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UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA) NO. 1:17-CR- 403
)
 v.) (JUDGE JONES)
)
 RAYMOND KRAYNAK)
 Defendant)

INDICTMENT

FILED
HARRISBURG, PA
DEC 20 2017
Per JK
Deputy Clerk

THE GRAND JURY CHARGES:

INTRODUCTION

At all times material to this Indictment:

1. Raymond Kraynak, was and is a Doctor of Osteopathy (D.O.) who practices medicine at Keystone Family Medicine Associates P.C., 28 East 5th Street, Mount Carmel, Pennsylvania 17851 and at 235 West Spruce Street, Shamokin, Pennsylvania 17872. As an osteopathic doctor, Kraynak is licensed by the Commonwealth of Pennsylvania to practice medicine and registered by the Drug Enforcement Administration to prescribe Schedule II, III, IV and V controlled substances.

2. In September of 2006, Kraynak received a letter from the

Commonwealth of Pennsylvania notifying him that he may have acted in an unprofessional manner by failing to properly record observations and physical examinations of patients to whom he supplied controlled substance prescriptions for weight loss, in violation of the Osteopathic Medical Practice Act.

3. In January of 2012, Kraynak entered into a "Consent Agreement and Order" to resolve case number 0506-53-11 before the Commonwealth of Pennsylvania Department of State, Board of Osteopathic Medicine. The "Consent Agreement and Order" indicated that, if the matter had proceeded to a hearing, the Commonwealth would have presented evidence to show, among other things, that: (a) during the period of January 2007 through June 2007, Kraynak prescribed large quantities of various controlled substances to seven separate patients; (b) Kraynak failed to perform a physical examination of several of the patients pursuant to the prescription of controlled substances to the patients; (c) Kraynak failed to document justification in the medical record for many of the controlled substances that he prescribed for the patients; (d) patients consistently requested new

prescriptions for controlled substances prior to the end of current prescriptions; (e) Kraynak prescribed increasing doses of controlled substances to the patients; (f) Kraynak did not document pill counts for patients; (g) Kraynak did not document a narcotic agreement with patients; and, (h) Kraynak did not document whether urine drug screening was provided to patients.

4. In the "Consent Agreement and Order," Kraynak admitted no wrongdoing but agreed to the entry of an Order finding that he "departed from, or failed to conform to, standards of acceptable and prevailing osteopathic medical practice in regard to the prescribing of controlled substances by a family physician to patients." Kraynak agreed to attend and complete an intensive course in controlled substance management. Kraynak was ordered to institute contracts for the management of patients with complaints of chronic pain and to enforce the terms, including that all controlled substances be filled at one pharmacy, that all controlled substances be prescribed by Kraynak and that unannounced urine or serum toxicology screens could be requested. Kraynak was ordered to engage a professional office

management company to review Kraynak's documentation practices for chronic pain patients. Kraynak was also ordered to pay a civil fine of \$2,500.

5. In a separate matter bearing docket number 1579-53-13, resolved in January of 2016, Kraynak was disciplined by the Commonwealth of Pennsylvania Department of State Board of Osteopathic Medicine for failure to annotate pertinent clinical information in a patient's medical record.

6. The Controlled Substances Act (the Act) governs the manufacture, distribution, and dispensing of controlled substances in the United States. Under the Act, there are five schedules of controlled substances – Schedules I, II, III, IV, and V. Controlled substances are scheduled into these levels based upon their potential for abuse, among other things. For example, abuse of Schedule II controlled substances may lead to severe psychological or physical dependence. Abuse of Schedule III controlled substances may lead to moderate or low physical dependence or high psychological dependence. Abuse of Schedule IV controlled substances may lead to more limited physical dependence or

psychological dependence relative to the drugs or other substances in Schedule III. The term "Schedule II" means the drug or other substance has a high potential for abuse, the drug has a currently accepted medical use with severe restrictions, and abuse of the drug or other substances may lead to severe psychological or physical dependence. Certain Schedule II drugs have a high potential for abuse. This abuse can lead to addiction, overdose, and sometimes death.

7. Morphine, a Schedule II controlled substance, is an opioid pain medication. Opioids are medications that relieve pain. An opioid is sometimes called a narcotic. Oxycodone is a narcotic analgesic (painkiller) that is similar to morphine and is classified as a Schedule II controlled substance, sometimes prescribed under the brand name Oxycontin®. Oxycodone, generic for Oxycontin®, is used to treat moderate to severe pain, and, even if taken only in prescribed amounts, can cause physical and psychological dependence. Oxycodone is a narcotic analgesic (opioid pain-killer) that is similar to Morphine and is classified by the Drug Enforcement Administration as a Schedule II

controlled substance. Oxycodone is an immediate release (IR) drug that needs to be taken every 4 to 6 hours and is the active ingredient in other drug combinations such as Percocet (Oxycodone and Acetaminophen). Oxycodone is used as a pain relief drug in varying strengths, including 5, 10, 15, 20, and 30 milligram amounts. Oxycontin (a brand name derived from "oxycodone continuous") contains pure Oxycodone and is formulated as an extended released (ER) drug in 40mg and 80mg strengths. Oxycodone is used to treat moderate to severe pain, and, even if taken only in prescribed amounts, can cause physical and psychological dependence when taken for a long time. Users who abuse pills containing Oxycodone frequently do so by crushing the pills and snorting the substance.

8. Oxycodone has a substantial euphoric effect subject to abuse; that is, there is a population that seeks to use the drug for its effect as a "high." It can also create physical dependence and tolerance over time, so that more of the drug is required to have the same effect. To avoid dependence and abuse, it must be used under a doctor's care so that the doctor can monitor and control any signs of addiction. As a controlled

substance, all of the products containing Oxycodone are classified by the Drug Enforcement Administration as Schedule II controlled substances, which mean they have a high potential for abuse, with use potentially leading to severe psychological or physical dependence.

9. A prescription monitoring report (PMP) contains prescription data for all Schedule II controlled substances dispensed by pharmacies in the Commonwealth of Pennsylvania. Pharmacies are required by law in Pennsylvania to report the patients name, the particular Schedule II controlled substance and dosage dispensed, quantity dispensed, number of days supplied, prescribing physician's name, DEA registration number, and the dispensing pharmacy's name and DEA registration number.

10. From May of 2012 until the end of January 2016, Kraynak prescribed 3,622,598 Oxycodone pills. That number represents 80.62% of all the controlled substances prescribed by the defendant during that period of time.

11. From January 1, 2016 through July 31, 2017, Kraynak prescribed an aggregate of 2,792,490 dosage units of oxycodone,

hydrocodone, OxyContin and fentanyl to approximately 2,838 patients. This made Kraynak the top prescriber for all of the Commonwealth of Pennsylvania for these controlled substances during this 19-month period of time.

The Controlled Substances Act

12. The Controlled Substances Act governs the manufacture, distribution, and dispensing of controlled substances in the United States. The Controlled Substances Act is contained in Title 21, United States Code, Sections 801-971.

13. Title 21, United States Code, Section 841(a)(1), provides that “[e]xcept as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute or dispense, a controlled substance;....”

14. Title 21, United States Code, Section 802(10), provides that the term “dispense” means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a

controlled substance and the packaging, labeling or compounding necessary to prepare the substance for delivery.

15. The term "distribute" means to deliver (other than by administering or dispensing) a controlled substance or a listed chemical. The term "distributor" means a person who so delivers a controlled substance or a listed chemical. (21 U.S.C. § 802(11)).

16. Title 21, United States Code, Section 821, provides that "[t]he Attorney General [of the United States] is authorized to promulgate rules and regulations relating to the registration and control of the manufacture, distribution and dispensing of controlled substances."

17. The Attorney General of the United States has exercised his rulemaking authority regarding the dispensing of controlled substances through the promulgation of 21 Code of Federal Regulations § 1306.04, governing the issuance of prescriptions, which provides, among other things, that a prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The

responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. Moreover, an order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act [21 U.S.C. § 829] and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the law relating to controlled substances.

Other Applicable Laws

18. The Pennsylvania Code of Professional and Vocational Standards, Title 49, Chapter 16.92, defines the authority of physicians licensed by the Commonwealth of Pennsylvania to prescribe or dispense controlled substances. Chapter 16.92 provides in pertinent part:

- (a) A person licensed to practice medicine and surgery in this Commonwealth or otherwise licensed or regulated by the Board, when prescribing, administering or dispensing controlled

substances, shall carry out, or cause to be carried out, the following minimum standards:

(1) Initial medical history and physical examination. Before commencing treatment that involves prescribing, administering or dispensing a controlled substance, an initial medical history shall be taken and an initial examination shall be conducted unless emergency circumstances justify otherwise. Alternatively, medical history and physical examination information recorded by another health care provider may be considered if the medical history was taken and the physical examination was conducted within the immediately preceding thirty days. The physical examination shall include an evaluation of the heart, lungs, blood pressure and body functions that relate to the patient's specific complaint.

(2) Reevaluations. Among the factors to be considered in determining the number and the frequency of follow-up evaluations that should be recommended to the patient are the condition diagnosed, the controlled substance involved, expected

results and possible side effects. For chronic conditions, periodic follow-up evaluations shall be recommended to monitor the effectiveness of the controlled substance in achieving the intended results.

(3) Patient counseling. Appropriate counseling shall be given to the patient regarding the condition diagnosed and the controlled substance prescribed, administered or dispensed. Unless the patient is in an inpatient care setting, the patient shall be specifically counseled about dosage levels, instructions for use, frequency and duration of use and possible side effects.

(4) Medical Records. Certain information shall be recorded in the patient's medical record on each occasion when a controlled substance is prescribed, administered or dispensed. This information shall include the name of the controlled substance, its strength, the quantity and the date it was prescribed, administered or dispensed to a patient. The medical record shall also include a specification of the symptoms observed and reported, the diagnosis of the condition for which the controlled

substance is being given and the directions given to the patient for the use of the controlled substance. If the same controlled substance continues to be prescribed, administered or dispensed, the medical record shall reflect changes in the symptoms observed and reported, in the diagnosis of the condition for which the controlled substance is being given and in the directions given to the patient.

19. The Pennsylvania Code of Professional and Vocational Standards (49 Pa. Code, Chapter 16.95), requires physicians to maintain timely and complete medical records for at least 7 years from the date of the last medical service for the patient. The DEA requires that a physician maintain records at his/her office of his/her purchases, distributions, and prescriptions of controlled substances for at least two years.

Kraynak's Illegal Distribution of Controlled Substances

20. During the time period alleged in this Indictment, the defendant distributed and dispensed, and caused to be distributed and dispensed, controlled substances that were not prescribed for a

legitimate medical purpose, and not in the usual course of professional practice in one or more of the following manners, among others:

- (a) inadequate verification of the patient's medical complaint;
- (b) cursory or no medical examinations by Kraynak;
- (c) inadequate patient medical history and no follow-up verification;
- (d) incomplete or inadequate mental or physical examinations;
- (e) insufficient dialogue with the patients regarding treatment options and risks and benefits of such treatments;
- (f) treating patients with highly addictive controlled substances while failing to consider other treatment options;
- (g) failure to refer patients to specialist for treatments;
- (h) lack of, or inadequate diagnostic testing;
- (i) increasing the patients' dosages over time unnecessarily;
- (j) prescribing inappropriate combinations of drugs to patients;
- (k) allowing patients to suggest or direct the medications to be prescribed;
- (l) directing patients to particular pharmacies that were known

to fill the prescriptions;

- (m) prescribing highly addictive controlled substances to patients with vague physical complaints where alternative treatment options would be indicated;
- (n) prescribing the maximum dose immediate release formula (30 mg tablets) without a long acting formulation;
- (o) failing to assess the risk of abuse by individual patients;
- (p) failing to monitor patients' responses to the medication.

21. A review of the defendant's medical records for the time frame of this indictment shows that the medical records failed to contain required information including, but not limited to, information regarding symptoms observed and reported, diagnosis of condition, direction for use, changes in symptoms observed and reported in their diagnosis of the condition for which the controlled substance is being given and in the directions given to the patient.

Counts 1 through 12

21 United States Code §841(a)(1)
(Unlawful Distribution and Dispensing of a Controlled Substance)

22. The allegations contained in paragraphs 1 through 21 of this

Indictment are incorporated herein.

23. On or about the dates set forth below, in Northumberland County, Pennsylvania, within the Middle District of Pennsylvania and elsewhere, the defendant,

RAYMOND KRAYNAK,

acting outside the usual course of professional practice and not for a legitimate medical purpose, did knowingly, intentionally and unlawfully prescribe, distribute and dispense, the Schedule II controlled substance, as listed below, each of which constitutes a separate count of this

Indictment:

COUNT	APPROXIMATE DATES OF DISTRIBUTION	PATIENT	CONTROLLED SUBSTANCES
1	December 21, 2012 through May 2, 2015	R.C.	Hydrocodone
2	December 21, 2012 through July 31, 2014	F.H.	Oxycodone
3	June 2013 through February 17, 2015	D.H.	Oxycodone
4	December 21, 2012 through October 24, 2013	A.K.	Oxycodone

5	December 21, 2012 through October 15, 2014	M.L.	Hydrocodone
6	December 21, 2012 through April 29, 2014	C.S.	Oxycodone
7	January 2014 through October 5, 2014	D.B.	Oxycodone
8	December 21, 2012 through December 14, 2014	W.E.	Oxycodone
9	December 21, 2012 through February 10, 2013	F.G.	Oxycodone
10	December 21, 2012 through April 28, 2014	T.M.	Oxycodone
11	January 2013 through July 6, 2016	J.S.	Fentanyl
12	February 2013 through September 15, 2016	R.W.	Oxycodone

All in violation of Title 21, United States Code, Section 841(a)(1) and 841 (b) (1) (C), and Title 18, United States Code, Section 2 (a) and (b).

THE GRAND JURY FURTHER CHARGES:

Counts 13 through 17

21 United States Code §841(a)(1)
(Unlawful Distribution and Dispensing of a Controlled Substance
Resulting in Death)

24. The allegations contained in paragraphs 1 through 23 of this Indictment are incorporated herein.

25. On or about the dates set forth below, in Northumberland County, Pennsylvania, within the Middle District of Pennsylvania, the defendant,

RAYMOND KRAYNAK,

acting outside the usual course of professional practice and not for a legitimate medical purpose, did knowingly, intentionally and unlawfully prescribe, distribute and dispense, the Scheduled controlled substance(s), as listed below, and death of a person and persons known to the grand jury resulted from the use of the controlled substance(s), each of which constitutes a separate count of this Indictment:

COUNT	APPROXIMATE DATES OF DISTRIBUTION	PATIENT	CONTROLLED SUBSTANCES
13	May 2, 2015	R.C.	Alprazolam Hydrocodone Carisoprodol
14	February 17, 2015	D.H.	Oxycodone
15	October 24, 2013	A.K.	Oxycodone Alprazolam
16	October 15, 2014	M.L.	Temazepam Alprazolam Hydrocodone
17	April 29, 2014	C.S.	Oxycodone Carisoprodol Diazepam Zolpidem

All in violation of Title 21, United States Code, Section 841(a) (1) and (b) (1) (C), and Title 18, United States Code, Section 2 (a) and (b).

THE GRAND JURY FURTHER CHARGES:

Count 18

**21 United States Code § 856(a)(1)
(Maintaining Drug-Involved Premises)**

26. The allegations contained in paragraphs 1 through 25 of this Indictment are incorporated herein.

27. From on or about January 2006, and continuing through November 2017, in the Middle District of Pennsylvania, the defendant,

RAYMOND KRAYNAK,

aided and abetted by others, knowingly, intentionally and unlawfully opened and maintained a place known as Keystone Family Medicine Associates, located at 28 East 5th Street, Mount Carmel, Pennsylvania, for the purposes of distributing Schedule II controlled substances outside the usual course of professional practice and without legitimate medical purpose.

In violation of Title 21, United States Code, Section 856(a)(1), and 18 United States Code, Section 2.

THE GRAND JURY FURTHER CHARGES:

Count 19

**21 United States Code § 856(a)(1)
(Maintaining Drug-Involved Premises)**

28. The allegations contained in paragraphs 1 through 25 of this Indictment are incorporated herein.

29. From on or about January 2006, and continuing through November 2017, in the Middle District of Pennsylvania, the defendant,

RAYMOND KRAYNAK

aided and abetted by others, knowingly, intentionally and unlawfully opened and maintained a place known as Keystone Family Medicine Associates, located at 235 West Spruce Street, Shamokin, Pennsylvania, for the purposes of distributing Schedule II controlled substances outside the usual course of professional practice and without legitimate medical purpose.

In violation of Title 21, United States Code § 856(a)(1) and 18 United States Code § 2.

FORFEITURE ALLEGATION

30. The allegations contained in Counts 1 through 19 of this Indictment are hereby realleged and incorporated by reference for the purpose of alleging forfeitures pursuant to Title 21, United States Code, Section 853.

31. Pursuant to Title 21, United States Code, Section 853, upon conviction of an offense in violation of Title 21, United States Code, Sections 841(a)(1) and 856, the defendant, Raymond Kraynak, shall forfeit to the United States of America any property constituting, or derived from, any proceeds obtained, directly or indirectly, as the result of such offenses and any property used, or intended to be used, in any manner or part, to commit, or to facilitate the commission of, the offenses. The property to be forfeited includes, but is not limited to, the following:

- a. Real property located at 28 East 5th Street, Mount Carmel, Northumberland County, Pennsylvania, titled to Raymond and Mary Ann Kraynak;

- b. Real property located at 235 West Spruce Street, Shamokin, Northumberland County, Pennsylvania, titled to Mary Ann Kraynak;
- c. All proceeds obtained, directly or indirectly, as the result of the Title 21, United States Code, Sections 841(a)(1) and 856 violations, including but not limited to, \$500,000 in currency, in that such sum of \$500,000 in the aggregate is property which was involved in the aforestated offenses and is traceable to such property in violation of Title 21, United States Code, Sections 841(a) and 856.; and
- d. Raymond Kraynak's Pennsylvania Medical License, number OS005323L.

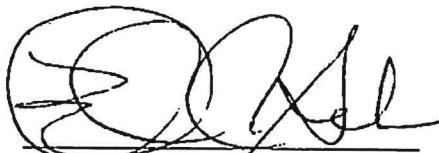
32. If any of the property described above, as a result of any act or omission of the defendant:

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

the United States of America shall be entitled to forfeiture of substitute property pursuant to Title 21, United States Code, Section 853(p).

DAVID J. FREED
UNITED STATES ATTORNEY



WILLIAM A. BEHE
Assistant United States Attorney

TRUE BILL


FOREPERSON

2017 - DEC - 20
Date

Francis P. Sempa /wabs
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