controlled the costs of prescription drugs by requiring, among other things, prior authorizations. While their specific requirements varied, almost all insurers required patients to obtain prior authorization before agreeing to pay for a Subsys prescription. In such cases, insurers would not authorize payment if the prescription was written in exchange for a bribe, or kickback, and was not medically necessary. In general, patients had to have a specific medical diagnosis before the insurer, including Medicare, would authorize payment for Subsys. Many insurers would not pay for Subsys until the patient had tried and failed certain other preferred medications.

Scheme to Defraud

8. Beginning in August 2012, and continuing until at least June 2015, the Defendants paid bribes to practitioners to induce them to prescribe Subsys.

9. Specifically, Defendants used pharmacy data acquired from third parties to identify practitioners who either prescribed high volumes of rapid-onset opioids, or who had demonstrated a capacity to prescribe high volumes of rapid-onset opioids. Defendants then bribed and paid kickbacks to targeted practitioners in exchange for the practitioners increasing Subsys prescriptions and increasing the dosage and units for new and existing Subsys prescriptions.

10. Defendants paid bribes to practitioners through their Speaker Program. The Speaker Program was a marketing program that purported to increase brand awareness of Subsys by sponsoring peer-to-peer educational lunches and dinners. Purportedly in exchange for a practitioner educating other prescribers about Subsys, Defendants agreed to pay the speaker a fee, also referred to as an "honoraria," for each speaking event.

11. For their Speaker Program, Defendants focused on certain speaker practitioners who had the potential to prescribe Subsys. Defendants then used the program to induce certain practitioners to write more prescriptions (many of which were medically unnecessary) in exchange for payment of money by Defendants in the form of speaker fees, or honoraria. Defendants fashioned the payments to practitioners as honoraria in order to hide the fact that they were in fact paying the practitioners bribes to induce them to write Subsys prescriptions.

12. Rather than educational gatherings, Speaker Program events were often just social gatherings at high-priced restaurants that involved no education nor presentation about the drug. Frequently, Speaker Program events did not have attendees who were licensed to prescribe Subsys, but rather included support staff employed by the speaker. Many speaker events had no attendees

at all. When this occurred, Defendants' sales representatives were directed by management to falsify the names of attendees and their signatures on sign-in sheets. Sham Speaker Program events occurred at restaurants within the District of Massachusetts and elsewhere, and functioned as bribes in the form of free dinners for speakers, friends, and, at times, family, and served as a vehicle to pay a bribe to the speaker disguised as an honoraria.

13. High-level officers, directors, executives, managers, and the executive chairman of Defendants' Board of Directors expressly required a practitioner to write a minimum number of Subsys prescriptions, write prescriptions at a minimum dosage, and write prescriptions for a minimum number of units of Subsys, in order for the speaker to continue receiving the bribe, that is, the so-called honoraria, for sham events. For all speakers, Defendants tracked return on investment by measuring the effect of the bribes on the speakers' Subsys prescribing habits, and, correspondingly, the effect of the bribes on the revenue that each bribed speaker generated for Defendants. If a speaker failed to meet the minimum prescription and return on investment requirements, Defendants took Speaker Program events and bribes away from practitioners, or reduced the total amount of bribes paid to practitioners, unless and until the practitioners wrote satisfactory numbers of new Subsys prescriptions or raised the dosage and volume of existing prescriptions. Each new Subsys prescription, refill, or existing prescription written for a higher dose generated greater income to Defendants.

14. One such practitioner targeted by Defendants and to whom Defendants, through their employees, offered bribes was a physician's assistant ("P.A.") who practiced with a pain clinic based in Somersworth, New Hampshire. The P.A. was authorized under the laws of the State of New Hampshire to prescribe controlled substances such as Subsys.

15. During the first year that Subsys was on the market, the P.A. did not write Subsys prescriptions. In or about April 2013, a sales representative working on behalf of Defendants catered a lunch at the P.A.'s pain clinic. In or about June 2013, the P.A. wrote his first prescription for Subsys. The sales representative encouraged the P.A. to submit his resume to Defendants for consideration in the Speaker Program, which the P.A. did on the same day. The P.A. had not published any articles on pain management, nor had he had previous speaking roles related to any rapid onset opioids.

16. Approximately one month later, Defendants approved the practitioner as a speaker upon the recommendation of Defendants' then Vice-President of Sales.

17. The P.A. was aware that the sham speaker events were a kickback – a way to get paid for writing Subsys prescriptions. The P.A. and Defendants' sales representative ("Sales Representative #1") frequently discussed new patients for whom the P.A. could prescribe Subsys.

18. Sales Representative #1 arranged a Speaker Program that took place on or about November 14, 2013 at a restaurant in Portsmouth, New Hampshire in which the P.A. was the purported Subsys speaker. No other medical practitioners who could prescribe Subsys were present at the dinner, and the P.A. did not make a presentation about the drug. At the direction of Sales Representative #1, the P.A. and others forged the signature of physician's assistant S.T. on a sign-in sheet to make it appear S.T. was present at the dinner when, in fact, he was not.

19. On or about November 21, 2013, Defendants issued check number 801 to the P.A. in the amount of \$1,200 as payment in part for the November 14, 2013 Speaker Program.

20. Sales Representative #1 arranged a Speaker Program that took place on or about November 19, 2013 at a second restaurant in Portsmouth, New Hampshire in which the P.A. was the purported Subsys speaker. No other practitioners who could prescribe Subsys were present at

the dinner, and the P.A. did not make a presentation about the drug. Defendants' employees directed the P.A. to forge the signature of nurse practitioner K.T. on a sign-in sheet to make it appear K.T. was present at the dinner when, in fact, she was not.

21. On or about November 25, 2013, Defendants issued check number 935 to the P.A. in the amount of \$2,000 as payment in part for the November 19, 2013 Speaker Program.

22. Sales Representative #1 arranged a Speaker Program that took place on or about January 13, 2014 at a restaurant in Boston, Massachusetts at which the P.A. purportedly spoke about Subsys. No other medical practitioners who could prescribe Subsys were present at the dinner, and the P.A. did not make a presentation about the drug. At the direction of the sales representative, the P.A. forged the signatures of physician's assistant L.C. and medical assistant P.M. on a sign-in sheet to make it appear they were present at the dinner when, in fact, they were not.

23. Defendants issued check number 1550 to the P.A. in the amount of \$1,000 as payment in part for the January 13, 2014 Speaker Program.

24. Defendants arranged a Speaker Program that took place on or about March 11, 2014 at a second restaurant in Boston, Massachusetts where the P.A. was the purported speaker. No other medical professionals who could prescribe Subsys were present, and the P.A. did not make a presentation about the drug. The only attendees at the dinner were the P.A., a relative of the P.A., and Sales Representative #1. Sales Representative #1 forged the signature of physician's assistant L.C. on a sign-in sheet to make it appear she was present at the dinner when, in fact, she was not.

25. On or about March 20, 2014, Defendants issued check number 2408 to the P.A. in the amount of \$2,000 as payment in part for the March 11, 2014 Speaker Program.

26. Defendants arranged a Speaker Program that took place on or about July 28, 2014 at a third restaurant in Portsmouth, New Hampshire where the P.A. was the purported speaker. No other medical practitioners who could prescribe Subsys were present at the dinner, and the P.A. did not make a presentation about the drug. At the direction of an employee of Defendants, the P.A. forged the signatures of S.M. and T.C., two medical assistants, on a sign-in-sheet to make it appear they were present at the dinner when, in fact, they were not.

27. On or about August 4, 2014, Defendants' agent, on behalf of Defendants, issued check number 25662 to the P.A. in the amount of \$1,000 as payment in part for the July 28, 2014 Speaker Program.

28. From in or about August 2013 to November 2014, insurers authorized payment for approximately 672 Subsys prescriptions written by the P.A, many of which were medically unnecessary.

29. Between August 2013 and October 2014, Defendants' employees invited the P.A. to approximately 44 Speaker Program events at various restaurants and other locations. For each of the events, the P.A. was paid a fee of between \$500 and \$2,000. Defendants paid the P.A. approximately \$44,000 for purportedly speaking about Subsys when, in fact, he had not. Instead, they were kickbacks paid by Defendants to the P.A. for the purpose of inducing the P.A. to write Subsys prescriptions, many of which were medically unnecessary.

30. Had the insurers known that Defendants paid bribes to the P.A. that caused the P.A. to write medically unnecessary Subsys prescriptions, the insurers would not have authorized payment for those prescriptions.

31. Defendants caused bribes in the form of the above-described honoraria checks to be sent and delivered in interstate commerce by the United States Postal Service and by private

and commercial interstate carriers. Each honoraria check was sent to the practitioner by the United States Postal Service or by private and commercial interstate carrier on behalf of Defendants.

COUNTS ONE-FIVE
18 U.S.C. § 1341 (Mail Fraud)

The United States Attorney charges:

32. The United States Attorney re-alleges and incorporates by reference paragraphs 1-31 of this Information.

33. On or about each of the dates set forth below, in the District of Massachusetts and elsewhere, Defendants,

INSYS THERAPEUTICS, INC., and
INSYS PHARMA, INC.,

having devised and intending to devise a scheme and artifice to defraud, and for obtaining money and property by means of materially false and fraudulent pretenses, representations and promises, did place and caused to be placed in any post office and authorized depository for mail to be sent and delivered by the United States Postal Service and deposited and caused to be deposited a matter and thing to be sent and delivered by a private and commercial interstate carrier as set forth below:

<u>Count</u>	<u>Check Issue Date</u>	<u>Description of Mailing</u>
1	11/21/2013	Check No. 801 for \$1,200 issued by Defendants
2	11/25/2013	Check No. 935 for \$2,000 issued by Defendants
3	01/23/2014	Check No. 1550 for \$1,000 issued by Defendants
4	03/20/2014	Check No. 2408 for \$2,000 issued by Defendants
5	08/04/2014	Check No. 25662 for \$1,000 issued by Defendants

All in violation of Title 18, United States Code, Section 1341.

FORFEITURE ALLEGATION
(18 U.S.C. § 981(a)(1)(C) and 28 U.S.C. § 2461(c))

35. Upon conviction of one or more of the offenses set forth in Counts 1 through 5 of this Information, Defendants,

INSYS THERAPEUTICS, INC., and
INSYS PHARMA, INC.,

shall forfeit to the United States, pursuant to Title 18, United States Code, Section 981(a)(1)(C) and Title 28, United States Code, Section 2461(c), any property, real or personal, which constitutes or is derived from proceeds traceable to the offense. The property to be forfeited includes, but is not limited to, the following: \$28,000,000 to be entered in the form of a forfeiture money judgment.


36. If any of the property described in paragraph 35, above, as being forfeitable pursuant to Title 18, United States Code, Section 981(a)(1)(C) and Title 28, United States Code, Section 2461(c), as a result of any act or omission of Defendants –

- a. cannot be located upon the exercise of due diligence;
- b. has been transferred or sold to, or deposited with, a third party;
- c. has been placed beyond the jurisdiction of the Court;
- d. has been substantially diminished in value; or
- e. has been commingled with other property which cannot be divided without difficulty;

it is the intention of the United States, pursuant to Title 28, United States Code, Section 2461(c), incorporating Title 21, United States Code, Section 853(p), to seek forfeiture of any other property of Defendants up to the value of the property described above.

All pursuant to Title 18, United States Code, Section 981(a)(1)(C) and Title 28, United States Code, Section 2461(c).

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