

BOSWELL

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
EASTERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

vs.

JAY SHIRES, M.D.,
LORAN KARLOSKY, M.D., and
MARY ANN BOND,

Defendants.

Cr. No.: 19-10043 JDB

21 U.S.C. § 846

21 U.S.C. § 841(a)(1)

18 U.S.C. § 2

FILED UNDER SEAL

INDICTMENT

THE GRAND JURY CHARGES:

At all times material to this indictment:

DEFENDANTS

1. Defendant **MARY ANN BOND** ("BOND") was a Nurse Practitioner, licensed by the State of Tennessee. **BOND** maintained a Drug Enforcement Administration Registration ("DEA") Number. **BOND** operated her medical practice out of DOWNTOWN MEDICAL CLINIC, PLLC (the "DOWNTOWN CLINIC") in Bells, TN. **BOND** issued prescriptions for controlled substances, including the Schedule II controlled substances Oxycodone, Hydrocodone, and others, and the Schedule IV controlled substances Alprazolam, Diazepam, Clonazepam, and others, at the DOWNTOWN CLINIC, outside the course of professional practice and without a legitimate medical purpose.

2. Defendant **LORAN KARLOSKY ("KARLOSKY")** was a Medical Doctor, licensed by the State of Tennessee. **KARLOSKY** maintained a Drug Enforcement Administration Registration ("DEA") Number. **KARLOSKY** was part-owner in the DOWNTOWN CLINIC. He acted as manager and supervising physician to **BOND** as **BOND** issued prescriptions for controlled substances, including the Schedule II controlled substances Oxycodone, Hydrocodone, and others, and the Schedule IV controlled substances Alprazolam, Diazepam, Clonazepam, and others at the DOWNTOWN CLINIC, outside the course of professional practice and without a legitimate medical purpose.

3. Defendant **JAY SHIRES ("SHIRES")** was a Medical Doctor, licensed by the State of Tennessee. **SHIRES** maintained a Drug Enforcement Administration Registration ("DEA") Number. **SHIRES** was a part-owner in the DOWNTOWN CLINIC. He was the supervising physician for **BOND** as **BOND** issued prescriptions for controlled substances, including the Schedule II controlled substances Oxycodone, Hydrocodone, and others, and the Schedule IV controlled substances Alprazolam, Diazepam, and Clonazepam, at the DOWNTOWN CLINIC, outside the course of professional practice and without a legitimate medical purpose.

CONTROLLED SUBSTANCE STATUTES AND CONTROLLING REGULATIONS

4. The Controlled Substances Act ("CSA") governed the manufacture, distribution, and dispensing of controlled substances in the United States. With limited exceptions for medical professionals, the CSA made it unlawful for any person to knowingly or intentionally manufacture, distribute, or dispense a controlled substance or conspire to do so.

5. Medical practitioners, such as physicians, nurse practitioners, and pharmacists, who were authorized to prescribe and/or dispense controlled substances by the jurisdiction in which they were licensed to practice medicine, were authorized under the CSA to prescribe, or otherwise distribute, controlled substances, if they were registered with the Attorney General of the United States. 21 U.S.C. § 822(b); 21 C.F.R. § 1306.03. Upon application by the practitioner, the DEA assigned a unique registration number to each qualifying medical practitioner including physicians and nurse practitioners.

6. The CSA and its implementing regulations set forth which drugs and other substances were defined by law as “controlled substances,” and assigned those controlled substances to one of five Schedules (Schedule I, II, III, IV, or V) depending on their potential for abuse, likelihood of physical or psychological dependency, accepted medical use, and accepted safety for use under medical supervision.

7. A controlled substance assigned to Schedule II meant that the drug had a high potential for abuse, was highly addictive, and that the drug had a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions. Abuse of a Schedule II controlled substance could lead to severe psychological and/or physical dependence. Pursuant to the CSA and its implementing regulations:

a. Hydrocodone was classified as a Schedule II controlled substance after October 2014, before which time it was classified as a Schedule III controlled substance. It was an opioid pain medication.

b. Oxycodone was classified as a Schedule II controlled substance. Oxycodone was sold generically and under a variety of brand names, including OxyContin®, Roxicodone®, Endocet®, and Percocet. Oxycodone, an opioid pain medication, is about fifty percent stronger than Morphine.

c. Most pharmaceutical amphetamines, including Adderall, were classified as Schedule II controlled substances and were powerful stimulant medications.

d. Hydrocodone, Oxycodone, and other Schedule II opioids like Morphine and Fentanyl were among the Schedule II opioid controlled substances that had the highest potential for abuse and associated risk of fatal overdose. Pharmaceutical amphetamines are also characterized as controlled substances having the highest potential for abuse.

8. A controlled substance assigned to Schedule IV meant that the drug or other substance had a lower potential for abuse than Schedule II drugs or other substances, the drug or other substance had a currently accepted medical use in the United States, and abuse of the drug or other substances may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in the higher Schedules. Pursuant to the CSA and its implementing regulations:

a. Alprazolam, a benzodiazepine, was classified as a Schedule IV controlled substance. Alprazolam, sometimes prescribed under brand name Xanax, was a medication used to treat anxiety.

b. Clonazepam, a benzodiazepine, was classified as a Schedule IV controlled substance. Clonazepam, sometimes prescribed under brand name

Klonopin, was a medication used to treat anxiety and seizures.

c. Diazepam, a benzodiazepine, was classified as a Schedule IV controlled substance. Diazepam, sometimes prescribed under brand name Valium, was a medication used to treat anxiety and seizures.

9. Chapter 21 of the Code of Federal Regulations, Section 1306.04 governed the issuance of prescriptions and provided, among other things, that a prescription for a controlled substance “must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.”

10. Chapter 21 of the Code of Federal Regulations, Section 1306.04, further directed that “[a]n order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of [the CSA] 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 provisions of law relating to controlled substances.”

11. Chapter 21 of the Code of Federal Regulations, Section 1306.06 governed the filling of prescriptions and provided, “A prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice and either registered individually or employed in a registered pharmacy, a registered central fill pharmacy, or registered institutional practitioner.”

12. All prescriptions for controlled substances must be “dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner.” 21 C.F.R. § 1306.05(a).

"The refilling of a prescription for a controlled substance listed in Schedule II is prohibited." 21 C.F.R. § 1306.12(a); 21 U.S.C. § 829(a).

13. It was well known that the combination of high-dose opioids and benzodiazepines (e.g., Alprazolam, Diazepam, and Clonazepam) in any dose had a significant impact upon the risk of patient intoxication and overdose. For a treating physician to prescribe this combination of high-dose opioids and benzodiazepines for a legitimate medical purpose, the physician needed to determine, at a minimum, that the benefits of the drugs outweighed the risk(s) to the patient's life.

14. On March 16, 2016, the Centers for Disease Control and Prevention ("CDC") issued CDC Guidelines for Prescribing Opioids for Chronic Pain. In that guidance, the CDC warned that medical professionals should avoid prescribing opioids and benzodiazepines (e.g. Alprazolam, Diazepam, and Lorazepam) concurrently whenever possible because of the risk of potentially fatal overdose.

15. Prescribing and issuing these two medications around the same time quadrupled the patient's risk of overdose and death from the prescribed drugs. Moreover, there was a significant risk of diversion when prescribing or issuing these drugs around the same time. Furthermore, a benzodiazepine served as a "potentiator" for the opioid's euphoric effect by increasing the "high" a user may obtain from opioid and was therefore often sought for this non-legitimate medical purpose.

16. On August 31, 2016, the U.S. Food and Drug Administration ("FDA") issued a "Black Box" Warning, its strongest warning, to the drug labeling of prescription opioid pain medicines and benzodiazepines. The FDA specifically warned that combined use of opioids and benzodiazepines depresses the central nervous system

and results in serious side effects, such as slowed or difficult breathing and death. The FDA further warned health care professionals to limit prescribing opioids with benzodiazepines and cautioned that such medications should only be prescribed together when alternative treatment options are inadequate.

17. Urine drug screens were relied upon in the pain-management industry as a means of identifying a patient's non-compliance with the patient's treatment plan. Urine drug screens were used to identify abuse of illicit and controlled substances not prescribed to a patient, and to identify a patient's failure to take drugs prescribed for the patient's treatment of pain.

18. Tennessee's controlled substance monitoring program ("CSMD") was a means of detecting a pain management patient's non-compliance with the patient's treatment plan. A CSMD report contained prescription data for all controlled substances dispensed by pharmacies in the State of Tennessee. Pharmacies were required to report the patient's name, the particular controlled substance and dosage dispensed, the quantity dispensed, the number of days supplied, the prescribing physician's name, the date the prescription was issued, the dispensing pharmacy's name, the type of payment, and the date the controlled substances were dispensed.

19. Chapter 0880-6 of the Rules of the Tennessee State Board of Medical Examiners governed the supervision of nurse practitioners by physicians in Tennessee. According to the regulations, a supervisory physician shall be responsible for ensuring compliance with the applicable standard of care. Rules of Tenn. Bd. Of Med. Ex. 0880-6-.02(6). Additionally, the supervising physician shall develop clinical guidelines in collaboration with the certified nurse practitioner to include a method for documenting

consultation and referral. *Id.* Once every ten business days, the supervising physician shall make a personal review of the historical, physical, and therapeutic data and shall so certify by signature on any patient within thirty days—when a controlled substance has been prescribed. Rules of Tenn. Bd. Med. Ex. 0880-6-.02(7)(e).

COUNT ONE
Conspiracy to Distribute and Dispense Controlled Substances
(21 U.S.C. § 846)

20. Paragraphs 1 through 19 of this Indictment are realleged and incorporated by reference as if fully set forth herein.

21. From in or around August 2014 through in or around April 2016, in the Eastern Division of the Western District of Tennessee, and elsewhere, the defendants, **MARY ANN BOND, LORAN KARLOSKY, and JAY SHIRES** did knowingly and intentionally combine, conspire, confederate, and agree with each other and with others known and unknown to the Grand Jury, to violate Title 21, United States Code, Section 841(a)(1), that is, to knowingly and intentionally unlawfully distribute and dispense, mixtures and substances containing a detectable amount of Schedule II controlled substances, including Hydrocodone, Oxycodone, and pharmaceutical amphetamines, not for a legitimate medical purpose and outside the course of professional practice.

All in violation of Title 21, United States Code, Section 846.

COUNTS TWO THROUGH SEVEN
Unlawfully Distributing and Dispensing Controlled Substances and Aiding and Abetting
(21 U.S.C. §§ 841(a)(1) and 18 U.S.C. § 2)

22. All prior paragraphs of this Indictment are realleged and incorporated by reference as though fully set forth herein.

23. During the dates specified below, in the Eastern Division of the Western District of Tennessee, Defendants **BOND, SHIRES, and KARLOSKY**, aiding and abetting and aided and abetted by others known and unknown to the Grand Jury, did intentionally and knowingly unlawfully distribute and dispense mixtures and substances containing a detectable amount of Schedule II controlled substances, as alleged in the following counts:

Count	Defendant	Rx Date	Pt. Name	DoB	Drug
2	BOND	2/8/2016	M.B.	11/10/1971	HYDROCODONE-ACETAMINOPHN TAB
3	BOND	2/1/2016	S.P.	5/16/1978	ADDERALL XR ORAL CAPSULE, EXTENDED RELEASE
4	BOND KARLOSKY	2/29/2016	P.M.	10/21/1962	HYDROCODONE-ACETAMINOPHIN TAB
5	BOND	11/13/2015	M.B.	8/24/1973	HYDROCODONE-ACETAMINOPHIN TAB
7	BOND KARLOSKY	2/8/2016	D.S.	7/27/1989	HYDROCODONE-ACETAMINOPHIN TAB
8	BOND KARLOSKY	12/4/2014	A.S.	12/13/1954	OXYCODONE HCL TAB

All in violation of Title 21, United States Code, Sections 841(a)(1) & Title 18, United States Code, Section 2.

NOTICE OF CRIMINAL FORFEITURE
(18 U.S.C. § 981(a)(1)(C) & 28 U.S.C. § 2461;
18 U.S.C. §§ 982(a)(1) & (7); 21 U.S.C. § 853)

24. The allegations contained in Counts 1 – 8 of this Indictment are re-alleged and incorporated by reference as though fully set forth herein for the purpose of alleging forfeiture against defendant,

LORAN EDWARD KARLOSKY

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

25. Pursuant to Title 18, United States Code, Section 981(a)(1)(C), together with Title 28, United States Code, Section 2461, upon being conviction 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.

26. Pursuant to Title 18, United States Code, Section 982(a)(7), upon being convicted of the crimes charged in Counts 1 through 8 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, including, but not limited to the sum of \$168,023.11.

27. Pursuant to Title 21, United States Code, Section 853, the United States gives notice to defendants **MARY ANN BOND, LORAN KARLOSKY, and JAY SHIRES** that upon conviction of an offense in violation of Title 21, United States Code, Section 841, the following property shall be subject to forfeiture:

a. All property constituting, or derived from, any proceeds obtained, directly or indirectly, as the result of such offense; and

b. All property used, or intended to be used, in any manner or part, to commit, or to facilitate the commission of, the offense.

28. The defendants **MARY ANN BOND, LORAN KARLOSKY, and JAY**

SHIRES are notified that upon conviction, a money judgment may be imposed equal to the total value of the property subject to forfeiture.

29. In the event that one or more conditions listed in Title 21, United States Code, Section 853(p) exists, the United States will seek to forfeit any other property of the defendants up to the total value of the property subject to forfeiture.

A TRUE BILL:

FOREPERSON

DATED: _____

JOSEPH BEEMSTERBOER
CHIEF, FRAUD SECTION, CRIMINAL DIVISION
U.S. DEPARTMENT OF JUSTICE

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) **21 U.S.C. § 846**

) **21 U.S.C. § 841(a)(1)**

) **18 U.S.C. § 2**
)
)

) **FILED UNDER SEAL**
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NOTICE OF PENALTIES

COUNT ONE

**Conspiracy to Distribute and Dispense Controlled Substances
(21 U.S.C. § 846)**

[A term of imprisonment for not more than twenty years, a fine of up to \$1,000,000, or both, and at least three years supervised release, and a mandatory special assessment of \$100, see 18 U.S.C. § 3013(a).]

COUNTS TWO THROUGH SEVEN

**Unlawfully Distributing and Dispensing Controlled Substances and Aiding and
Abetting
(21 U.S.C. § 841(a)(1) & 18 U.S.C. § 2)**

[A term of imprisonment for not more than twenty years, a fine of up to \$1,000,000, or both, and at least three years supervised release, and a mandatory special assessment of \$100, see 18 U.S.C. § 3013(a).]