

disabled. Medicare was administered by the Centers for Medicare and Medicaid Services (“CMS”), a federal agency within the U.S. Department of Health and Human Services (“HHS”). Individuals who received Medicare benefits were referred to as Medicare “beneficiaries.”

d. Medicare was a “Federal health care program” as defined in Title 42, United States Code, Section 1320a-7b(f) and a “health care benefit program” as defined in Title 18, United States Code, Section 24(b).

e. Medicare was divided into four parts: hospital insurance (Part A), medical insurance (Part B), Medicare Advantage (Part C), and prescription drug benefits (Part D).

f. CMS contracted with drug plan sponsors to administer the Medicare Part D program and provide prescription drug benefits to Medicare beneficiaries. The plan sponsors decided which drugs they covered and how much they would pay for those medications. CMS, through the federal treasury, reimbursed the Part D plan sponsors for the covered drugs.

g. In order for Medicare to pay for medications, they had to be prescribed by a physician. Physicians could enroll as Medicare providers. To enroll in Medicare, providers had to agree to abide by all provisions of the Social Security Act, the regulations promulgated under the Act, and applicable policies, procedures, rules, and regulations issued by CMS and its authorized agents and contractors.

h. Medicare regulations required health care providers enrolled with Medicare to maintain complete and accurate patient medical records

reflecting the medical assessment and diagnoses of their patients, as well as records documenting actual treatment of the patients to whom services were provided.

i. Medicare paid for claims only if the services were medically reasonable and necessary. Medicare would not pay for medications if the prescriptions were written in exchange for a bribe or kickback.

Insys and Subsys

j. Insys Therapeutics, Inc. (“Insys”) was a company incorporated in Delaware and headquartered in Arizona.

k. In or around January 2012, the U.S. Food and Drug Administration (“FDA”) approved Insys’s application to sell and market a drug (hereinafter, “Subsys”) to patients suffering from breakthrough cancer pain. Breakthrough cancer pain is a sudden, short-term increase in pain that may occur in patients who have chronic pain from cancer.

l. Subsys was a potent opioid designed to rapidly enter a patient’s bloodstream upon being sprayed under the tongue. Subsys contained fentanyl, which is a synthetic opioid pain reliever that was classified as a Schedule II controlled substance under the Controlled Substances Act, meaning that it has a high potential for abuse. Fentanyl is approximately 50 to 100 times more potent than morphine.

m. The FDA approved Subsys solely for the “management of breakthrough pain in adult cancer patients who are already receiving and who

are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.”

n. Subsys was in a category of drugs known as Transmucosal Immediate Release Fentanyl (“TIRF”). Because of the risk of misuse, abuse, addiction, and overdose associated with TIRF drugs, including Subsys, only practitioners enrolled in the FDA-mandated TIRF Risk Evaluation and Mitigation Strategy program (the “TIRF REMS Program”) were allowed to prescribe TIRF drugs. Practitioners were required to complete training and testing to enroll in the TIRF REMS Program.

o. Insys manufactured and sold Subsys in dosage strengths of 100, 200, 400, 600, 800, 1,200, and 1,600 micrograms.

p. Subsys was expensive and profitable for Insys. The approximate average retail cost of a one-month supply of four daily doses of Subsys at 100 micrograms was \$3,000. Higher dosage strengths were more expensive. The approximate average retail cost of a one-month supply of four daily doses of Subsys at 800 micrograms was \$15,000.

The Conspiracy

2. From in or around 2012 through in or around 2016, in the District of New Jersey and elsewhere, defendant

KENNETH SUN

did willfully and knowingly, combine, conspire, confederate, and agree with others known and unknown to the Grand Jury, to commit certain offenses against the United States, namely:

a. to defraud the United States by cheating the United States government or any of its agencies out of money or property, or by impairing, impeding, obstructing, and defeating through deceitful and dishonest means, the lawful government functions of HHS in its administration and oversight of Medicare, and the lawful government functions of the FDA in its administration and oversight of the TIRF REMS Program;

b. to violate Title 42, United States Code, Section 1320a-7b(b)(1)(B), by knowingly and willfully soliciting and receiving remuneration, specifically, kickbacks and bribes, directly and indirectly, overtly and covertly, in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program; and

~~c. to violate Title 42, United States Code, Section 1320a-7b(b)(2)(B), by knowingly and willfully offering and paying remuneration, specifically, kickbacks and bribes, directly and indirectly, overtly and covertly, in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.~~

Object of the Conspiracy

3. It was the object of the conspiracy for defendant KENNETH SUN and his co-conspirators to unlawfully enrich themselves by, among other things: (a) offering, paying, soliciting, and receiving kickbacks and bribes in exchange for

prescribing Subsys; (b) submitting and causing the submission of false and fraudulent claims to Medicare and private insurance companies for prescription drugs that were medically unnecessary and ineligible for reimbursement; (c) concealing the submission of false and fraudulent claims to Medicare and private insurance companies; (d) concealing the receipt and transfer of proceeds of the fraud; and (e) diverting proceeds of the fraud for the personal use and benefit of the defendant and his co-conspirators.

Manner and Means of the Conspiracy

4. The manner and means by which defendant KENNETH SUN and his co-conspirators sought to accomplish the purpose of the conspiracy included, among others, the following:

a. KENNETH SUN applied for and maintained various Medicare, U.S. Drug Enforcement Administration, TIRF REMS, and other provider numbers associated with KENNETH SUN personally, and Progressive Pain Solutions, LLC.

b. In or around April 2010 and September 2015, KENNETH SUN falsely certified to Medicare that he would comply with all Medicare rules and regulations, including that he would not present or cause to be presented a false or fraudulent claim for payment by Medicare and that he would refrain from violating the federal anti-kickback statute.

c. In or around September 2013 and June 2015, KENNETH SUN falsely certified to the FDA that he would assess patients to whom he prescribed TIRF drugs, including Subsys, “for appropriateness of the dose” of the TIRF drug,

and “for signs of misuse and abuse” at “all follow-up visits.” KENNETH SUN also certified that he understood that TIRF drugs, including Subsys, were “indicated only for the management of breakthrough pain in patients with cancer, who are already receiving, and who are tolerant to, around-the-clock opioid therapy for their underlying persistent pain,” and that “an increased risk of misuse, abuse, or overdose” of TIRF drugs “should be considered” before prescribing.

d. Due to the limited number of patients suffering from breakthrough cancer pain, Insys, by and through its officers, managers, and employees, designed and implemented an illegal kickback and bribery scheme to induce KENNETH SUN and others to prescribe Subsys for pain caused by conditions other than breakthrough cancer pain.

e. In order to conceal and disguise that kickbacks and bribes were being paid to induce KENNETH SUN and other doctors to prescribe Subsys, Insys falsely designated the payments to KENNETH SUN and other doctors as “honoraria” for purportedly providing educational presentations regarding Subsys (“Speaker Programs”).

f. Insys selected KENNETH SUN and other doctors to deliver Speaker Programs based on their prescribing practices, and not on their qualifications, abilities, or speaking performance.

g. In or around September 2012 and September 2013, KENNETH SUN entered into written agreements with Insys where he agreed to be paid to provide Speaker Programs and falsely represented that the Speaker Programs would be “of a professional quality conforming to generally accepted

industry standards and practices.” KENNETH SUN further falsely represented that the Speaker Program honoraria he received from Insys would be consistent with “fair market value” and would not affect his decisions about prescribing Subsys.

h. KENNETH SUN solicited and received more than \$140,000 in illegal kickbacks and bribes from Insys for purportedly providing Speaker Programs.

i. In exchange for the kickbacks and bribes, KENNETH SUN prescribed over 28 million micrograms of Subsys to patients, including patients for whom Subsys was medically unnecessary, not eligible for insurance reimbursement, and/or not desired.

j. KENNETH SUN, employees of Insys, and others concealed and disguised that KENNETH SUN’s Speaker Programs for Insys were a sham: they lacked the appropriate audience of licensed practitioners seeking educational information regarding Subsys; there was no presentation about Subsys whatsoever; the same attendees attended over and over again; and/or KENNETH SUN did not attend the Speaker Program at all.

k. KENNETH SUN, employees of Insys, and others fabricated, falsified, altered, and caused the fabrication, falsification, and alteration of sign-in sheets and other documents to falsely make it appear that KENNETH SUN’s Speaker Programs were legitimate.

1. KENNETH SUN caused Medicare to pay in excess of \$847,000 for Subsys prescriptions that were procured by the payment of kickbacks and bribes, medically unnecessary, and/or not eligible for Medicare reimbursement.

Overt Acts in Furtherance of the Conspiracy

5. In furtherance of the conspiracy, and to accomplish its purposes and objects, defendant KENNETH SUN and his co-conspirators committed or caused the commission of the following overt acts, among others, in the District of New Jersey and elsewhere:

6. On or about July 11, 2014, KENNETH SUN and his co-conspirators at Insys purported to provide a Speaker Program at Clinic 1 in Easton, Pennsylvania. No presentation actually took place and no licensed practitioners seeking educational information regarding Subsys actually attended.

7. On or about July 15, 2014, KENNETH SUN received check number 25329 issued by Insys's third-party payer, in the amount of \$2,200, as payment in part for the purported July 11, 2014 Speaker Program.

8. On or about January 16, 2015, KENNETH SUN and his co-conspirators at Insys purported to provide a Speaker Program at Clinic 1 in Bethlehem, Pennsylvania. No presentation actually took place and no licensed practitioners seeking educational information regarding Subsys actually attended.

9. On or about January 19, 2015, KENNETH SUN received check number 28804 issued by Insys's third-party payer, in the amount of \$2,200, as payment in part for the purported January 16, 2015 Speaker Program.

10. On or about January 8, 2015, KENNETH SUN and his co-conspirators at Insys purported to provide a Speaker Program at Blue Grillhouse restaurant in Bethlehem, Pennsylvania. Nurse Practitioner 1, a friend of KENNETH SUN, was the only licensed practitioner who attended. Nurse Practitioner 1 had already attended at least approximately seven prior Speaker Programs on Subsys with KENNETH SUN.

11. On or about January 12, 2015, KENNETH SUN received check number 28656 issued by Insys's third-party payer, in the amount of \$2,200, as payment in part for the purported January 8, 2015 Speaker Program.

12. On or about May 5, 2015, KENNETH SUN and his co-conspirators at Insys purported to provide a Speaker Program at Clinic 2 in Phillipsburg, New Jersey. Nurse Practitioner 1, a friend of KENNETH SUN, was the only licensed practitioner who attended. Nurse Practitioner 1 had already attended at least approximately ten prior Speaker Programs on Subsys with KENNETH SUN.

13. On or about May 11, 2015, KENNETH SUN received check number 31122 issued by Insys's third-party payer, in the amount of \$2,200, as payment in part for the purported May 5, 2015 Speaker Program.

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

COUNTS TWO THROUGH FIVE
Soliciting and Receiving Health Care Kickbacks

14. Paragraphs 1 and 3 through 13 of this Indictment are re-alleged and incorporated by reference as though fully set forth herein.

15. On or about the dates set forth below, in the District of New Jersey and elsewhere, the defendant

KENNETH SUN

did knowingly and willfully solicit and receive remuneration (including kickbacks and bribes), directly and indirectly, overtly and covertly, in cash and in kind, in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part by Medicare, as set forth below:

	Approximate Date of Payment to	Check Number	Payment Amount	Approximate Date and Place of Purported Speaker Program
Count	KENNETH SUN			
2	7/15/14	25329	\$2,200	7/11/14 at Clinic 1
3	1/12/15	28656	\$2,200	1/8/15 at Blue Grillhouse Restaurant
4	1/19/15	28804	\$2,200	1/16/15 at Clinic 1
5	5/11/15	31122	\$2,200	5/5/15 at Clinic 2

All in violation of Title 42, United States Code, Section 1320a-7b(b)(1)(B) and Title 18, United States Code, Section 2.

FORFEITURE ALLEGATIONS

18 U.S.C. § 981(a)(1)(C) and 28 U.S.C. § 2461; 18 U.S.C. § 982(a)(7)

16. The allegations contained in Counts 1-5 of this Indictment are re-alleged and incorporated by reference as though fully set forth herein for the purpose of alleging forfeiture against defendant

KENNETH SUN

pursuant to Title 18, United States Code, Sections 981 and 982, and Title 28, United States Code, Section 2461.

17. Pursuant to Title 18, United States Code, Section 981(a)(1)(C), together with Title 28, United States Code, Section 2461, upon being convicted of the crime charged in Count 1 of this Indictment, the convicted defendant shall forfeit to the United States any property, real or personal, which constitutes or is derived from proceeds traceable to the commission of the offense.

18. Pursuant to Title 18, United States Code, Section 982(a)(7), upon being convicted of the crimes charged in Counts 1 through 5 of this Indictment, the convicted defendant shall forfeit to the United States any property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offense.

Substitute Assets Provision

19. If any of the above-described forfeitable property, as a result of any act or omission of the defendant:

- a. cannot be located upon the exercise of due diligence;
- b. has been transferred or sold to, or deposited with, a third person;

- 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 subdivided without difficulty;

it is the intent of the United States, pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 18, United States Code, Section 982(b), to seek forfeiture of any other property of defendant KENNETH SUN up to the value of the forfeitable property described above.

A True Bill,

Foreperson



CRAIG CARPENITO
United States Attorney

JOSEPH BEEMSTERBOER
Chief, Health Care Fraud Unit
Criminal Division, Fraud Section

ALLAN MEDINA
Assistant Chief
Criminal Division, Fraud Section



REBECCA YUAN
Trial Attorney
Criminal Division, Fraud Section

CASE NUMBER: _____

19-cr-438-AET

**United States District Court
District of New Jersey**

UNITED STATES OF AMERICA

v.

KENNETH SUN

INDICTMENT FOR

18 U.S.C. §§ 371, 2; 42 U.S.C. § 1320a-7b(b)(1)(B)

A True Bill

Foreperson

CRAIG CARPENTO
UNITED STATES ATTORNEY
FOR THE DISTRICT OF NEW JERSEY

REBECCA YUAN
TRIAL ATTORNEY
NEWARK, NEW JERSEY
(202) 262-3520