

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

No. 17-mj-02939-AOR

UNITED STATES OF AMERICA

vs.

REYNALDO OCANA,

Defendant.

CRIMINAL COVER SHEET

1. Did this matter originate from a matter pending in the Northern Region of the United States Attorney's Office prior to October 14, 2003? ___ Yes X No
2. Did this matter originate from a matter pending in the Central Region of the United States Attorney's Office prior to September 1, 2007? ___ Yes X No

Respectfully submitted,

BENJAMIN G. GREENBERG
ACTING UNITED STATES ATTORNEY

BY:



JAMES V. HAYES
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UNITED STATES DISTRICT COURT

for the
Southern District of Florida

United States of America

v.

REYNALDO OCANA

Case No. 17-mj-02939-AOR

Defendant(s)

CRIMINAL COMPLAINT

I, the complainant in this case, state that the following is true to the best of my knowledge and belief.

On or about the date(s) of July - August, 2016 in the county of Miami-Dade in the
Southern District of Florida, the defendant(s) violated:

Code Section

21 U.S.C. § § 331(t) and 333(b)(1)
(D) and 352(e)(2)(A), and 353(e)

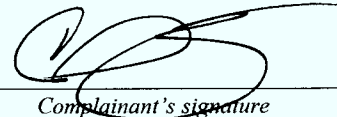
Offense Description

Prescription drug diversion, in violation of Title 21, United States Code, Sections 331(t), 333(b)(1)(D), 353(e)(2)(A), and 353(e)(1)(A)(i)(I) by knowingly engaging in the wholesale distribution in interstate commerce of prescription drugs subject to 21 U.S.C. § 353(b)(1) in a State, to wit, the State of Florida, without being licensed to engage in such activity by the State of Florida which required such licensure.

This criminal complaint is based on these facts:

SEE ATTACHED AFFIDAVIT.

☒ Continued on the attached sheet.


Complainant's signature

CESAR D ZAYAS, HHS-OIG
Printed name and title

Sworn to before me and signed in my presence.

Date: 7/2/17


Judge's signature

City and state: Miami, Florida

ALICIA M. OTAZO REYES, U.S. MAG. JUDGE
Printed name and title

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

No. 17-mj-02939-AOR

File under seal

**AFFIDAVIT OF SPECIAL AGENT CESAR ZAYAS IN SUPPORT OF
CRIMINAL COMPLAINT**

I, Special Agent Cesar D. Zayas, being duly sworn, do hereby depose and state:

Affiant's Background

1. I am a Special Agent with the Department of Health and Human Services Office of the Inspector General (HHS/OIG) and I am currently assigned to the Miami Regional Office. Prior to this, I was a Special Agent with the U.S. Food and Drugs Administration Office of Criminal Investigations. I have been employed in this capacity for over seven years. I am assigned to the South Florida Healthcare Fraud Strikeforce, which consists of Agents from the FBI and Health and Human Services - Office of the Inspection General, along with attorneys from The Department of Justice and the United States Attorney's Office. The Healthcare Fraud Strikeforce is responsible for investigating healthcare related crimes, primarily against the Medicare program.

2. The statements contained in this affidavit are based in part on information provided by Special Agents with the Department of Health and Human Services Office of the Inspector General ("HHS/OIG"), Homeland Security Investigations ("HIS), Food and Drugs Administration Office of Criminal Investigations ("FDA/OCI"), other law enforcement officers, and my experience and background as a special agent. Except where indicated, all statements referred to below are set forth in substance and in part, rather than verbatim. I am personally involved in conducting this investigation along with

investigators and representatives from the Medicare Prescription Drug Integrity Contractor ("MEDIC"). The statements contained in this affidavit are based upon information and analysis conducted by law enforcement, and a review of both public and private records. Because this affidavit is provided for the limited purpose of establishing probable cause, it does not include every fact known by myself and others concerning this investigation, but rather sets forth only those facts that I believe are necessary to establish probable cause.

3. I have set forth herein only such information as I believe necessary to establish probable cause to believe that Reynaldo OCANA committed several violations of federal law, to wit, diversion of prescription drugs by acting as an improper wholesale distributor of prescription drugs in violation of Title 21, United States Code, Sections 331(t), 333(b)(1)(D), 353(e)(2)(A), and 353(e)(1)(A)(i)(I), by knowingly engaging in the wholesale distribution in interstate commerce of prescription drugs subject to 21 U.S.C. § 353(b)(1) in a State, to wit, the State of Florida, without being licensed to engage in such activity by the State of Florida, and to defraud the United States by impairing, impeding, obstructing, and defeating through deceitful and dishonest means, the lawful government functions of the FDA in its administration and oversight of prescription drug distribution, and to commit certain offenses against the United States, that is with the intent to defraud and mislead, failing to provide transaction history, transaction information, and a transaction statement as required by 21 U.S.C. § 360eee-1(c)(1)(A)(iii), in violation of 21 U.S.C. § 331(t) and 333(a)(2).

FEDERAL LAW GOVERNING PRESCRIPTION DRUG DISTRIBUTION

4. The United States Food and Drug Administration (“FDA”) was the federal agency charged with the responsibility of protecting the health and safety of the American public by enforcing the Federal Food, Drug and Cosmetic Act (“FDCA”). Title 21, United States Code, § 301 et seq., including regulating the wholesale distribution of prescription drugs.

5. The FDA was also responsible for, among other things, the regulatory supervision and oversight of the pharmaceutical industry and related business sectors involved in the manufacture, labeling, packaging, sale, distribution or dispensing of prescription drugs.

6. One purpose of the FDCA was to ensure that drugs sold for use by humans were safe and genuine. The FDA’s responsibilities under the FDCA included regulating the manufacture, labeling, and distribution of all drugs, including prescription drugs shipped and received in interstate commerce.

7. Under the FDCA, the term “drug” included articles, which were intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans, and articles which were intended to affect the structure or function of the human body. 21 U.S.C. § 321(g)(1)(B) and (C).

8. Under the FDCA, a “prescription drug” included a drug that: (a) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, was not safe for use except under the supervision of a practitioner licensed by law to administer such drug, *see* 21 U.S.C. § 353(b)(1)(A); or (b) was limited by an approved application under Section 505 of the

9. FDCA (21 U.S.C. § 355) to use under the professional supervision of a practitioner licensed by law to administer such drug, see 21 U.S.C. § 353(b)(1)(B).

Wholesale Distribution of Prescription Drugs

10. United States drug manufacturers generally distributed their prescription drugs to pharmacies, hospitals, and customers through licensed wholesale distributors.

11. Prescription drug manufacturers generally supplied their prescription drug products to pharmacies, hospitals and other prescription drug dispensing facilities at the retail level (hereinafter collectively referred to as “dispensers”) through a chain of wholesale distributors in connection with a process regulated by the FDA, which was commonly referred to as “wholesale distribution.”

12. A prescription drug was frequently bought and sold by numerous licensed wholesale distributors before being purchased by a pharmacy, hospital, or consumer.

13. Some pharmacies obtained drugs from unlicensed sources who sold drugs at prices significantly below the average wholesale price of the drug. Those sources may have stolen these drugs themselves and/or purchased counterfeit, stolen or expired drugs, or drugs that were previously dispensed and resold by the patient for whom the drug was prescribed, and were thus reintroduced into the wholesale distribution chain.

14. The term “prescription drug diversion” described certain wholesale distributions of prescription drugs, which had earlier been obtained and removed (“diverted”) from the chain of lawful wholesale distributors through unlawful means, including theft, fraud, or purchases from individual patients for whom prescription drugs had been prescribed and dispensed but intentionally not consumed. Through this same process, diverted prescription drugs were unlawfully distributed and resold by individuals

acting as unlicensed wholesale distributors to other individuals also acting as unlicensed wholesale distributors, or to pharmacies and other dispensers unlawfully engaged in such activity, all for the purpose of illegal sales. This illegal form of wholesale distribution resulted in the unlawful reintroduction of such diverted prescription drugs back into the wholesale distribution chain.

Wholesale Prescription Drug Distribution Licensing Requirements

11. To prevent prescription drug diversion, as well as the distribution of counterfeit, stolen, or substandard drugs, Congress enacted the Prescription Drug Marketing Act (“PDMA”) which amended and was incorporated into the FDCA and remained in effect until January 1, 2015.

12. Before January 1, 2015, under the FDCA and PDMA, no person could engage in the wholesale distribution in interstate commerce of prescription drugs in a State unless such person was licensed by the State in accordance with guidelines established under 21 U.S.C. § 353(e)(2)(B). *See* 21 U.S.C. § 353(e) (2) (A).

13. In order to further protect the integrity of the nation’s prescription drug distribution system, Congress passed relevant portions of the Drug Supply Chain Security Act (“DSCSA”) which made a variety of additional amendments to the FDCA effective January 1, 2015. Under the DSCA, the above prohibition concerning wholesale prescription drug distribution was modified and the applicable statute was renumbered as 21 U.S.C. § 353(e) (1) (A). Under these DSCA amendments, no person could engage in the unlicensed wholesale distribution of a prescription drug in any State from which the prescription drug was distributed if that State had an established wholesale drug distribution licensure requirement. *See* 21 U.S.C. § 353(e)(1)(A).

14. Throughout the relevant period, both before and after January 1, 2015, the State of Florida had an established licensure requirement in effect which mandated that an individual engaged in the wholesale distribution of prescription drugs in the State of Florida was required to be licensed by the State of Florida. Under the PDMA, no person may engage in the wholesale distribution in interstate commerce of prescription drugs in a State unless such person is licensed by the State. *See* 21 U.S.C. § 353(e)(1)(A). As such, every wholesale distributor in a State who engages in wholesale distributions of prescription drugs in interstate commerce must be licensed by the State licensing authority. *See* 21 C.F.R. § 205.4.

15. “Wholesale distribution” was defined in the FDCA to include the distribution of prescription drugs to other than the consumer or patient but not including intra-company sales and certain other types of exempt prescription drug transactions. *See* 21 U.S.C. § 353(e)(3)(B) (effective prior to January 1, 2015) and 21 U.S.C. § 353(e)(4) (effective January 1, 2015). “Wholesale distribution” means distribution of prescription drugs to a person other than a consumer or patient or receipt of prescription drugs by a person other than the consumer or patient, excluding intra-company sales. *See* 21 U.S.C. § 353 (e)(4). A wholesale distributor is a person other than a manufacturer, a manufacturer’s licensed partner, a third party logistics provider or re-packager engaged in wholesale distribution as defined in 21 U.S.C. § 353(e)(4).

16. Under Title 21 U.S.C. § 331(t), it was a prohibited act to engage in the distribution of prescription drugs in violation of either 21 U.S.C. § 353(e)(2)(A) or, as amended effective January 1, 2015, in violation of 21 U.S.C. § 353(e)(1)(A).

17. Under the FDCA, it is unlawful to engage in the distribution of drugs in violation of 21 U.S.C. § 353(e), and it is unlawful to fail to otherwise comply with the requirements of 21 U.S.C. § 353(e). *See* 21 U.S.C. § 331(t).

18. The PDMA defines the term "authorized distributors of record," as those distributors with whom a manufacturer has an established ongoing relationship to distribute such manufacturer's products. *See* 21 U.S.C. § 353(d)(4).

Transaction History Requirements

19. On November 27, 2013, the Drug Supply Chain Security Act (DSCSA) was enacted to protect the integrity of the nation's drug distribution system. Effective January 1, 2015, the FDCA, as amended by the DSCSA, imposes several requirements on wholesale distributors of most prescription drugs, including certain product tracing requirements. Specifically, wholesale distributors of prescription drugs who did not purchase a prescription drug product directly from the manufacturer, the exclusive distributor of the manufacturer, or a repackager that purchased directly from the manufacturer must, prior to or at the time of each transaction, provide to the subsequent purchaser a transaction history, transaction information, and transaction statement. 21 U.S.C. 360eee-1 (c) (I) (A) (iii).¹

20. Transaction history means a statement in paper or electronic form that includes the transaction information for each prior transaction going back to the manufacturer of the drug product. 21 U.S.C. § 360eee (25). Transaction information

¹ On December 31, 2014, FDA issued a Compliance Policy Guidance that announced that FDA did not intend to take action against trading partners, including wholesale drug distributors, who did not prior to May 1, 2015 provide transaction history, transaction information, and transaction statement as required by the DSCSA.

includes, among other things, the strength and dosage form of the drug product, the number of containers, the lot number of the drug product, the business name and address of the persons from whom and to whom ownership is being transferred. 21 U.S.C. § 360eee (26). Transaction statement means a statement in paper or electronic form that the entity transferring ownership of a drug product that complies with certain provisions of the DSCSA. 21 U.S.C. § 360eee (27).

21. The failure to provide the transaction statement, transaction history, and transaction information as required by 21 U.S.C. § 360eee-1(c)(1)(A)(iii) is a prohibited act under the FDCA.. See 21 U.S.C. § 331 (t). If the offense is committed with intent to defraud or mislead, the offense is a felony punishable by up to three years in prison for each count.

THE OFFENSE CONDUCT

22. On August 15, 2016, CS (confidential source) conducted a consented monitored telephonic conversation with target subject REYNALDO OCANA at approximately 11:46am. Present during this telephonic conversation ^{wac CD. 2. aof} law enforcement officers, OCANA called the CS from telephone number 954-505-6701. During the conversation, OCANA asked if the CS had talked with his friend or contact in regards to the purchase of diverted prescription drugs per a previous undocumented encounter between them (CS and OCANA). CS informed OCANA that his contact was willing to buy if he could pay just 35% of the actual price or WAC (wholesale acquisition cost). OCANA agreed to these terms and agreed to meet later at OCANA's place of business (LUXURIA BESPOKE AUTO) to discuss the exact prescription drugs, the amounts and other pertinent details.

23. On August 17, 2016, CS sent a text message to target subject REYNALDO OCANA at cellular phone number 954-505-6701 indicating that he would meet with his friend/contact at 1:30pm for lunch, to discuss the possibility of purchasing diverted prescription drugs from OCANA. CS indicated that he would meet with OCANA after the meeting with his friend/contact. At approximately 4:00pm, law enforcement met with CS at an undisclosed location to brief CS prior to his meeting with OCANA and discuss all operational details and electronic surveillance equipment and provided the CS with a writing list of the alleged diverted prescription drugs that the alleged CS's contact would be interested in purchasing. The list was comprised of three different HIV drugs, TRUVADA, ISENTRESS and COMPLERA with willing price to be paid \$445.00, \$400.00 and \$725.00 all these prices per bottle.

24. At approximately 4:45pm, law enforcement conducted a consensual monitored recorded meeting between CS and REYNALDO OCANA at 711 NW 23rd Street, Miami, FL 33127, LUXURIA BESPOKE AUTO, OCANA's alleged place of business. Once the CS arrived at this location, CS provided OCANA with list of the desired prescription drugs. OCANA informed the CS that the higher the volume of the ordered made the more money everyone would make on these deals. CS stated to OCANA that his contact had been burned in the past and he would only do a small purchase to ensure the quality of the prescription drugs. OCANA also stated that he would pay the CS 3 points (3%) for any purchases the CS would bring to him. After the discussion, OCANA decided to bring the CS inside his office. Inside the CS, recognize at least three individuals that are frequently at this location. CS waited for OCANA for a few minutes and later OCANA walked the CS to his car. Inside the CS car OCANA

office, he g's C.D.2. AOR

explained the CS how the prices are based on WAC (wholesale acquisition cost) and emphasized that the money in this business depends in on the volume of orders made. OCANA asked the CS if his contact had any concerns with the expiration dates and the CS stated that they could not have less than a year of expiration because these drugs would go straight to pharmacies. OCANA also emphasized to the CS to tell his contact that he has all the medications he would need. Upon the conclusion of the conversation, OCANA exited the CS's vehicle.

25. On August 30, 2016, at approximately 11:45am agents conducted a consensual monitored recorded meeting between CS and REYNALDO OCANA near 711 NW 23rd Street, Miami, FL 33127, LUXURIA BESPOKE AUTO. Once the CS arrived, OCANA instructed the CS to remain in his vehicle at which time OCANA entered the CS vehicle. Once inside the vehicle OCANA informed the CS that for the amount of money he was bringing for the transaction, 12 bottles of COMPLERA was the right amount instead of 15, for the \$10,000. The CS proceeded to exchange the \$10,000 for the 12 bottles of COMPLERA with OCANA. Following the transaction, OCANA gave the CS 6 bottles of the HIV prescription drug ATRIPLA. OCANA stated that this was for the CS to show his business associate and for him to keep these bottles at \$700 each. OCANA and the CS also discuss an additional business opportunity in which the CS would provide OCANA his mailing address in order for OCANA to have large boxes of the diverted prescription drugs that he receives from a source through the mail. OCANA stated to the CS that he does these type of business with other people and that he is willing to pay \$400 per shipment. Both agreed to pursue this opportunity in the near future. After this discussion, the meeting concluded.

26. On 09/08/2016, at approximately 2:35pm agents conducted a consensual monitored recorded meeting between CS and REYNALDO OCANA near 711 NW 23rd Street, Miami, FL 33127, LUXURIA BESPOKE AUTO. Once the CS arrived, OCANA took the CS inside the auto shop. There they engaged in conversation with unidentified males. Later both the CS and OCANA entered the CS vehicle where the exchange of \$4,600 in cash for the diverted prescription drugs previously delivered by OCANA. CS inquired if OCANA was going to have a box deliver to his address per their last meeting when OCANA offered the CS the opportunity to make extra money by receiving a box of diverted prescription drugs to his home address. OCANA told him he was working on that and that it would be coming soon. OCANA also stated to the CS that he was ready to accept any new orders of drugs at any time.

CONCLUSION

WHEREFORE, based on the foregoing, your affiant believes there is probable cause to believe that Reynaldo OCANA did engage in the diversion of prescription drugs by acting as an improper wholesale distributor of prescription drugs in violation of Title 21, United States Code, Sections 331(t), 333(b)(1)(D), 353(e)(2)(A), and 353(e)(1)(A)(i)(I), by knowingly engaging in the wholesale distribution in interstate commerce of prescription drugs subject to 21 U.S.C. § 353(b)(1) in a State, to wit, the State of Florida, without being licensed to engage in such activity by the State of Florida, and to defraud the United States by impairing, impeding, obstructing, and defeating through deceitful and dishonest means, the lawful government functions of the FDA in its administration and oversight of prescription drug distribution, and to commit certain offenses against the United States, that is with the intent to defraud and mislead, failing to

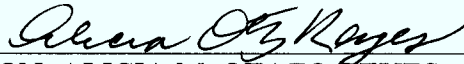
provide transaction history, transaction information, and a transaction statement as required by 21 U.S.C. § 360eee-l(c)(l)(A)(iii), in violation of 21 U.S.C. § 331(t) and 333(a)(2).

FURTHER AFFIANT SAYETH NAUGHT



Cesar D. Zayas
Special Agent
US Department of Health Human Services
Office of the Inspector General

Subscribed and sworn before me this 7th day of July, 2017 in Miami, Florida.



HON. ALICIA M. OTAZO REYES
UNITED STATES MAGISTRATE JUDGE