

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

FILED
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2019 JUL 17 PM 2:54

U.S. DISTRICT COURT
SOUTHERN DIST. OHIO
WEST. DIV. CINCINNATI

UNITED STATES OF AMERICA,

Plaintiff,

vs.

ANTHONY RATTINI (1),
JAMES BARCLAY (2),
DEVONNA MILLER-WEST (3),
SAMUEL R. BALLENGEE (4), and
MIAMI-LUKEN, INC. (5),

Defendants.

CASE NO. **1:19CR 081**

JUDGE **DLOTT**

INDICTMENT

21 U.S.C. § 846

THE GRAND JURY CHARGES:

Introduction

At all times relevant to this Indictment:

1. **MIAMI-LUKEN** was incorporated as a “for profit” organization in Montgomery County, Ohio. **MIAMI-LUKEN** was a distributor of pharmaceuticals, including controlled substances. At all times relevant to this Indictment, **MIAMI-LUKEN** generated more than \$173,000,000 in consolidated sales per year. Over 70% of **MIAMI-LUKEN**’s profits came from their wholesale distribution. **MIAMI-LUKEN** supplied pharmaceuticals to over 200 pharmacies located within Ohio, West Virginia, Kentucky, Indiana, and Tennessee.

2. **MIAMI-LUKEN** was registered with the DEA as a wholesale distributor, which permitted it to order and to distribute to pharmacies Schedule II, III, IV and V controlled substances for legitimate medical purposes within the scope of professional practice.

3. Beginning on or around January 1, 2008, to at least December 7, 2015, **ANTHONY RATTINI** was the President of **MIAMI-LUKEN** located in Springboro, Ohio and, as the President, was responsible for supervising **MIAMI-LUKEN's** compliance with federal and state drug laws.

4. Beginning on or around January 1, 2008, to on or about April, 2015, **JAMES BARCLAY** was the Compliance Officer of **MIAMI-LUKEN**. As Compliance Officer, **BARCLAY** was responsible for supervising **MIAMI-LUKEN's** compliance with federal and state drug laws.

5. **DEVONNA MILLER-WEST**, a pharmacist licensed in the State of West Virginia, owned and operated **WESTSIDE PHARMACY** located in Oceana, West Virginia. **MILLER-WEST's** pharmacy purchased controlled substances from **MIAMI-LUKEN**.

6. **SAMUEL R. BALLENGEE**, a/k/a "Randy Ballengee," a pharmacist licensed in the State of West Virginia, owned and operated **TUG VALLEY PHARMACY**, in Williamson, West Virginia. **BALLENGEE's** pharmacy purchased controlled substances from **MIAMI-LUKEN**.

The Controlled Substances Act

7. The Controlled Substances Act (CSA) governs the manufacture, distribution, and dispensation of controlled substances in the United States. The term "controlled substance" means a drug or other substance, or immediate precursor, included in Schedule I, II, III, IV, and V, as designated by 21 U.S.C. § 802(6) and the Code of Federal Regulations. With limited exceptions for medical professionals, the CSA makes it "unlawful for any person knowingly or intentionally" to "distribute or dispense a controlled substance" or conspire to do so.

8. To distribute controlled substances, a company such as **MIAMI-LUKEN**, must register with the DEA and comply with the laws and regulations imposed by the CSA. A company registered with the DEA to distribute controlled substances is required to maintain “effective control[s] against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels.” 21 U.S.C. § 823(b)(1). A registered distributor is also required to report suspicious orders to the DEA, which are defined by regulation as “orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” 21 C.F.R. § 1301.74(b).

9. The DEA is responsible for enforcing the CSA and its implementing regulations by conducting audits and inspections, reviewing sales data and suspicious order reports, and issuing guidance to registrants as necessary. In 2006, and again in 2007, the DEA issued two letters to all registered distributors outlining the specific obligations of distributors. Specifically, the 2006 letter articulated “[i]n addition to reporting all suspicious orders, a distributor has the statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific and industrial channels.” Rannazzisi letter (2006). Further, the 2007 letter articulated a distributor’s obligation to “conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels.” Rannazzisi letter (2007). The letter further explained that “[r]eporting an order as suspicious w[ould] not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.” Rannazzisi letter (2007).

10. Under 21 C.F.R. § 1304.33, DEA registrants, such as **MIAMI-LUKEN**, must submit information about all transactions in which a Schedule II or Schedule III-N (narcotic) controlled substance is acquired or distributed (i.e., from a supplier to a pharmacy). This

information is transmitted to DEA's Automation of Reports and Consolidated Ordering System ("ARCOS") Unit on a quarterly basis and maintained in a DEA database.

11. 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; it includes the prescribing of controlled substances. The term "distribute" means to deliver (other than by administering or dispensing) a controlled substance.

12. Medical professionals, including doctors and pharmacists, who want to distribute or dispense controlled substances in the course of professional practice, are required to register with the Attorney General of the United States (Attorney General) before they are legally authorized to do so. Such medical professionals are assigned a registration number by the DEA.

13. Medical professionals registered with the Attorney General are authorized under the CSA to write prescriptions for, or to otherwise dispense, Schedule II, III, IV, and V controlled substances, as long as they comply with the requirements of their registration. 21 U.S.C. § 822(b).

14. For doctors, compliance with the terms of their registration means that they can not issue a prescription unless it is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). A doctor violates the CSA and Code of Federal Regulations if he or she issues an order for a controlled substance outside the usual course of professional medical practice and not for a legitimate medical purpose. Such an order is "not a prescription within the meaning and intent of the CSA," and such knowing and intentional violations subjects the doctor to criminal liability under Section 841 of Title 21, United States Code. 21 C.F.R. § 1306.04(a).

15. Under 21 C.F.R. § 1306.04(a), while a prescribing practitioner is responsible for the proper prescribing and dispensing of controlled substances, a corresponding liability rests upon

the pharmacist who fills a prescription. That is, a pharmacist may not fill a prescription issued outside the scope of professional practice and not for a legitimate medical purpose.

16. In a Federal Register Notice dated April 27, 2001 (Vol. 66, Number 82) and entitled “Dispensing and Purchasing Controlled Substance over the Internet,” the DEA set forth the accepted criteria for establishment of a legitimate physician-patient relationship in the prescribing context, based upon that used by state authorities with the endorsement of medical societies. The notice provided that the following four conditions must be met: (1) the patient comes to the physician with a medical complaint; (2) a medical history is taken; (3) the physician performs a physical examination; and (4) there is a logical nexus between the drug prescribed, dispensed, or administered, the medical complaint, the medical history, and the physical examination. Prescriptions not issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice, if knowingly and intentionally made, may form the basis for criminal liability under Title 21, United States Code, Section 841(a)(a).

17. The CSA’s scheduling of controlled substances is based on the controlled substances’ potential for abuse, among other considerations. There are five Schedules of controlled substances: Schedules I, II, III, IV and V. 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 the abuse of the drug or other substance may lead to severe psychological or physical dependence. The term “Schedule III” means the drug or other substance has a potential for abuse and could lead to moderate or low physical and psychological dependence. The term “Schedule IV” means the drug or other substance has a low potential for abuse and low risk of dependence. The term “Schedule V” means the drug or other substance has a low potential for abuse.

18. Pursuant to the CSA and its implementing regulations, oxycodone is classified as a Schedule II narcotic controlled substance based on its high potential for abuse and potential for severe psychological and physical dependence. Oxycodone is sold under a variety of brand names, including OxyContin and Percocet, as well as generic forms. Oxycodone is one of the strongest prescription painkilling substances approved for use in the United States, and it is highly addictive. When abused, oxycodone can be taken orally (in pill form), chewed, or crushed and snorted. Oxycodone causes euphoria and a high that persons with a dependency seek, despite not having a medical need for the drug.

19. Oxycodone, including OxyContin and Percocet, is typically sold on the street in Ohio for up to \$1 per milligram. Percocet is manufactured in strengths containing 5 mg, 7.5 mg, or 10 mg of oxycodone per Percocet tablet.

20. Pursuant to the CSA and its implementing regulations, hydrocodone is classified as a Schedule II drug, effective October 6, 2014. Prior to its classification as a Schedule II drug, hydrocodone was a Schedule III drug. Hydrocodone was changed to a Schedule II narcotic controlled substance based on its potential for abuse and physical and psychological dependence. Hydrocodone is sold generically or under a variety of brand names, including Vicodin, and comes in varying strengths. Hydrocodone can be used to treat pain symptoms under the careful supervision of a physician, but is highly addictive. Hydrocodone causes euphoria and a high that persons with a dependency seek, despite not have a medical need for the drug.

COUNT 1
(Conspiracy to Distribute and Dispense a Controlled Substance)

21. Paragraphs 1 through 20 of the Indictment are realleged and incorporated by reference as though fully set forth herein.

22. From on or about January 1, 2008 through on or about December 7, 2015, in the Southern District of Ohio, and elsewhere, defendants **ANTHONY RATTINI, JAMES BARCLAY, DEVONNA MILLER-WEST, SAMUEL R. BALLENGEE, MIAMI-LUKEN** and unnamed co-conspirators, did knowingly and willfully combine, conspire, confederate and agree with others, both known and unknown to the Grand Jury, to violate 21 U.S.C. § 841(a), that is, to knowingly and intentionally distribute and dispense a mixture and substance containing a detectable amount of oxycodone and hydrocodone, Schedule II and III controlled substances, outside the scope of professional practice and not for a legitimate medical purpose.

Purpose of the Conspiracy

23. It was the purpose of the conspiracy that defendants **ANTHONY RATTINI, JAMES BARCLAY, DEVONNA MILLER-WEST, SAMUEL R. BALLENGEE, MIAMI-LUKEN** and unnamed co-conspirators, unlawfully enriched themselves by: (1) profiting from the unlawful distribution and dispensation of controlled substances; (2) distributing and dispensing large amounts of opioids to known pill mills; and (3) facilitating the diversion of oxycodone and hydrocodone, Schedule II and III controlled substances, for illicit use.

Manner and Means of the Conspiracy

24. It was part of the conspiracy that defendants **ANTHONY RATTINI, JAMES BARCLAY,** and **MIAMI-LUKEN** distributed millions of dosage units of oxycodone and hydrocodone to doctors and pharmacies in the Southern District of Ohio, Kentucky, and West Virginia.

25. It was further part of the conspiracy that defendants **ANTHONY RATTINI, JAMES BARCLAY,** and **MIAMI-LUKEN** failed to maintain effective controls against

diversion of controlled substances, failed to report suspicious orders to the DEA, and continued to ship the dangerous addictive drugs to pharmacies in rural Appalachia where the opioid epidemic was at its peak.

26. It was further part of the conspiracy that defendants **ANTHONY RATTINI** and **JAMES BARCLAY**, and **MIAMI-LUKEN** continued to distribute millions of unit doses of oxycodone and hydrocodone to **WESTSIDE**, **TUG VALLEY**, and other unnamed pharmacies known to the Grand Jury, even after being advised by the DEA of their responsibilities as a wholesaler to ensure drugs are not being diverted for reasons other than legitimate medical purposes and to report suspicious orders.

27. It was further part of the conspiracy that defendants **ANTHONY RATTINI**, **JAMES BARCLAY**, and **MIAMI-LUKEN** filled suspicious orders placed by **DEVONNA MILLER-WEST**, **SAMUEL R. BALLENGEE**, and other unnamed physicians, pharmacists and pharmacies known to the Grand Jury, and continued to supply them with millions of dosage units of oxycodone and hydrocodone.

28. It was further part of the conspiracy that defendants **ANTHONY RATTINI**, **JAMES BARCLAY**, and **MIAMI-LUKEN** failed to maintain effective controls against diversion, and failed to exercise due care in confirming the legitimacy of all orders by continuing to supply millions of dosage units of oxycodone and hydrocodone to **DEVONNA MILLER-WEST**, **SAMUEL R. BALLENGEE**, and other unnamed physicians, pharmacists and pharmacies known to the Grand Jury.

29. It was further part of the conspiracy that defendants **ANTHONY RATTINI**, **JAMES BARCLAY**, **DEVONNA MILLER-WEST**, **SAMUEL R. BALLENGEE**, **MIAMI-LUKEN**, and unnamed co-conspirators, dispensed and distributed oxycodone and hydrocodone,

Schedule II and III controlled substances, knowing the controlled substances were being diverted or likely to be diverted.

30. It was further part of the conspiracy that, in September 2008, defendants **ANTHONY RATTINI, JAMES BARCLAY,** and **MIAMI-LUKEN** distributed more than 10,000 dosage units of oxycodone to an unnamed co-conspirator (hereinafter PHARMACY 1), known to the Grand Jury, after PHARMACY 1 returned thousands of dosage units of oxycodone to **MIAMI-LUKEN** indicating it would no longer fill orders for an unnamed physician (hereinafter PHYSICIAN), known to the Grand Jury, due to concerns over illegal distribution.

31. It was further part of the conspiracy that, during the next month, October 2008, defendants **ANTHONY RATTINI, JAMES BARCLAY,** and **MIAMI-LUKEN** distributed more than 100,000 dosage units of oxycodone to PHARMACY 1, despite knowing the pharmacy and prescribing PHYSICIAN were under DEA investigation for illegal distribution.

32. It was further part of the conspiracy that, beginning in November 2008, defendants **ANTHONY RATTINI, JAMES BARCLAY,** and **MIAMI-LUKEN** distributed more than 750,000 dosage units of oxycodone directly to PHYSICIAN, knowing PHYSICIAN was under DEA investigation for illegal distribution, and knowing other pharmacies refused to fill PHYSICIAN's prescriptions.

33. It was further part of the conspiracy that, despite these red flags, distribution to PHARMACY 1 and PHYSICIAN continued. In fact, from 2008 through 2010, defendants **ANTHONY RATTINI, JAMES BARCLAY,** and **MIAMI-LUKEN** distributed more than 1.8 million dosage units of oxycodone to PHARMACY 1, despite knowing PHARMACY 1 and prescribing PHYSICIAN were under DEA investigation for illegal distribution.

34. It was further part of the conspiracy that, from 2011 through 2015, defendants **ANTHONY RATTINI, JAMES BARCLAY,** and **MIAMI-LUKEN** ignored obvious signs of

abuse and diversion by distributing more than 2.3 million dosage units of oxycodone and 2.6 million dosage units of hydrocodone to **DEVONNA MILLER-WEST** and **WESTSIDE** in a town of approximately 1,394 people.

35. It was further part of the conspiracy that defendants **ANTHONY RATTINI**, **JAMES BARCLAY**, and **MIAMI-LUKEN** distributed tens of thousands of dosage units to **DEVONNA MILLER-WEST**, **SAMUEL R. BALLENGEE** and other unnamed co-conspirators, both known and unknown to the Grand Jury, which violated **MIAMI-LUKEN**'s own internal control policy.

36. It was further part of the conspiracy that defendants **ANTHONY RATTINI**, **JAMES BARCLAY**, and **MIAMI-LUKEN** regularly exceeded the internal threshold limit that they had set for **DEVONNA MILLER-WEST** at **WESTSIDE**, which was at 6,000 dosage units of oxycodone per month. For example, in March 2011, **ANTHONY RATTINI**, **JAMES BARCLAY**, and **MIAMI-LUKEN** distributed 68,400 dosage units of oxycodone to **WESTSIDE**, more than eleven times the limit. In May 2011, **MIAMI-LUKEN**'s internal records indicated that **WESTSIDE**'s oxycodone purchases should be monitored. That same month, however, **ANTHONY RATTINI**, **JAMES BARCLAY**, and **MIAMI-LUKEN** distributed 63,900 dosage units of oxycodone to **WESTSIDE**, more than ten times the limit. Similarly, in December 2012, **ANTHONY RATTINI**, **JAMES BARCLAY**, and **MIAMI-LUKEN** distributed 50,300 dosage units of oxycodone to **WESTSIDE**, approximately eight times the limit. In January 2014, **ANTHONY RATTINI**, **JAMES BARCLAY**, and **MIAMI-LUKEN** distributed 54,700 dosage units of oxycodone to **WESTSIDE**, more than nine times the limit.

37. It was further part of the conspiracy that, in August 2008, defendants **ANTHONY RATTINI**, **JAMES BARCLAY**, and **MIAMI-LUKEN** began shipping to **SAMUEL R. BALLENGEE** and **TUG VALLEY**. In September 2008, the first full month as a client, **SAMUEL**

R. BALLENGEE and TUG VALLEY purchased 120,700 dosage units of hydrocodone from **MIAMI-LUKEN**.

38. It was further part of the conspiracy that, from 2008 through 2014, defendants **ANTHONY RATTINI, JAMES BARCLAY,** and **MIAMI-LUKEN** distributed more than 6 million dosage units of hydrocodone to **SAMUEL R. BALLENGEE** and TUG VALLEY.

39. It was further part of the conspiracy that, in distributing the more than 6 million dosage units, defendants **ANTHONY RATTINI, JAMES BARCLAY,** and **MIAMI-LUKEN** regularly exceeded the internal threshold limit that they set for TUG VALLEY, which was 36,000 dosage units of hydrocodone per month. For example, in December 2013, **ANTHONY RATTINI, JAMES BARCLAY,** and **MIAMI-LUKEN** distributed 67,200 dosage units of hydrocodone to TUG VALLEY, almost double the limit.

40. It was further part of the conspiracy that, from 2012 through 2014, defendants **ANTHONY RATTINI, JAMES BARCLAY,** and **MIAMI-LUKEN** distributed more than 2.2 million dosage units of oxycodone and more than 200,000 dosage units of hydrocodone to an unnamed co-conspirator, known to the Grand Jury (herein after PHARMACY 3).

41. It was further part of the conspiracy that, from December 2012 through March 2014, defendants **ANTHONY RATTINI, JAMES BARCLAY,** and **MIAMI-LUKEN** regularly exceeded the internal threshold limit that they set for PHARMACY 3, which was 86,000 dosage units of oxycodone per month. For example, in March 2013, **ANTHONY RATTINI, JAMES BARCLAY,** and **MIAMI-LUKEN** distributed 139,500 dosage units of oxycodone to PHARMACY 3, more than 53,000 dosage units above the limit.

42. It was further part of the conspiracy that when **MIAMI-LUKEN's** internal Suspicious Order Monitoring System (SOMS) flagged many of these orders, the defendants

ANTHONY RATTINI, JAMES BARCLAY, and MIAMI-LUKEN failed to conduct any due diligence or report the suspicious orders of PHARMACY 3 to the DEA, as is required by law.

43. It was further part of the conspiracy that, from 2008 through 2011, defendants **ANTHONY RATTINI, JAMES BARCLAY, and MIAMI-LUKEN** distributed more than 3.7 million dosage units of hydrocodone to an unnamed co-conspirator Pharmacy, known to the Grand Jury, (herein after PHARMACY 6), located in Kermit, West Virginia, a town of approximately 400 people.

44. It was further part of the conspiracy that, from 2008 through 2014, defendants **ANTHONY RATTINI, JAMES BARCLAY, and MIAMI-LUKEN** distributed more than 5 million dosage units of oxycodone to an unnamed co-conspirator Pharmacy, known to the Grand Jury (herein after PHARMACY 7).

45. It was further part of the conspiracy that defendants **ANTHONY RATTINI, JAMES BARCLAY, and MIAMI-LUKEN** distributed more than 5 million dosage units of oxycodone to PHARMACY 7.

46. It was further part of the conspiracy that, from at least June 2012 through July 2014, defendants **ANTHONY RATTINI, JAMES BARCLAY, and MIAMI-LUKEN** regularly exceeded the internal threshold limit that they had set for PHAMRACY 7, which was 41,000 dosage units of oxycodone per month. For example, in January 2013, **ANTHONY RATTINI, JAMES BARCLAY, and MIAMI-LUKEN** distributed 124,400 dosage units of oxycodone to PHARMACY 7, which more than triple the limit.

47. It was further part of the conspiracy that, from 2013 to 2014, defendants **ANTHONY RATTINI, JAMES BARCLAY, and MIAMI-LUKEN** distributed more than 500,000 dosage units of oxycodone to an unnamed co-conspirator, known to the Grand Jury (herein after PHARMACY 8).

48. It was further part of the conspiracy that, from 2012 to 2014, defendants **ANTHONY RATTINI**, **JAMES BARCLAY**, and **MIAMI-LUKEN** distributed more than 150,000 dosage units of oxycodone and more than 600,000 dosage units of hydrocodone to an unnamed co-conspirator, known to the Grand Jury (herein after PHARMACY 9).

49. It was further part of the conspiracy that **MIAMI-LUKEN** treated its subsidiary pharmacies differently than co-conspirator pharmacies by tracking their sales and annual prescriptions. On average, **MIAMI-LUKEN's** subsidiary pharmacies filled around 40,000 prescriptions annually, including controlled and non-controlled substances.

50. It was further part of the conspiracy that defendants **ANTHONY RATTINI**, **JAMES BARCLAY** and **MIAMI-LUKEN** obtained utilization reports on co-conspirator pharmacies, which indicated the payment methods accepted by co-conspirator pharmacies. Both **RATTINI** and **BARCLAY** knew pharmacies that accepted cash only payment was a red flag of diversion.

51. It was further part of the conspiracy that defendants **ANTHONY RATTINI**, **JAMES BARCLAY** and **MIAMI-LUKEN** obtained a report of Schedule II controlled substance dispensing history from co-conspirator **DEVONNA MILLER-WEST**, which identified patients paying cash and those paying with West Virginia Medicaid.

52. It was further part of the conspiracy that **DEVONNA MILLER-WEST** and **SAMUEL R. BALLENGEE** purchased excessive amounts of controlled substances from **MIAMI-LUKEN** through their respective pharmacies. As pharmacists, **DEVONNA MILLER-WEST** and **SAMUEL R. BALLENGEE** failed to ensure that controlled substances were distributed properly, for a legitimate medical purpose, ignoring obvious signs of abuse and diversion. **DEVONNA MILLER-WEST** and **SAMUEL R. BALLENGEE** distributed controlled substances, namely oxycodone and hydrocodone, Schedule II and III controlled

substances, to customers outside the scope of professional practice and not for a legitimate medical purpose.

53. It was further part of the conspiracy that defendants **ANTHONY RATTINI, JAMES BARCLAY, DEVONNA MILLER-WEST, SAMUEL R. BALLENGEE, MIAMI-LUKEN** and unnamed co-conspirators dispensed and distributed oxycodone and hydrocodone, Schedule II and III controlled substances, outside the scope of professional practice and not for a legitimate medical purpose.

All in violation of 21 U.S.C. § 846.

A TRUE BILL.

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FOREPERSON

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