Case 1:17-cr-20486-RNS Document 1 Entered on FLSD Docket 07/10/2017

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UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF FLORIDA

17-20486-CR-SCOLA/TORRES

18 U.S.C. § 371 21 U.S.C. § 331(t) 21 U.S.C. § 333(b)(1)(D) 21 U.S.C. § 353(e)(1)(A) 21 U.S.C. § 353(e)(2)(A) 18 U.S.C. § 982(a)(7)

UNITED STATES OF AMERICA

VS.

JOSE DE JESUS RODRIGUEZ,

Defendants.	

INDICTMENT

The Grand Jury charges that:

GENERAL ALLEGATIONS

At all times material to this Indictment:

- 1. 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.
- 2. 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.
- 3. 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.

- 4. 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).
- 5. 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)(l)(A); or (b) was limited by an approved application under Section 505 of the 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

- 6. United States drug manufacturers generally distributed their prescription drugs to pharmacies, hospitals, and customers through licensed wholesale distributors.
- 7. 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."
- 8. A prescription drug was frequently bought and sold by numerous licensed wholesale distributors before being purchased by a pharmacy, hospital, or consumer.

- 9. 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.
- 10. 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 repackager 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).

The Prescription Drugs

- 19. The prescription drugs listed below in paragraph 20 were drugs within the meaning of 21 U.S.C. § 321(g)(1)(c), and were prescription drugs within the meaning of 21 U.S.C. § 353(b)(1) that could be safely used only under the professional supervision of a licensed practitioner.
- 20. The respective manufacturers and approved uses of these prescription drugs were as follows:

PRESCRIPTION DRUG	MANUFACTURER	APPROVED USE(S)
Abilify	Otsuka America Pharm, Inc.	Anti-Depressant
Advair	GlaxoSmithKline	Asthma
Atripla	Bristol-Myers Squibb and Gilead	HIV Medication

PRESCRIPTION DRUG	MANUFACTURER	APPROVED USE(S)
Complera	Gilead	HIV Medication
Cymbalta	Eli Lilly	Anti-Depressant
Isentress	Merck	HIV Medication
Neulasta	Amgen Ltd.	Cancer Medication
Nexium	AstraZenca	Acid Reflux
Norvir	AbbVie	HIV Medication
Prezista	Janssen	HIV Medication
Reyataz	Bristol-Myers Squibb	HIV Medication
Stribild	Gilead	HIV Medication
Tivicay	GlaxoSmithKline	HIV Medication
Truvada	Gilead	HIV Medication
Valcyte	Hoffman La-Rouche	HIV Medication
Viread	Gilead	HIV Medication / Hepatitis B
Zyprexa	Eli Lilly	Schizophrenia and Bipolar Disorder

21. The manufacturers listed in paragraph 20 were the only legal manufacturers of each listed prescription drug. The listed prescription drugs were all manufactured at facilities outside the state of Florida, and were each distributed in interstate commerce throughout the United States, including in the State of Florida.

The Defendant and Related Entities

22. Defendant **JOSE DE JESUS RODRIGUEZ** was a resident of Miami-Dade County, Florida, and was the President and Registered Agent of Universal Community Mental Care, Inc.

- 23. Co-conspirator 1 was a resident of Miami-Dade County, Florida.
- 24. Co-conspirator 2 was a resident of Miami-Dade County, Florida.
- 25. Co-conspirator 3 was a resident of Miami-Dade County, Florida.
- 26. Co-conspirator 4 was a resident of Fort Bend County, Texas.
- 27. Co-conspirator 5 was a resident of Fort Bend County, Texas.
- 28. Co-conspirator 6 was a resident of Miami-Dade County, Florida.
- 29. Co-conspirator 7 was a resident of Miami-Dade County, Florida.
- 30. Cobra Wholesale & Distributor, Inc., located at 8000 N.W. 42nd Terrace, Miami, Florida, was a Florida corporation, incorporated on or about July 4, 2011, that purportedly did business in Miami-Dade County.
- 31. Allied Supplies, Inc., located at 840 N.W. 7th Street, Miami, Florida, was a Florida corporation, incorporated on or about April 13, 2012, that purportedly did business in Miami-Dade County.
- 32. West Star Supply, Inc., located at 5560 W. 7th Avenue, Hialeah, Florida, was a Florida corporation, incorporated on or about May 18, 2012, that purportedly did business in Miami-Dade County.
- 33. Southpoint Wholesale, Inc., located at 2730 N.W. 20th Street, Miami, Florida, was a Florida corporation, incorporated on or about May 18, 2012, that purportedly did business in Miami-Dade County.
- 34. Amerisol Wholesale & Distributor, Inc., located at 8040 S.W. 8th Street, Miami, Florida, was a Florida corporation, incorporated on or about March 1, 2012, that purportedly did business in Miami-Dade County.

35. Universal Community Mental Care, Inc., locate at 928 S.W. 82nd Avenue, Miami, Florida, was a Florida corporation, incorporated on or about January 14, 2008, that purportedly did business in Miami-Dade County providing health care services.

COUNT 1

Conspiracy to Defraud the United States and Engage in Unlicensed Wholesale Distribution of Prescription Drugs (18 U.S.C. § 371)

- 1. The General Allegations section of this Indictment is re-alleged and incorporated by reference as though fully set forth herein.
- 2. From in or around August 2011, through on or about March 2015, in Miami-Dade County, in the Southern District of Florida, and elsewhere, the defendant,

JOSE DE JESUS RODRIGUEZ,

did willfully, that is with the intent to further the objects of the conspiracy, and knowingly combine, conspire, confederate and agree with other persons, known and unknown to the Grand Jury:

- a. 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;
- b. to violate Title 21, United States Code, Sections 331(t), 333(b)(1)(D), and 353(e)(2)(A), 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; and

c. to violate Title 21, United States Code, Sections 331(t), 333(b)(1)(D), 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.

THE PURPOSE OF THE CONSPIRACY

3. It was the purpose of the conspiracy for the defendant and his co-conspirators to unlawfully enrich themselves and others by engaging in the unlawful wholesale distribution of prescription drugs.

MANNER AND MEANS

The manner and means by which the defendant and his co-conspirators sought to accomplish the objects and purpose of the conspiracy included, among others, the following

- 4. **JOSE DE JESUS RODRIGUEZ** illegally obtained prescription drugs from Co-Conspirators 1, 2, and 3, and from other unidentified sources.
- 5. **JOSE DE JESUS RODRIGUEZ**, without a license from the State of Florida to engage in the wholesale distribution of prescription drugs in Florida, then supplied Co-conspirators 4, 5, 6, and 7 with these diverted prescription drugs and did not provide a transaction statement, transaction history or transaction information as required by the PDMA.
- 6. In return for the diverted prescription drugs delivered to Co-conspirators 4, 5, 6, 7, and others, **JOSE DE JESUS RODRIGUEZ** received payment in cash and by checks written to shell companies that he controlled in the approximate amount of \$3.8 million.

7. **JOSE DE JESUS RODRIGUEZ** set up the shell companies that received payment for diverted prescription drugs by using the identities of patients that were billed at Universal Community Mental Care, Inc., a clinic that he owned and controlled.

OVERT ACTS

In furtherance of the conspiracy, and to accomplish its purpose and objects, at least one of the co-conspirators committed and caused to be committed, in the Southern District of Florida and elsewhere, at least one of the following overt acts, among others:

- 1. In or around August 2011, **JOSE DE JESUS RODRIGUEZ** bought diverted prescription drugs from Co-conspirator 3.
- 2. On or about August 30, 2011, Co-conspiraor 3 paid **JOSE DE RODRIGUEZ** for diverted prescription drugs by a corporate bank check to Cobra Wholesale & Distributor, Inc., in the approximate amount of \$14,752.
- 3. In or around September 2011, **JOSE DE JESUS RODRIGUEZ** bought diverted prescription drugs from Co-conspirator 3.
- 4. On or about September 1, 2011, Co-conspirator 3 paid **JOSE DE RODRIGUEZ** for diverted prescription drugs by a corporate bank check to Cobra Wholesale & Distributor, Inc., in the approximate amount of \$15,248.
- 5. In or around November 2011, **JOSE DE JESUS RODRIGUEZ** bought diverted prescription drugs from Co-conspirator 3.
- 6. On or about November 15, 2011, Co-conspirator 3 paid **JOSE DE RODRIGUEZ** for diverted prescription drugs by a corporate bank check to Cobra Wholesale & Distributor, Inc., in the approximate amount of \$33,000.

- 7. In or around February 2012, **JOSE DE JESUS RODRIGUEZ** bought diverted prescription drugs from Co-conspirator 3.
- 8. On or about February 17, 2012, Co-conspirator 3 paid **JOSE DE RODRIGUEZ** for diverted prescription drugs by a corporate bank check to Cobra Wholesale & Distributor, Inc., in the approximate amount of \$46,781.
- 9. In or around May 2012, **JOSE DE JESUS RODRIGUEZ**, illegally distributed diverted prescription drugs to Co-conspirators 4 and 5.
- 10. On or about May 9, 2012, Co-conspirators 4 and 5 paid **JOSE DE RODRIGUEZ** for diverted prescription drugs by a cashier's check to Allied Supplies, Inc., in the approximate amount of \$68,469.
- 11. In or around June 2012, **JOSE DE JESUS RODRIGUEZ**, illegally distributed diverted prescription drugs to Co-conspirators 4 and 5.
- 12. On or about June 27, 2012, Co-conspirators 4 and 5 paid **JOSE DE RODRIGUEZ** for diverted prescription drugs by a cashier's check to West Star Supply, Inc.., in the approximate amount of \$92,768.
- 13. In or around July 2012, **JOSE DE JESUS RODRIGUEZ**, illegally distributed diverted prescription drugs to Co-conspirators 4 and 5.
- 14. On or about July 10, 2012, Co-conspirators 4 and 5 paid **JOSE DE RODRIGUEZ** for diverted prescription drugs by a cashier's check to Southpoint Wholesale, Inc.., in the approximate amount of \$88,931.
- 15. In or around February 2013, **JOSE DE JESUS RODRIGUEZ**, illegally distributed diverted prescription drugs to Co-conspirator 6.

- 16. On or about February 8, 2013, Co-conspirator 6 paid **JOSE DE RODRIGUEZ** for diverted prescription drugs by a corporate bank check to Allied Supplies, Inc., in the approximate amount of \$20,000.
- 17. In or around March 2013, **JOSE DE JESUS RODRIGUEZ**, illegally distributed diverted prescription drugs to Co-conspirator 6.
- 18. On or about March 6, 2013, Co-conspirator 6 paid **JOSE DE RODRIGUEZ** for diverted prescription drugs by a corporate bank check to Allied Supplies, Inc., in the approximate amount of \$10,000.
- 19. In or around November 2014, **JOSE DE JESUS RODRIGUEZ** bought diverted prescription drugs from Co-conspirators 1 and 2.
- 20. In or around December 2014, **JOSE DE JESUS RODRIGUEZ** bought diverted prescription drugs from Co-conspirators 1 and 2.
- 21. On or about December 16, 2014, **JOSE DE JESUS RODRIGUEZ** illegally distributed diverted prescription drugs to Co-conspirator 7.
- 22. On or about December 18, 2014, **JOSE DE JESUS RODRIGUEZ** illegally distributed diverted prescription drugs to Co-conspirator 7.
- 23. On or about March 17, 2015, **JOSE DE JESUS RODRIGUEZ** illegally distributed diverted prescription drugs to Co-conspirator 7.

All in violation of Title 18, United States Code, Section 371

COUNTS 2-4 Unlicensed Wholesale Distribution of Prescription Drugs (21 U.S.C. §§ 331(t), 333(b)(1)(D), and 353(e)(1)(A))

1. The General Allegations section of this Indictment is re-alleged and incorporated by reference as though fully set forth herein.

2. On or about the dates set forth below, in Miami-Dade County, in the Southern District of Florida, and elsewhere, the defendant,

JOSE DE JESUS RODRIGUEZ,

as specified in each count below, did knowingly engage in, and knowingly cause another person to engage in, the wholesale distribution in interstate commerce of prescription drugs that were each subject to Title 21, United States Code, Section 353(b), in a State, that is, Florida, without being licensed by that State, as set forth below:

COUNT	APPROXIMATE DATE	PRESCRIPTION DRUGS
2	December 16, 2014	Abilify, Advair, Complera, Norvir, Stribild, Tivicay, Truvada, Valcyte, Viread
3	December 18, 2014	Abilify, Atripla
4	March 17, 2015	Abilify, Advair, Atripla, Complera, Isentress, Norvir, Prezista, Reyataz, Truvada, Viread.

In violation of Title 21, United States Code, Sections 331(t), 333(b)(1)(D), and 353(e)(1)(A), and Title 18, United States Code, Section 2

FORFEITURE (18 U.S.C. § 982(a)(7))

- 1. The allegations of this Indictment are re-alleged and incorporated by reference as though fully set forth herein, for the purpose of alleging forfeitures to the United States of certain property in which each of the defendant, **JOSE DE JESUS RODRIGUEZ**, has an interest.
- 2. Upon conviction of a violation of Title 21, United States Code, Sections 331, as alleged in this Indictment, each of the defendants 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, pursuant to Title 18, United States Code, Section 982(a)(7).

All pursuant to Title 18, United States Code, Section 982(a)(7), and the procedures set forth at Title 21, United States Code, Section 853, as made applicable by Title 18, United States Code, Section 982(b)(1).

A TRUE BILL

BENJAMIN G. GREENBERG

ACTING UNITED STATES ATTORNEY

JAMES V. HAYES

ASSISTANT U.S. ATTORNEY

Case 1:17-cr-20486-RNS Docum**southernostracooffication**

UNITED STATES OF AMERICA vs. JOSE DE JESUS RODRIGUEZ,		OF AMERICA	CERTIFICATE OF TRIAL ATTORNEY*	
		RODRIGUEZ,		
		Defendant/	Superseding Case Information:	
Court I	Division : (Miami FTL	(Select One) Key West FTP	New Defendant(s) Number of New Defendants Total number of counts Yes No —— No —— Total number of counts	
	I do he	reby certify that:		
	1.	I have carefully considered the a probable witnesses and the legal of	allegations of the indictment, the number of defendants, the number of complexities of the indictment/information attached hereto.	
	2.	I am aware that the information s setting their calendars and schedu Section 3161.	supplied on this statement will be relied upon by the Judges of this Court in Iling criminal trials under the mandate of the Speedy Trial Act, Title 28 U.S.C.	
	3.	Interpreter: (Yes or No) List language and/or dialect	<u>Yes</u> Spanish	
	4.	This case will take 5 days for the p	parties to try.	
	5.	Please check appropriate category	y and type of offense listed below:	
		(Check only one)	(Check only one)	
	I II IV V:	0 to 5 days 6 to 10 days 11 to 20 days 21 to 60 days 61 days and over	X	
	Has a co	Has this case been previously filed copy of dispositive order) omplaint been filed in this matter?	Case No. (Yes or No) No (Yes or No) No	
	Related Defend Defend	l Miscellaneous numbers: ant(s) in federal custody as of ant(s) in state custody as of from the	District of	
	Is this a	potential death penalty case? (Yes	or No) <u>No</u>	
	7.	Does this case originate from a macoctober 14, 2003?	atter pending in the Northern Region of the U.S. Attorney's Office prior to Yes X No	
	8.	Does this case originate from a m September 1, 2007?	natter pending in the Central Region of the U.S. Attorney's Office prior to Yes X No	

ames V. Hayes

ASSISTANT UNITED STATES ATTORNEY Florida Bar No. A5501717

*Penalty Sheet(s) attached

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF FLORIDA

PENALTY SHEET

^{*}Refers only to possible term of incarceration, overlap does not include possible fines, restitution, special assessments, parole terms, or forfeitures that may be applicable.