

UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

UNITED STATES OF AMERICA

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CRIMINAL NO. 3:17CR 147 (MPS)

v.

VIOLATIONS:
18 U.S.C. § 371
(Conspiracy)

NATALIE LEVINE

INFORMATION

The United States Attorney charges:

COUNT ONE

(Conspiracy to Violate the Anti-Kickback Law)

General Allegations

1. At all times relevant to the Information, the defendant, NATALIE LEVINE (“LEVINE”), was employed by Insys Therapeutics (“Insys”), which was headquartered in Chandler, Arizona. The defendant was employed by Insys from approximately March 2013 until October 2014.

2. Every manufacturer of a new drug was required to obtain approval through a new drug application (“NDA”) from the United States Food and Drug Administration (“FDA”) before introducing its new drug into interstate commerce, unless subject to an exemption not applicable here. To obtain approval of an NDA, the manufacturer had to demonstrate to the FDA that the new drug was safe and effective for its intended uses. Labeling on the drug also had to be truthful, accurate and non-misleading.

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U.S. DISTRICT COURT

3. On or about March 4, 2011, Insys submitted an NDA to the FDA seeking approval of its fentanyl spray, known as Subsys. The FDA approved Subsys in or about January 2012 for the management of breakthrough pain in patients with cancer, 18 years of age or older, who were already receiving and who were already tolerant to opioid therapy for their underlying persistent cancer pain. The label for Subsys warned that the drug posed risks of misuse, abuse, addiction, overdose, and serious complications due to medication errors. Explicit warnings on the Subsys label included that, as an opioid agonist, the drug could be abused in a manner similar to other opioid agonists, legal or illicit.

4. Insys hired LEVINE as a sales representative in March 2013 and at all times relevant to this Information, LEVINE was responsible for covering the territories that included Connecticut, New Hampshire and Rhode Island. As part of her duties as an Insys sales representative, LEVINE called on licensed health care providers, including physicians, advanced practice registered nurses (“APRNs”), and physician assistants in order to get them to prescribe the drug Subsys.

5. Licensed medical practitioners who were registered with the Drug Enforcement Administration (“DEA”) and able to prescribe opioids in the usual course of professional practice for a legitimate medical purpose, owed a fiduciary duty to their patients to refrain from accepting or agreeing to accept bribes and kickbacks in exchange for prescribing any drug.

6. At all times relevant to the information, Practitioner # 1, whose identity is known to the United States, was a licensed medical practitioner who was registered by the DEA to prescribe opioids in the usual course of professional practice for a legitimate medical purpose. Practitioner # 1 practiced as an APRN for a pain management practice with offices in Derby and

Meriden, Connecticut. Practitioner # 1 was associated with Insys and conspired with LEVINE and other persons and entities known and unknown to the United States to engage in various criminal activities as described below.

7. At all times relevant to the information, Practitioner # 2, whose identity is known to the United States, was a licensed medical practitioner who was registered by the DEA to prescribe opioids in the usual course of professional practice for a legitimate medical purpose. Practitioner # 2 practiced as a Physician's Assistant (P.A.) for a pain management practice with an office in Somersworth, New Hampshire. Practitioner # 2 was associated with Insys and conspired with LEVINE and other persons and entities known and unknown to the United States to engage in various criminal activities as described below.

8. At all times relevant to the information, Practitioner # 3, whose identity is known to the United States, was a licensed medical practitioner who was registered by the DEA to prescribe opioids in the usual course of professional practice for a legitimate medical purpose. Practitioner # 3 practiced as a physician for a physical medicine and rehabilitation practice with an office in Providence, Rhode Island. Practitioner # 3 was associated with Insys and conspired with LEVINE and other persons and entities known and unknown to the United States to engage in various criminal activities as described below.

9. The Medicare Program was established in 1965 pursuant to amendments to the Social Security Act. The Medicare Program is a health care benefit program that provides basic health insurance coverage to certain disabled persons as well as to individuals 65 years or older. Eligible persons can elect to participate in the program by completing an application and either agreeing to pay a premium for Medicare benefits, or arranging for a third party to pay such

premiums. Persons enrolled in the Medicare programs are hereinafter referred to as “beneficiaries.”

10. The Medicare program also includes a prescription drug program known as “Part D,” which is funded by insurance premiums paid by enrolled Medicare beneficiaries and contributions from the United States Treasury. The Part D program is administered by many “Plan Sponsors,” each of which dictates the specific drugs it will cover and how much it will pay for those medications. The Centers for Medicare and Medicaid Services (“CMS”), through the United States Treasury, reimburses the Part D Plan Sponsors for the covered drugs. Medicare is a “federal health care program” under Title 42, United States Code, Section 1320a-7b(f) and a “health care benefit program” under Title 18, United States Code, Section 1347.

11. Each of these Part D Plan Sponsors will approve payment for the Subsys that is prescribed to a Medicare patient only if certain criteria are met, including (i) that the patient has a diagnosis of cancer, (ii) that the use of Subsys is for breakthrough cancer pain, and (iii) that other strong-acting narcotic pain relievers have been tried and been ineffective, not tolerated or contraindicated.

12. In or about March 2012 through in or about August 2012, Insys created, operated, and funded a marketing program (the “Speaker Program”) purportedly intended to increase brand awareness using peer-to-peer educational lunches and dinners (the “events”). Insys policy required sales representatives, also called Specialty Sales Professionals, to recruit licensed practitioners to lecture other licensed practitioners regarding the use of Subsys for the treatment of breakthrough cancer pain in opioid tolerant patients. Insys policy also required speakers to be chosen and approved based upon various criteria, including skill in the use of opioids as treatment,

experience with Subsys, geography, prominence, and experience as speakers. In exchange for practitioners speaking to other prescribers about Subsys, Insys agreed to pay each speaker a fee, also referred to as an “honorarium,” for each event. Speakers were required to sign written agreements with Insys that, among other things, required them to attend organized training sessions. Insys did not adhere to this policy. As described below, LEVINE and Insys used the Speaker Program to reward licensed practitioners, including Practitioners # 1, # 2 and # 3 for prescribing Subsys.

The Conspiracy

13. From in or about March 2013 until in or around October 2014, within the District of Connecticut and elsewhere, the defendant, NATALIE LEVINE, knowingly conspired with others known and unknown to commit an offense against the United States, that is, to knowingly and willfully offer and pay remuneration, directly and indirectly, overtly and covertly, in cash and in kind, that is, kickbacks and bribes, from Insys, to induce physicians and other health care professionals to purchase, order, and arrange for goods, services and items, that is, prescriptions for Subsys, for which payment may be made in whole and in part by a federal health care program, in violation of Title 42, United States Code, Section 1320a-7b(b)(2).

Object of the Conspiracy

14. The object of the conspiracy was for LEVINE to cause the unlawful payment of kickbacks to Practitioners #1, # 2 and # 3, and the receipt of kickbacks by Practitioners #1, # 2 and # 3, as an inducement and in exchange for prescribing Subsys to their patients.

Manner and Means of the Conspiracy

The manner and means by which defendant NATALIE LEVINE sought to accomplish the object of the conspiracy included the following:

15. It was part of the conspiracy that, in order to induce pain specialists and other providers to prescribe Subsys to patients who were not suffering from breakthrough cancer pain, Insys created the Speaker Program. Insys officials publicly claimed that the purpose of the Speaker Program was to educate other providers concerning the benefits of Subsys. In reality, the primary purpose of the Speaker Program was to provide a financial reward to providers, like Practitioners # 1, # 2 and # 3, who were prescribing large amounts of Subsys and to incentivize those providers to continue to prescribe Subsys in the future.

16. It was part of the conspiracy that LEVINE would and did use the Insys Speaker Program to induce Practitioners # 1, # 2 and # 3 to write more prescriptions for Subsys for current patients and to increase the titration of such prescriptions.

17. It was part of the conspiracy that LEVINE would and did use the Insys Speaker Program as a way to get Practitioners # 1, # 2 and # 3 to write new prescriptions for Subsys for new patients.

18. It was part of the conspiracy that LEVINE knew that the Insys Speaker Program was a sham program disguised as a way to induce Practitioners # 1, # 2 and # 3 and other licensed practitioners to write prescriptions for Subsys.

19. It was part of the conspiracy that many of the sham Speaker Program events for Practitioner # 1, # 2 and # 3 had no attendees, other than Practitioners # 1, # 2 and # 3 and the Insys sales representative, despite Insys falsely stating that other people were present.

20. It was part of the conspiracy that for numerous of the sham Speaker Program events conducted by Practitioners # 1, # 2 and # 3 at LEVINE's direction, the attendees were friends and family members of Practitioner # 1, # 2 and # 3. In addition, the attendees' signatures at such sham Speaker Program events were regularly forged to falsely make it appear that medical professionals attended the programs. In addition, extra meals were often ordered to make it appear on the restaurant receipt that other persons attended the event.

21. It was part of the conspiracy that LEVINE caused speaker fees to be paid to Practitioners # 1, # 2 and # 3 only after they wrote more prescriptions for Subsys, including prescriptions that were paid for by federal programs.

Overt Acts

22. In furtherance of the conspiracy, and to accomplish its purposes and objects, the defendant, NATALIE LEVINE, together with others known and unknown to the United States, committed and caused others to commit at least one of the following overt acts, among others, in the District of Connecticut and elsewhere:

a. On or about June 4, 2014, LEVINE and Practitioner # 1 attended a Speaker Program at a restaurant in West Hartford, Connecticut, where Practitioner # 1 allegedly gave a presentation about Subsys. However, in truth and in fact, Practitioner # 1 did not actually give a presentation at all and no other medical professionals capable of prescribing Subsys were present. Insys paid Practitioner # 1 a speaking fee for allegedly conducting this program.

b. On or about November 14, 2013, LEVINE and Practitioner # 2 attended a Speaker Program at a restaurant in Portsmouth, New Hampshire, where Practitioner # 2

purportedly spoke about Subsys. In truth and in fact, no such presentation actually occurred and no other medical professionals were present. Practitioner # 2 and others known to the United States forged another P.A.'s name on the sign-in sheet to make it appear that this P.A. was present when he was not. Insys paid Practitioner # 2 a speaking fee for allegedly conducting this program.

c. On or about October 3, 2013, LEVINE and Practitioner # 3 attended a Speaker Program at a restaurant in East Greenwich, Rhode Island, where Practitioner # 3 supposedly spoke about Subsys. In truth and in fact, no other medical personnel were present for the program and Practitioner # 3 did not give any kind of presentation about Subsys at all. Practitioner # 3 forged the signature of M.M., an individual whose identity is known to the United States, on the sign-in sheet to make it appear that another person attended then dinner when they did not. Insys paid Practitioner # 3 a speaking fee for allegedly conducting this program.

d. Between in or about March 2013 and October 2014, many of the Speaker Program events attended by Practitioners # 1, # 2 and # 3 were sham events that were mere social gatherings also attended by the friends and office staff of Practitioners # 1, # 2 and # 3, many of which were facilitated by LEVINE.

e. Between in or about March 2013 and October 2014, Medicare Part D plans authorized payment for hundreds of Subsys prescriptions written by Practitioners # 1, # 2 and # 3 due to their participation in the sham Speaker Program.

f. Between in or about March 2013 and October 2014, LEVINE and co-conspirators known and unknown to the United States, sent and caused to be sent to

Practitioners # 1, # 2 and # 3 thousands of dollars in bribes and kickbacks resulting from these practitioners' participation in the Speaker Program.

All in violation of Title 18, United States Code, Section 371.

UNITED STATES OF AMERICA


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UNITED STATES ATTORNEY


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ASSISTANT UNITED STATES ATTORNEY