UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

OZKAN SEMIZOGLU and
SABAHADDIN AKMAN,

Defendants.

4:14CR003 AGF/TCM

INDICTMENT

The Defendants

1. At all times relevant to this Indictment, defendant Ozkan Semizoglu ("Semizoglu") was a citizen of Turkey who lived in Instanbul, Turkey. Semizoglu was the Foreign Trade Director of a Turkish prescription drug wholesaler. Semizoglu distributed unapproved, adulterated, misbranded, and counterfeit prescription drugs to various purchasers in the United States, including a purchaser in the Eastern District of Missouri. As explained in greater detail below, defendant committed offenses in St. Louis County, Missouri, within the Eastern Division of the Eastern District of Missouri, and also continued and completed offenses in St. Louis County, Missouri, within the Eastern Division of the Eastern District of Missouri, that were begun in other Districts.

2. At all times relevant to this Indictment, defendant Sabahaddin Akman ("Akman") was a citizen of Turkey who lived in Instanbul, Turkey. Akman was the supervisor of Semizoglu, and was a Manager for a Turkish prescription drug wholesaler. Akman distributed unapproved, adulterated, misbranded, and counterfeit prescription drugs to various purchasers in the United States, including a purchaser in the Eastern District of Missouri. As explained in greater detail

below, defendant committed offenses in St. Louis County, Missouri, within the Eastern Division of the Eastern District of Missouri, and also continued and completed offenses in St. Louis County, Missouri, within the Eastern Division of the Eastern District of Missouri, that were begun in other Districts.

Background

3. The United States Department of Homeland Security, Immigration and Customs Enforcement ("ICE"), was responsible for border control and customs enforcement. ICE monitored packages coming to the United States from foreign countries, and seized packages that contain illegal merchandise and contraband, including packages containing adulterated, misbranded, unapproved, and counterfeit prescription drugs.

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 Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et. seq. ("FDCA"). FDA's responsibilities under the FDCA included regulating the manufacture, labeling, and distribution of all drugs and drug components shipped or received in interstate commerce and foreign commerce, including the wholesale distribution of prescription drugs. To meet those responsibilities, the FDA enforced statutes which required that drugs bore labels and labeling that enabled health care providers and consumers to use them in a safe manner as well as drug labels that identified whether the drugs were manufactured by companies that registered with FDA as drug establishments. 21 U.S.C. §§ 352(f), 352(o) and 360(c).

Prescription Drugs

5. Under the FDCA, drugs included articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man and articles intended to affect the structure or any function of the body of man. 21 U.S.C. § 321(g)(1)(B) and (c).

6. Under the FDCA a drug was deemed to be a prescription drug if, because of its toxicity and other potential harmful effects, it was not safe for use except under the supervision of a practitioner licensed by law to administer the drug. A drug was also deemed to be a prescription drug if a new drug application approved by the FDA limited the drug to use under the professional supervision of a practitioner licensed by law to administer the drug. 21 U.S.C. §§ 353(b)(1), 355. The drugs listed below, using the names under which the drugs are marketed in the United States, are used primarily to treat cancer patients, and are often "infused" into cancer patients intravenously, meaning the purity and efficacy of these prescription drugs is very important for patients: Neupogen®, Herceptin®, Rituxan®, Gemzar®, Taxotere®, Eloxatin®, Zometa®, and Venofer®.

7. Some of these prescription drugs require a uniform cold temperature during storage and shipment to remain safe and effective. For example, the U.S. labeling for Neupogen® requires storage of this drug in a refrigerator at 2° to 8°C (36° to 46°F), and cautions that the drug should not be shaken. According to the U.S. labeling for this drug, if it is left at room temperature for longer than 24 hours, it should be discarded and not used with patients. Similarly, the FDA-approved U.S. labeling for the prescription drugs Herceptin® and Rituxan® requires that these drugs be kept at a constant temperature between 36 and 46 degrees Fahrenheit, and not shaken or frozen.

Misbranding

8. Under the authority of the FDCA, 21 U.S.C. §§ 301-399, a drug is misbranded under the FDCA if the labeling is false or misleading in any particular. 21 U.S.C. § 352(a). Each drug's label needs to use the established name of the drug and contain a lot number that is capable of yielding the complete manufacturing history of the drug. 21 U.S.C. § 352(e)(1)(A)(i); 21 C.F.R. §§ 201.50(b), 201.18, and 201.100(b)(6). A drug was misbranded if it failed to bear

adequate directions for its use. 21 U.S.C. § 352(f)(1). "Adequate directions for use" meant directions under which a layman can use a drug or device safely and for the purposes for which it was intended. 21 C.F.R. §§ 201.5.

Adulteration

9. A drug was "adulterated" if the methods used in, or the facilities or controls used for its manufacturing, processing, packing, and holding do not conform with current good manufacturing practices ("cGMP") to assure that the drug is safe and has the identity and strength and meets quality and purity characteristics which it purports or is represented to possess. 21 U.S.C. § 351(a)(2)(B).

Smuggling Misbranded and Adulterated Drugs and Devices Into Missouri

10. During on or about March 27, 2013 through on or about January 15, 2014, defendants shipped seven packages of merchandise from Turkey to an address in St. Louis County, Missouri. Each package bore a customs declaration that falsely described the contents of the package as a "gift." Semizoglu listed himself as the "sender" of some of these six packages. Each package contained prescription drugs with labeling and dosage and use instructions in foreign languages. Some prescription drugs sent by defendants had counterfeit exterior box packaging, counterfeit vial labeling, and different lot numbers on the exterior packaging of the drugs than the lot numbers found on the actual vials of the drug. The illegal prescription drugs distributed by defendants were not held, packed, or shipped to purchasers in Missouri and elsewhere in conformity with current good drug manufacturing practices. Instead, defendants repeatedly shipped drugs requiring temperature protection with no effort or ineffective efforts at maintaining temperature protection for the drugs in the shipments. Accordingly, defendants' methods of holding and shipping these prescription drugs did not keep the prescription drugs at the cold temperatures required by the drugs' labeling, or protect their sterility and efficacy.

COUNT 1 - CONSPIRACY

The Conspiracy and its Objects

11. Paragraphs 1 through 10 are re-alleged and incorporated by reference as though fully set forth herein.

12. From on or about March 27, 2013 through on or about January 15, 2014, the exact dates being unknown to the Grand Jury, in the Eastern Division of the Eastern District of Missouri and elsewhere, defendants

Ozkan Semizoglu and Sabahaddin Akman

and others, known and unknown to the Grand Jury, knowingly and willfully conspired and agreed together to commit offenses against the United States, to wit:

(a) fraudulently and knowingly importing and bringing into the United States certain merchandise, that is, packages of the prescription drugs and devices bearing false customs declarations, contrary to law, and;

(b) defrauding the United States and its agencies by impeding, impairing, and defeating the lawful functions of the FDA to protect the health and safety of the public by ensuring that drugs found in the United States were safe, effective, labeled properly, and stored and shipped in compliance with federal law, in violation of 21 U.S.C. §§ 301-397.

Manner and Means of the Conspiracy

13. The manner and means by which defendants and their coconspirators sought to accomplish the objects and purpose of the conspiracy included, among others, the following which occurred during the entire period of the conspiracy:

14. Defendants and their coconspirators obtained prescription drugs and devices from Turkey and other foreign countries outside the United States, and shipped or caused others to ship the prescription drugs to purchasers in the United States, including purchasers in Missouri,

Washington, California, Louisiana, and New York. Defendants and their co-conspirators utilized exterior packaging that concealed the illegal nature of the prescription drug shipments from the United States, such as sending packages with customs declarations falsely describing the contents as "gifts" or "documents" or "product sample" with no or low declared monetary values. Defendants also ensured that large drug shipments were broken into several smaller packages to reduce the likelihood of seizures by U.S. Customs authorities and the corresponding loss of expensive drug shipments.

15. Defendants shipped prescription drugs requiring constant cold temperatures in shipping boxes without insulation from Turkey to the United States. Defendants further shipped prescription drugs requiring constant cold temperatures in shipping boxes from Turkey to the United States without any temperature protection whatsoever, or sometimes used only small freezer packs instead of dry ice inside the packages. Given the length of time required to ship products from Turkey to the United States, defendants were aware that on many occasions their packages of their prescription drugs arrived in the United States at temperatures outside the constant cold temperature range discussed on the drugs' labeling.

Overt Acts

16. In furtherance of the conspiracy, and to achieve the objects thereof, defendants and their co-conspirators, known and unknown, committed and caused to be committed the following overt acts, in the Eastern Division of the Eastern District of Missouri, and elsewhere:

a. Each of the allegations set forth in Counts 2 through 4 is incorporated and realleged as though restated herein, as an individual overt act done in furtherance of the conspiracy. All in violation of Title 18, United States Code, Section 371.

COUNT 2

17. The United States adopts paragraphs 1-10 and as for paragraph 17.

18. On or about May 8, 2013, in the Eastern District of Missouri, and elsewhere, defendants Ozkan Semizoglu and Sabahaddin Akman, aiding and abetting others and aided and abetted by others, fraudulently and knowingly did import and bring into the United States certain merchandise, that is, a package containing the drugs labeled in the United States as Neupogen®," contrary to law, in that the package's customs declaration stated that it contained a "gift" when in fact the package contained approximately 6 packages each containing five pre-filled syringes with 0.5 ml of Neupogen® that were adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), and misbranded within the meaning of 21 U.S.C. §§ 353(b)(4)(A) and 352(a), (f)(1), and (f)(2)), in violation of 21 U.S.C. Section 331(a). All, in violation of Title 18, United States Code, Sections 545 and 2.

COUNT 3

19. The United States adopts paragraphs 1-10 and as for paragraph 19.

20. On or about June 27, 2013, in the Eastern District of Missouri, and elsewhere, defendants Ozkan Semizoglu and Sabahaddin Akman, aiding and abetting others and aided and abetted by others, fraudulently and knowingly did import and bring into the United States certain merchandise, that is, a package containing 4 packages of the drugs marketed in the United States as Rituxan® with each package containing 2 10 ml vials, contrary to law, in that the package's customs declaration stated it contained a "gift" when in fact the package contained misbranded prescription drugs within the meaning of 21 U.S.C. § 352(a), (f)(1), and (f)(2) in violation of 21 U.S.C. Sections 331(a). All, in violation of Title 18, United States Code, Sections 545 and 2.

COUNT 4

21. On or about December 15, 2013, in the Eastern District of Missouri, and elsewhere, defendants Ozkan Semizoglu and Sabahaddin Akman, aiding and abetting others and aided and abetted by others, fraudulently and knowingly did import and bring into the United States certain

merchandise, that is, a package containing the drugs labeled in Turkey and other foreign markets as "Altuzan®," contrary to law, in that the package's customs declaration stated that it contained a "gift" when in fact the package contained approximately 5 packages of Altuzan® that were adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), and misbranded within the meaning of 21 U.S.C. §§ 353(b)(4)(A) and 352(a), (f)(1), and (f)(2)), in violation of 21 U.S.C. Section 331(a). All, in violation of Title 18, United States Code, Sections 545 and 2.

A TRUE BILL.

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FOREPERSON

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