

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Criminal Case No. 20-cr-00291-DDD

UNITED STATES OF AMERICA,

Plaintiff,

v.

1. JEFFREY KESTEN,

Defendant.

INDICTMENT

The Grand Jury charges:

COUNT 1
Conspiracy to Offer/Pay and Solicit/Receive Kickbacks
18 U.S.C. § 371

At all times relevant to this Indictment, unless otherwise set forth herein:

The Defendant and His Medical Practice

1. Jeffrey Kesten (“KESTEN”) was a physician licensed to practice medicine in the State of Colorado. KESTEN’s specialty was pain medicine.

2. KESTEN held a registration from the Drug Enforcement Administration (“DEA”) to prescribe controlled substances.

3. KESTEN owned and operated Red Rocks Center for Rehabilitation, P.C. (“Red Rocks”), a medical practice located in Golden, Colorado, until in or around May 2014, when he sold the practice. Thereafter, KESTEN continued to practice medicine in Colorado at medical practices owned by others.

The Pharmaceutical Company and Fentanyl Spray

4. The Pharmaceutical Company manufactured, marketed, and sold a sublingual fentanyl spray (the “Fentanyl Spray”). The Fentanyl Spray was a Schedule II controlled substance approved by the Food and Drug Administration for use in adult patients suffering from breakthrough cancer pain.

5. Depending on the dosage and number of units prescribed, a prescription for the Fentanyl Spray usually cost thousands of dollars each month. The drug came in dosage strengths ranging from 100 micrograms to 1600 micrograms, and the higher the dose, the higher the cost. The Fentanyl Spray label instructed that the “[t]he initial dose of [the Fentanyl Spray] to treat episodes of breakthrough cancer pain is always 100 [micrograms].”

6. Federal health care programs, including Medicare and the Colorado Medicaid Program, paid for the drug under certain circumstances.

7. The Pharmaceutical Company hired sales representatives to work with physicians known to write a high volume of controlled substances to treat pain. Sales representative and, later, manager C.G., also known as C.S., was assigned to work with KESTEN.

The Conspiracy

8. From in or about November 2012 up to in or about November 2015, in the State and District of Colorado and elsewhere, defendant JEFFREY KESTEN did knowingly and willfully conspire and agree with employees of the Pharmaceutical Company, including C.G., those persons known and unknown to the grand jury, to

commit an offense against the United States, to wit, knowingly and willfully to offer, pay, solicit, or receive any remuneration, directly and indirectly, overtly and covertly, in cash or in kind, in return for purchasing and ordering, and arranging for the purchase and order of goods, services, and items, that is, prescriptions for the Fentanyl Spray, for which payment may be made in whole or in part by a Federal health care program, in violation of 42 U.S.C. § 1320a-7b(b).

The Object of the Conspiracy

9. The object of the conspiracy was the unlawful offer of and payment to KESTEN of kickbacks and bribes by the Pharmaceutical Company, and the unlawful solicitation of and receipt of, kickbacks and bribes by KESTEN, as an inducement and in exchange for prescribing the Fentanyl Spray to his patients.

Manner and Means of the Conspiracy

10. The Pharmaceutical Company established a speaker's bureau, purportedly to contract with licensed medical practitioners to provide educational programs to other medical providers and prescribers. Instead, the Pharmaceutical Company used the speaker's bureau to offer and pay kickbacks and bribes to the speakers, including KESTEN, to induce them to write more and higher dose prescriptions for the Fentanyl Spray.

11. KESTEN became a speaker for the Pharmaceutical Company in or around 2012. The Pharmaceutical Company designated its speakers as local, regional or national, and compensated each level at a different rate. The Pharmaceutical Company paid KESTEN as a "national" speaker—the most highly compensated of the three

speaker levels—receiving payment between \$2,400 to \$4,700 per speaker program.

The Pharmaceutical Company paid KESTEN at the “national” rate regardless of where the speaker program was held, including when the program was in KESTEN's own clinic.

12. Between November 2012 and November 2015, the Pharmaceutical Company paid KESTEN for approximately 100 speaker programs. In 2013, KESTEN was paid to be the “speaker” for 17 programs at which the only attendees were his own staff and of which 16 took place at his own clinic. The same two Physician Assistants were the only medical providers in attendance at the majority of these programs.

13. As the number of speaker programs for which the Pharmaceutical Company paid KESTEN increased, so did the number of prescriptions he wrote for the Fentanyl Spray. The Pharmaceutical Company, through its employees, solicited KESTEN's commitment to a certain number of prescriptions or a certain revenue goal in exchange for allocating him speaker programs. When KESTEN wanted to be paid for more speaker programs, he would suggest that he may have to write prescriptions for competitor drugs or may not be able to commit to writing prescriptions for the Fentanyl Spray. KESTEN allowed sales representative C.G. access to his patient files and reviewed his patient schedule with her to facilitate identification of patients for whom he could prescribe the Fentanyl Spray.

14. In addition to payment for speaker programs, the Pharmaceutical Company also paid kickbacks and bribes for provider participation in “advisory boards” or to speak at training events for Pharmaceutical Company employees or other

prescribers. KESTEN was a participant in advisory boards and a speaker at events for the Pharmaceutical Company, and he solicited these opportunities from the Pharmaceutical Company.

15. The Pharmaceutical Company also paid for employees of the Pharmaceutical Company to work in the offices of prescribers to complete administrative tasks associated with the prescription of the Fentanyl Spray that would otherwise fall on employees of the practice. These Pharmaceutical Company employees were sometimes called “Area Business Liaisons” or “Business Relationship Managers.” The Pharmaceutical Company assigned an “Area Business Liaison” to work in KESTEN’s office and perform tasks that would otherwise have to be performed by KESTEN’s medical assistants and office staff, thereby providing a direct benefit to KESTEN.

16. From November 2012 through November 2015, the Pharmaceutical Company paid KESTEN over \$300,000 for speaker programs, advisory boards, other meetings, and costs for travel, food, and beverages.

17. KESTEN wrote prescriptions for the Fentanyl Spray totaling millions of dollars that were paid for by Medicare and the Colorado Medicaid Program, both Federal health care programs as defined under 42 U.S.C. § 1320a-7b(f).

Overt Acts

18. In furtherance of the conspiracy, and to accomplish its objectives and purposes, the following acts, among others, were committed by one or more of the co-conspirators in the District of Colorado and elsewhere:

a. On or about September 23, 2013, KESTEN deposited or caused the deposit of check number 012619 from the Pharmaceutical Company for \$4,800. The check was payment for programs documented as occurring on September 3, 2013, and September 4, 2013. The only provider attendee at the September 3, 2013, program was Physician Assistant 1, who worked for KESTEN, and it was the thirteenth program the Pharmaceutical Company paid KESTEN to deliver to Red Rocks staff and to Physician Assistant 1. The only provider attendee at the September 4, 2013, program was Physician Assistant 2, who worked for KESTEN, and it was the fourteenth program the Pharmaceutical Company paid KESTEN to deliver to Red Rocks staff and the fourth program Insys paid KESTEN to deliver to Physician Assistant 2.

b. On or about October 15, 2013, KESTEN signed a sign-in sheet for a “speaker presentation” at Red Rocks, the sixteenth presentation scheduled to be delivered to Red Rocks staff. There were no provider attendees at the presentation, and the Pharmaceutical Company sales representative completed paperwork for the speaker program even though the program did not occur. KESTEN received payment of \$2,400 from the Pharmaceutical Company for this program.

c. On or about October 21, 2013, KESTEN deposited or caused the deposit of check number 000263 from the Pharmaceutical Company for \$4,800. The payment, in part, was for a program documented as occurring on October 8, 2013 at Red Rocks. The October 8, 2013, speaker program was the fifteenth

presentation the Pharmaceutical Company paid KESTEN to deliver to Red Rocks staff.

d. On or about November 19, 2013, KESTEN signed a sign-in sheet for a “speaker presentation” at Red Rocks, the seventeenth program the Pharmaceutical Company paid KESTEN to deliver to Red Rocks staff. KESTEN received payment of \$2,400 from the Pharmaceutical Company for this program.

e. On or about November 25, 2013, C.G. texted her supervisor that KESTEN had 27 new patients coming the next day and that KESTEN was “marking candidates on his charts as we speak like he used to do for me :-”).

f. On or about December 13, 2013, C.G. texted her supervisor, “Just spent over an hour with Dr[.] Kesten. [A competitor drug] is still courting him big time. He was personally offended he wasn’t invited to last week’s advisory board and it appears [a prescription for a competitor drug] may have been written this week. He committed if we keep him busy speaking he won't need to do [a competitor drug] trial or speak for [a competitor drug company] anymore either. I've got to get him more programs.”

g. On or about December 18, 2013, C.G. forwarded her supervisor an e-mail from a sales representative assigned to work with KESTEN who reported that KESTEN was asking about the advisory board and that “[h]e was questioning his role / relationship with [the Pharmaceutical Company].”

h. On or about December 20, 2013, A.B. gave approval for KESTEN to be paid as a speaker at the company's National Sales Meeting to compensate him for not being a paid participant at the referenced advisory board.

i. On or about December 20, 2013, C.G. texted her supervisor, "I spent over an hour with Dr. Kesten this morning and all is good. Got to get more programs though...."

j. On or about January 29, 2014, C.G. texted her supervisor regarding obtaining more speaker programs for KESTEN after he had asked two days in a row why he did not have more programs. C.G. texted, "Any word on the Kesten programs? He asked [Pharmaceutical Company employees] AGAIN this morning. He told [one employee] [that a competitor drug company] is offering him a lot and he doesn't want to jump ship but feels like he is fulfilling his end of the bargain but we aren't fulfilling ours. He told her he is going to start seeing new patients again and that could really be big for us, implying we had better step it up."

k. On or about January 31, 2014, C.G. informed KESTEN that the Pharmaceutical Company was committing to schedule him fifty speaker programs in 2014.

l. After talking to KESTEN on or about January 31, 2014, regarding the fifty speaker programs, C.G. texted her supervisor, "Kesten is pumped!! Just spent an hour and a half with him. [A Pharmaceutical Company employee] is in there right now scheduling programs and he said with the changes he is making in his practice in feb he will be able to double or triple the business!!"

m. On or about March 21, 2014, KESTEN signed a contract with the Pharmaceutical Company to receive \$3,000 for each speaker program plus \$1,500 for each additional speaker program given the same day and \$4,700 for each travel speaker program plus \$2,350 for each additional travel speaker program given the same day.

n. On or about September 25, 2014, KESTEN signed a sign-in sheet for a speaker program dinner meeting given the same day in Boise, Idaho, to employees of a medical practice in Boise. The Pharmaceutical Company paid KESTEN \$4,700 for this presentation.

o. On or about September 26, 2014, KESTEN signed a sign-in sheet for a speaker program given as a breakfast in Boise, Idaho, to the same prescribing practitioners who attended the dinner program the day before. The Pharmaceutical Company paid KESTEN \$4,700 for this presentation.

p. On or about November 30, 2015, KESTEN signed a sign-in sheet as speaker for a presentation at a medical practice in Colorado for which the Pharmaceutical Company paid him \$3,000.

The foregoing is in violation of 18 U.S.C. § 371.

COUNTS 2 – 64
42 U.S.C. § 1320a-7b(b)(1)(B)

19. Paragraphs 1 through 7 are re-alleged and incorporated herein.

20. On or about the dates identified below, in the State and District of Colorado, defendant JEFFREY KESTEN did knowingly and willfully solicit and receive remuneration, that is, kickbacks and bribes, directly and indirectly, overtly and covertly,

in cash and in kind, as identified below, in return for purchasing and ordering, and arranging for the purchase and order of goods, services, and items, that is, prescriptions for the Fentanyl Spray, for which payment may be made in whole or in part under Federal health care programs.

Count	Check Number	Payment Received Date	Payment Amount
2	012619	09/23/2013	\$4,800
3	013047	10/09/2013	\$4,800
4	000263	10/21/2013	\$4,800
5	000380	10/30/2013	\$4,800
6	000614	11/22/2013	\$8,400
7	000712	11/22/2013	\$6,000
8	000951	11/29/2013	\$8,400
9	001027	12/13/2013	\$2,400
10	001104	12/20/2013	\$2,400
11	001237	01/02/2014	\$4,800
12	001493	01/24/2014	\$2,400
13	001826	02/14/2014	\$2,400
14	001965	02/21/2014	\$2,400
15	002064	02/27/2014	\$2,400
16	002163	03/10/2014	\$9,700
17	002441	03/28/2014	\$7,200
18	002549	04/08/2014	\$2,400
19	002804	04/18/2014	\$17,750
20	002647	04/18/2014	\$6,000
21	002900	4/30/2014	\$6,000
22	003018	05/08/2014	\$6,000
23	003222	05/28/2014	\$3,000
24	25314	07/25/2014	\$3,000
25	25265	07/25/2014	\$3,000
26	25422	07/30/2014	\$3,000
27	25410	07/30/2014	\$3,000
28	25566	08/13/2014	\$3,000
29	25983	09/11/2014	\$3,000
30	26843	10/06/2014	\$4,700
31	26698	10/06/2014	\$3,000
32	26845	10/06/2014	\$4,700
33	27443	11/05/2014	\$3,000
34	27470	11/05/2014	\$3,000

35	28865	01/26/2015	\$3,000
36	29038	02/10/2015	\$3,000
37	29458	03/04/2015	\$3,000
38	29681	03/13/2015	\$4,700
39	29702	03/13/2015	\$4,700
40	30050	04/02/2015	\$3,000
41	30147	04/08/2015	\$3,000
42	30136	04/08/2015	\$3,000
43	30421	04/17/2015	\$3,000
44	30574	04/24/2015	\$3,000
45	30506	04/24/2015	\$2,350
46	30507	04/24/2015	\$4,700
47	30760	05/01/2015	\$3,000
48	30953	05/07/2015	\$3,000
49	31298	05/26/2015	\$3,000
50	31438	06/01/2015	\$4,700
51	31548	06/01/2015	\$3,000
52	31619	06/01/2015	\$4,700
53	31646	06/05/2015	\$3,000
54	31936	06/24/2015	\$3,000
55	32219	06/29/2015	\$3,000
56	32344	07/02/2015	\$3,000
57	32559	07/10/2015	\$3,000
58	33048	08/13/2015	\$3,000
59	33198	08/20/2015	\$3,000
60	33349	08/28/2015	\$3,000
61	33959	10/02/2015	\$4,700
62	34413	10/23/2015	\$3,026.88
63	35140	11/27/2015	\$3,000
64	35334	12/10/2015	\$3,000

The foregoing is in violation of Title 42, United States Code, Section 1320a-7b(b)(1)(B).

NOTICE OF FORFEITURE

21. The allegations contained in Counts 1 through 64 of this Indictment hereby are re-alleged and incorporated by reference for the purpose of alleging forfeiture

pursuant to the provisions of Title 18, United States Code, Sections 981(a)(1)(C) and 982(a)(7), and Title 28, United States Code, Section 2461(c).

22. Upon conviction of the violation of Title 18, United States Code, Section 371, alleged in Count 1 of this Indictment, and Title 42, United States Code, Section 1320a-7b(b)(1)(B), alleged in Counts 2 through 64 of this Indictment, defendant JEFFREY KESTEN shall forfeit to the United States, pursuant Title 18, United States Code, Sections 982(a)(7) and 981(a)(1)(C), any and all rights, title, and interest in all property constituting and derived from any proceeds they obtained directly and indirectly as a result of such offense or offenses, including, but not limited to, the entry of a money judgment in the amount of proceeds obtained by the scheme and by the defendant.

A TRUE BILL

Ink signature on file in Clerk's Office
FOREPERSON

JASON R. DUNN
United States Attorney

By: /s/ Anna K. Edgar
Anna K. Edgar
Assistant United States Attorney
United States Attorney's Office
1801 California Street, Suite 1600
Denver, Colorado 80202
Telephone: (303) 454-0100
Fax: (303) 454-0405
E-mail: Anna.Edgar@usdoj.gov
Attorney for the United States