

controlled substances outside the usual scope of professional practice and without a legitimate medical purpose.

CONTROLLED SUBSTANCE STATUTES AND CONTROLLING REGULATIONS

3. 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.

4. Medical practitioners, such as physicians and nurse practitioners, who were authorized to prescribe 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.

5. 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.

6. 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 Percacet. Oxycodone, an opioid pain medication, is about fifty percent stronger than Morphine.

c. Hydrocodone and Oxycodone were among the Schedule II opioid controlled substances that had the highest potential for abuse and associated risk of fatal overdose.

7. 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.

8. 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.”

9. 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.”

10. 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).

11. It was well known that the combination of high-dose opioids and benzodiazepines (e.g., Alprazolam) 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.

12. 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. Xanax, Alprazolam, Lorazepam) concurrently whenever possible because of the risk of potentially fatal overdose. Prescribing and issuing these two medications around the same time compounds the patient's risk of overdose and death from the prescribed drugs, by four times. Moreover, there is a significant diversion risk of prescribing or issuing these drugs around the same time. A benzodiazepine serves as a "potentiator" for the opioid's euphoric effect by increasing the "high" a user may obtain from opioid and is therefore often sought for this non-legitimate medical purpose.

13. 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.

14. 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.

15. 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.

COUNT 1
Conspiracy to Distribute and Dispense Controlled Substances
(21 U.S.C. § 846)

16. Paragraphs 1 through 15 of this Indictment are realleged and incorporated by reference as if fully set forth herein.

17. From in or around July 2016 through in or around April 2019, in the Western District of Tennessee, and elsewhere, the defendants, **PETWAY** and **ALSTON**, 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 Oxycodone and Hydrocodone, not for a legitimate medical purpose and outside the scope of professional practice.

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

Purpose of the Drug Conspiracy

18. It was the purpose and object of the conspiracy for Defendants to unlawfully enrich themselves by, among other things: (a) prescribing controlled substances without a legitimate medical purpose and outside the scope of professional practice; (b) generating large profits from those prescriptions; and (c) diverting the proceeds from those controlled substance prescriptions for the personal use and benefit of Defendants and their coconspirators known and unknown to the Grand Jury.

Manner and Means

19. The manner and means by which the defendants sought to accomplish the purpose and object of the conspiracy included, among other things:

20. **PETWAY** would and did use her status as a licensed Nurse Practitioner, her DEA Registration Number, and her medical practice SUPERIOR HEALTH, to knowingly and intentionally prescribe Oxycodone, Morphine, and Hydrocodone; in addition to various benzodiazepines, including Alprazolam and Clonazepam; and other controlled substances, outside the course of professional practice and not for a legitimate medical purpose.

21. **PETWAY** paid **ALSTON** to be her supervising physician.

22. **ALSTON** gave **PETWAY's** practice the appearance of legitimacy by

signing the State of Tennessee Board of Nursing's "Advanced Practice Nurse Notice and Formulary" form, filed with the State, and stating that he was PETWAY's supervising physician from on or about March 11, 2016 to at least through on or about April of 2019.

23. **ALSTON** purported to supervise **PETWAY** at SUPERIOR HEALTH, and was responsible for reviewing all of **PETWAY's** patient charts for the patients who were issued prescriptions for controlled substances. **ALSTON** approved **PETWAY's** prescriptions for controlled substances even though the majority were not for a legitimate medical purpose and were outside the scope of professional practice.

24. **PETWAY** and **ALSTON** were required under Tennessee law to register SUPERIOR HEALTH as a pain management clinic with the State of Tennessee, but did not.

25. Under **ALSTON's** supervision, **PETWAY** often:

- a. Signed blank prescriptions for purported patients and gave them to SUPERIOR HEALTH employees to complete as to the type of controlled substance and as to the patient's name;
- b. Prescribed controlled substances without ever seeing or treating purported patients;
- c. Prescribed controlled substances to close friends and relatives;
- d. Prescribed the dangerous drug combination known as the "Holy Trinity," comprised of opioids (usually Oxycodone), benzodiazepines (usually Alprazolam), and the muscle relaxer Carisoprodol;
- e. Prescribed dangerous combinations of opioids and

benzodiazepines;

- f. Failed to monitor patients for addiction;
- g. Failed to monitor patients for diversion of the prescribed drugs into the illicit drug market;
- h. Ignored drug screens showing patients were taking illicit drugs;
- i. Ignored drug screens showing patients were not taking the controlled substances prescribed them, and therefore, were likely diverting the drugs to other users;
- j. Failed to corroborate patients' reports of pain through x-rays, MRI's, and other diagnostic tools;
- k. Failed to properly examine patients;
- l. Failed to properly diagnose patients;
- m. Failed to provide treatment plans for patients; and
- n. Failed to recommend alternative forms, or modalities, of treatment for pain.

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

NOTICE OF CRIMINAL FORFEITURE
(21 U.S.C. § 853)

26. The allegations contained in Count One 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.

27. Pursuant to Title 21, United States Code, Section 853, the United States gives notice to defendants **PETWAY** and **ALSTON** 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 **PETWAY** and **ALSTON** 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: _____

D. MICHAEL DUNAVANT
UNITED STATES ATTORNEY

JOSEPH BEEMSTERBOER
CHIEF, FRAUD SECTION, CRIMINAL DIVISION

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