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IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA)	
)	
v)	Criminal No. 17-88
)	(18 U.S.C. §§ 371 and 1956(h))
QUANTUM SOLUTIONS SRL)	

INFORMATION

FILED

COUNT ONE

MAR 27 2017

CLERK U.S. DISTRICT COURT
WEST. DIST. OF PENNSYLVANIA

The United States Attorney charges:

At times material to this Information:

1. The defendant, QUANTUM SOLUTIONS SRL (hereinafter QUANTUM) was a business organization registered under the laws of Barbados in the business of selling in the United States and elsewhere wholesale quantities of prescription drugs manufactured and labeled for the foreign market. Quantum purchased the prescription drugs from suppliers located in Turkey, Great Britain and other countries, and caused these prescription drugs to be delivered to New York and Washington State where they were repackaged and distributed in the United States.

2. Billy Lee operated Quantum, and was a resident of Vancouver, British Columbia, Canada.

3. Tony Lee operated Quantum, and was a resident of Vancouver, British Columbia, Canada.

4. Tarnjeet S. Uppal operated Quantum, and was a resident of Vancouver, British Columbia, Canada.

5. KKN, known to the U.S. Attorney, was a manager of Quantum and a resident of New York who re-packaged prescription drugs that were manufactured and labeled for the foreign market and distributed them to customers in the United States. KKN did not have a wholesale

license for distributing prescription drugs in New York State as required by law.

6. Billy Lee, Tony Lee, Tarnjeet S. Uppal and QUANTUM used other companies and numerous websites to market and sell prescription drugs. BILLY LEE and Tony Lee were registrants and administrative contacts for many of these websites.

7. MI, known to the U.S. Attorney, was a Washington state re-shipper who received in interstate commerce wholesale quantities of prescription drugs that were manufactured and labeled for the foreign market, re-packaged these prescription drugs and delivered them to customers throughout the United States. MI did not have a wholesale license for distributing prescription drugs in Washington state as required by law.

8. JM, known to the U.S. Attorney, was a pharmacist and owner of a retail pharmacy in the Western District of Pennsylvania.

9. BP, known to the U.S. Attorney, was a pharmacist and owner of a retail pharmacy in the Western District of Pennsylvania.

10. KE, known to the U.S. Attorney, was a pharmacist and owner of a retail pharmacy in the Western District of Pennsylvania.

FOOD, DRUG AND COSMETIC ACT

11. The Food and Drug Administration (“FDA”) was the agency of the United States responsible for regulating the manufacture, labeling, and distribution of drugs in the United States. Among other things, the FDA was responsible for enforcing the provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. (“FDCA”), including regulating the wholesale distribution of prescription drugs.

12. A “drug” was defined by the FDCA as, among other things, any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;

articles (other than food) intended to affect the structure or any function of the body of man or other animals; and articles intended for use as a component of any such articles. See 21 U.S.C. § 321(g).

13. A prescription drug was defined by the FDCA as “a drug intended for use by man which because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe except under the supervision of a practitioner licensed by law to administer such drug.” 21 U.S.C. § 353(b)(1)(A). A drug may also be limited to prescription use in its new drug application filed with FDA. 21 U.S.C. § 353(b)(1)(B).

14. The distribution of prescription drugs in the United States was regulated by the FDA and was subject to a series of strict controls. To prevent prescription drug diversion and the introduction of counterfeit, ineffective, or substandard drugs into interstate commerce Congress enacted the Prescription Drug Marketing Act (“PDMA”), which it incorporated into the FDCA.

15. Under the 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. See 21 U.S.C. §353(e)(1)(A). FDA regulations set forth the minimum standards, terms and conditions for the state licensing of wholesale prescription drug distributors, including guidelines for the storage and handling of such drugs and for the establishment and maintenance of records regarding the distributions of such drugs. See 21 U.S.C. § 353(e)(1)(B); 21 C.F.R. § 205.5, 205.6, and 205.50. The regulations further provided that wholesale prescription drug distributors were required to allow state licensing authorities and authorized federal, state and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures. 21 C.F.R. § 205.50(i).

16. The PDMA also required that each person engaged in the wholesale distribution of prescription drugs who is not the manufacturer or authorized distributor of record of such drug shall have provided to the person who receives the drug, before each wholesale distribution, a statement identifying each prior sale, purchase, or trade of such drug (including the date of the transaction and the names and addresses of all parties to the transaction). See 21 U.S.C. § 353(e)(1)(A). This was known as the “pedigree” requirement.

17. The distribution of drugs in violation of 21 U.S.C. § 353(e) or the failure to otherwise comply with the requirements of 21 U.S.C. § 353(e) was a prohibited act under the FDCA. 21 U.S.C. § 331(t). Knowingly distributing drugs in violation of 21 U.S.C. § 353(e) was a felony punishable by up to 10 years imprisonment or a maximum \$250,000 fine, or both. 21 U.S.C. § 333(b)(1)(D).

18. The FDCA prohibited the introduction, and delivery for introduction and causing the introduction or delivery for introduction into interstate commerce of any drug that was misbranded. See 21 U.S.C. § 331(a).

19. A drug was misbranded if, among other things, its labeling lacked adequate directions for use. See 21 U.S.C. § 352(f)(1). By regulation, the FDA defined “adequate directions for use” to mean “directions under which the layman can use a drug safely and for the purposes for which it is intended.” 21 C.F.R. § 201.5. Prescription drugs could never contain adequate directions for lay use and were therefore misbranded unless they qualified for an exemption. By regulation, a prescription drug was exempt from Section 352(f)(1) if it met all enumerated conditions, including: (1) the drug was in the possession of a person regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of prescription drugs; (2) the label of the drug bore the statement “Rx Only”; and (3) if the drug was

a new drug, labeling in or within the package from which the drug was to be dispensed was the labeling authorized by the new drug application.

20. The United States Customs and Border Protection (“CBP”), and Immigration and Customs Enforcement, Homeland Security Investigations (“ICE-HSI”), two agencies within the United States Department of Homeland Security (“DHS”), were the federal agencies responsible for administering and enforcing violations of the laws governing the importation into the United States of goods and merchandise including drugs.

THE CONSPIRACY
(18 U.S.C. § 371)

21. From in and around January 2007, and continuing thereafter to in and around July 2011, defendant, QUANTUM SOLUTIONS SRL, Billy Lee, Tony Lee, Tarnjeet S. Uppal, and KKN, JM, BP and KE, and others known and unknown to the United States Attorney (hereafter members of the conspiracy), engaged in a conspiracy to distribute wholesale quantities of misbranded prescription drugs manufactured and labeled for the foreign market with intent to defraud and mislead in violation of 21 U.S.C. §§ 331(t) and 333(a)(2).

22. These misbranded drugs, as sold to pharmacies in the Western District of Pennsylvania, did not have and were not exempt from having FDA approved labeling, were not approved for distribution in the United States, were not an approved generic equivalent to the brand name versions of the drugs, and did not qualify for the personal use exception.

23. Neither the defendant nor any individuals or companies through which this business was conducted was licensed as a prescription drug wholesaler by the states of Washington, New York or Pennsylvania.

MANNER AND MEANS OF THE CONSPIRACY

It was part of the conspiracy that:

24. Members of the conspiracy caused a re-shipper in the United Kingdom known to the U.S. Attorney to receive shipments of wholesale quantities of prescription drugs that were manufactured and labeled for the foreign market.

25. Members of the conspiracy caused said re-shipper in the United Kingdom to unpack the said shipments and repack them in several small packages in order to create the appearance to CBP and ICE-HIS that the packages of drugs were health care products for the personal use of the addressee.

26. Members of the conspiracy caused the said re-shipper in the United Kingdom to place on the outside of the small packages misleading labeling and shipping documentation that falsely represented to CBP and ICE-HIS that the contents of packages were "Personal Healthcare Products" for the personal use of the addressee, and falsely understated the dollar value of the contents.

27. Members of the conspiracy caused the said re-shipper in the United Kingdom to ship the small packages to Washington State and New York State re-shippers known to the U.S. Attorney.

28. Members of the conspiracy caused the said re-shippers in New York and Washington to unpack the several small packages and repackage them into larger packages and send the larger packages in interstate commerce by mail and common carrier to pharmacies and individuals known to the United States Attorney located in the Western District of Pennsylvania, and elsewhere.

29. Members of the conspiracy sent and received emails to facilitate the collection of payment for said misbranded prescription drugs manufactured and labeled for the foreign market.

30. Members of the conspiracy caused payments for misbranded prescription drugs manufactured and labeled for the foreign market to be made from the Western District of Pennsylvania to Canada and Barbados by wire transfers, checks and credit card payments.

OVERT ACTS

31. In furtherance of the conspiracy, and to effect the objects of the conspiracy, members of the conspiracy did commit and cause to be committed, the following overt acts, among others, in the Western District of Pennsylvania and elsewhere, that is:

32. During the course of the conspiracy, members of the conspiracy sent and caused to be sent emails containing information about (a) orders from wholesale customers for prescription drugs manufactured and labeled for the foreign market; (b) shipments from the United Kingdom to BP and KE of prescription drugs manufactured and labeled for the foreign market; (c) packaging shipments of wholesale quantities of prescription drugs manufactured and labeled for the foreign market in numerous small packages; (d) labeling multiple packages of prescription drugs manufactured and labeled for the foreign market "personal health supplies"; and (e) instructing wholesale customers to send payments for prescription drugs manufactured and labeled for the foreign market to Canada.

33. On or about the following dates, members of the conspiracy did cause payments for prescription drugs manufactured and labeled for the foreign market to be made by check or credit card as designated below, from the Western District of Pennsylvania to Canada and Barbados by the following persons, to the following entities, in the following amounts:

	Date	Check or Credit Card	From	To	Amount
a	9/21/10	Check	BP	Quantum	\$42,643.00
b	11/26/10	Check	BP	Quantum	\$80,981.00
c	5/30/11	credit card	KE	Global Health Supplies	\$11,325.04
d	6/6/11	credit card	KE	Global Health Supplies	\$10,212.25

34. Members of the conspiracy did receive and cause to be received in Canada the monies referred to in paragraph 35, and did send and cause to be sent those monies from Canada to Barbados.

35. Members of the conspiracy did cause to be sent into the United States and delivered to BP and KE wholesale quantities of misbranded prescription drugs manufactured and labeled for the foreign market, to-wit, Plavix, Zyprexa, Lipitor, Seroquel, Zeldox, Abilify, Celebrex, and others known to the United States Attorney, shipped from the United Kingdom, using the United States Postal Service, Fed Ex and UPS.

In violation of Title 18, United States Code, Section 371.

COUNT TWO

The United States Attorney further charges:

36. Paragraphs 1-23 of this indictment are incorporated herein as if fully set forth.

CONSPIRACY
(18 U.S.C §§ 1956(a)(2)(A)and (h))

37. From in and around January 2007, and continuing thereafter to in and around July 2011, in the Western District of Pennsylvania and elsewhere, defendant QUANTUM, Billy Lee, Tony Lee, and Tarnjeet S. Uppal, did knowingly, intentionally and unlawfully conspire together with one another, and with KKN, JM, BP and KE, not defendants herein, and with other persons both known and unknown to the United States Attorney, to commit certain offenses against the United States, that is, violations of Title 18 U.S.C. § 1956(a)(2)(A), by transporting, transmitting and transferring, and attempting to transport, transmit and transfer, monetary instruments and funds from a place in the United States to and through a place outside the United States with the intent to promote the carrying on of a specified unlawful activity, that is, conspiracy to engage in unlawful wholesale distribution of misbranded prescription drugs with intent to defraud and mislead in violation Title 21, United States Code, Section 331(t) and Section 333(a)(2), a federal health care offense.

MANNER AND MEANS OF THE CONSPIRACY

38. Paragraphs 24-30 of this indictment are incorporated herein as if fully set forth.

OVERT ACTS

39. Paragraphs 31-35 of this indictment are incorporated herein as if fully set forth.

All in violation of Title 18, United States Code, Section 1956(h).

FORFEITURE ALLEGATION

40. The United States hereby gives notice to the defendant charged in Counts 1 and 2 that, upon its conviction of such offenses, the government will seek forfeiture in accordance with:

(a) Title 18, United States Code, Section 982(a)(7), which requires any person convicted of a Federal health care offense to forfeit any property that constitutes or is derived, directly or indirectly, from proceeds traceable to the offense, including but not limited to the following:

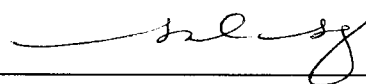
\$4,235,000, and all right, title and interest in the website domains named on Attachment A, incorporated herein and attached hereto.

41. If any of the above-described forfeitable property, as a result of any act or omission of the defendant:

- (a) cannot be located upon the exercise of due diligence;
- (b) has been transferred or sold to, or deposited with, a third party;
- (c) has been placed beyond the jurisdiction of the court;
- (d) has been substantially diminished in value; or
- (e) has been commingled with other property which cannot be divided without

difficulty;

it is the intent of the United States, pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 18, United States Code, Section 982(b)(1), to seek forfeiture of any other property of such defendant up to the value of the forfeitable property described in this forfeiture allegation.



Soo C. Song
Acting United States Attorney
DC ID No. 457268