BOSWELL

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

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	**Cr. No.:** 19-20083 SHL
	)	
vs.	)	**21 U.S.C. § 846**
	)	
JAMES LITTON,	)	**FILED UNDER SEAL**
	)	
Defendant.	)	

INDICTMENT

THE GRAND JURY CHARGES:

At all times material to this indictment:

DEFENDANT

1. Defendant **JAMES LITTON ("LITTON")** was a Nurse Practitioner, licensed by the State of Tennessee. **LITTON** maintained a Drug Enforcement Administration Registration ("DEA") Number. **LITTON** issued prescriptions for controlled substances, including the Schedule II controlled substances of Oxycodone and Hydrocodone, and the Schedule IV controlled substances Alprazolam, Clonazepam, and Carisoprodol at Consolidated Health Services of Memphis, in Memphis, Tennessee ("CONSOLIDATED HEALTH"), outside the usual course of professional practice and without a legitimate medical purpose.

CONTROLLED SUBSTANCE STATUTES AND CONTROLLING REGULATIONS

2. 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.

3. 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.

4. 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.

5. 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.

6. 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. Carisoprodol was classified as a Schedule IV controlled substance.

21 C.F.R. § 1308.14(c). Carisoprodol, sometimes prescribed under brand name Soma, was a muscle relaxant.

7. 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."

8. 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."

9. 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.

10. 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.

11. 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.

12. 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.

13. 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.

14. 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)

15. Paragraphs 1 through 14 of this Indictment are realleged and incorporated by reference as if fully set forth herein.

16. From in or around August 2017 through in or around February 2018, in the Western District of Tennessee, and elsewhere, the defendant, **LITTON** and his coconspirators, known and unknown to the Grand Jury, 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 course of professional practice.

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

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

17. 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.

18. Pursuant to Title 21, United States Code, Section 853, the United States gives notice to defendant **LITTON** 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.

19. The defendant **LITTON** is notified that upon conviction, a money judgment may be imposed equal to the total value of the property subject to forfeiture.

20. 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 defendant 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