UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	4:17CR152 HEA/SPM
	)	
NIKHIL BUHECHA,	)	
	)	
Defendant.	)	

INDICTMENT

The Grand Jury charges:

The Defendant

1. At all times relevant to this Indictment, defendant Nikhil Buhecha, also known as Nikhil Kantilal Buhecha ("Buhecha"), was a resident of Vancouver, British Columbia, Canada. Buhecha was a licensed pharmacist, with special training regarding the handling and distribution of prescription drugs. 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 and outside the United States.

2. Defendant, along with others known and unknown to the Grand Jury, operated a business called "online botox." Defendant's marketing materials described "online botox" as a "department" of another company called "Panacea Services Inc." Canadian government records identify Buhecha as a director and president of "Panacea Services Inc." Defendant's business obtained adulterated, misbranded, and unapproved prescription drugs from Turkey and other foreign countries, smuggled the illegal drugs into the United States using false and fraudulent

customs declarations, and sold them to physicians throughout the United States, including two physicians practicing in St. Louis County, Missouri. Defendant's business marketed these illegal prescription drugs to U.S. doctors with substantially lower prices than the legal FDA-approved versions of the prescription drugs. For example, some of defendant's marketing materials offered "Botox (Turkish)" for $354.99 per vial, when the FDA-approved version of Botox® was sold through licensed wholesalers at higher prices in the United States, often for $525 per vial. Ultimately, patients in Missouri and elsewhere received the adulterated and misbranded drugs without knowing of the illegal source of the drugs. From 2009 through 2013, defendant shipped and caused to be shipped over one hundred separate illegal prescription drug shipments to physicians located within the Eastern District of Missouri.

The U.S. Food and Drug Administration

3. 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

4. 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). A "biological product," defined as a toxin, therapeutic serum, blood, or blood component or derivative applicable to the prevention, treatment, or cure of a disease or condition of human beings, can also be a "drug." 21 U.S.C. § 321(g)(1); 42 U.S.C. § 262(i).

5. 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.

6. Onabotulinumtoxin A is the established name for the drug and biological product marketed in the United States as Botox® Cosmetic. Botox® Cosmetic is a "prescription drug" within the meaning of 21 U.S.C. § 353(b)(1) because of its toxicity or other potentiality for harmful effect. Botox® Cosmetic is the Type A toxin produced by the bacteria *Clostridium botulinum*. The Type A toxin is a highly potent and potentially dangerous toxin, and could cause the disease botulism when present in human beings in a sufficient amount. Botulism is a muscle-paralyzing condition in which the toxin from *Clostridium botulinum* binds to nerve endings at the point where nerves join muscles, preventing the nerves from signaling the muscles to contract. As such, Botox® Cosmetic could lawfully be dispensed only upon the prescription of a practitioner licensed

by law to administer such drugs. On July 31, 2009, FDA approved several revisions to the labeling for Botox® Cosmetic, including the addition of a "black box warning" under 21 C.F.R. § 201.57(c)(1) cautioning that the effects of Botox® Cosmetic may spread from the area of injection to other areas of the body, causing symptoms similar to those of botulism. Botox® Cosmetic is typically injected directly into patients, making the sterility and efficacy of this prescription drug important. According to the label for FDA approved Botox® Cosmetic, unopened vials of Botox® Cosmetic should be stored in a refrigerator at temperatures between 2 to 8 Celsius before dispensing to patients.

Misbranding

7. Under the authority of the FDCA, 21 U.S.C. §§ 301-399, a drug or device 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 or device is misbranded if it fails 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. A drug or device is also misbranded if its labeling fails to bear adequate warnings where use of the drug may be dangerous to the health of users. 21 U.S.C. § 352 (f)(2).

Adulteration

8. A drug is "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).

Counterfeit Drugs

9. 21 U.S.C. § 321(g)(2) defines a "counterfeit drug" as either a drug or a label that bears a trade name that falsely represents who actually manufactured, packed, or distributed it.

Counterfeit, Misbranded, and Adulterated Drugs in Missouri

10. The prescription drugs distributed by defendant through "online botox," a "department" of "Panacea Services," were not held, packed, or shipped to U.S. doctors in Missouri and elsewhere in conformity with current good drug manufacturing practices. The 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. FDA obtained prescription drugs from "online botox" and tested them at FDA's Forensic Chemistry Center. FDA determined that the labeling for the Botox® it obtained from "online botox" was counterfeit.

COUNT ONE – 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 August 14, 2009 through on or about February 28, 2013, the exact dates being unknown to the Grand Jury, in the Eastern Division of the Eastern District of Missouri and elsewhere, defendant

NIKHIL BUHECHA

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 containing prescription drugs bearing false customs declarations, contrary to law, including 18 U.S.C. § 545, 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.

Manner and Means of the Conspiracy

13. The manner and means by which defendant and his co-conspirators 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. First, defendant and his co-conspirators obtained wholesale quantities of prescription drugs from Turkey and other countries from outside the United States. In order to save money on shipping costs, the prescription drugs were not temperature-protected with dry ice or freezer packs during transport from Turkey and other foreign countries, making the packages lighter and smaller.

15. Second, even though defendant owned multiple pharmacies in Canada, defendant and his co-conspirators sent and caused to be sent the international drug shipments from Turkey and other foreign countries to commercial post office boxes located in the State of Washington, near the Canadian border. Defendant and his co-conspirators used 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 "gift" or "healthcare items and remedies for personal use" with false low declared monetary values. After the drugs were smuggled into the United States, defendant and his co-conspirators directed persons inside the United States to store and hold for sale the prescription drugs at hard-to-find locations, including the bedroom and kitchen refrigerator of a mobile home residence in Washington.

16. Third, defendant and his co-conspirators marketed low prescription drug prices to U.S. doctors using employees in Canada and other locations. Once drug orders were received from U.S. doctors and clinic employees, defendant and his co-conspirators directed persons inside the United States to pack and ship smaller drug quantities to fill the orders and send them to U.S. doctors. Defendant and his co-conspirators set up credit card processing and banking arrangements in Panama to process some of these transactions, even though he maintained multiple Canadian bank accounts for his legitimate Canadian pharmacy business during this time frame. Defendant used these unorthodox shipping and payment methods in order to increase the chances that his illegal drug shipments to U.S. doctors would not be discovered by either the United States or Canadian governments, and to conceal his receipt of illicit profits from this business.

Overt Acts

17. In furtherance of the conspiracy, and to achieve the objects thereof, defendant and his 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, in the Western District of Washington, 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 TWO – SMUGGLING

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

19. On or about January 14, 2013, in the Western District of Washington, the Eastern District of Missouri, and elsewhere, defendant

NIKHIL BUHECHA

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 "Botox®," contrary to law, in that the package's customs declaration stated that it contained a "noncommercial gift" when in fact the package contained approximately fifty vials of drugs labeled as "Botox®" 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. § 352(a), (f)(1), and (f)(2), in violation of 21 U.S.C. § 331(a).

All, in violation of Title 18, United States Code, Sections 545 and 2.

COUNTS THREE AND FOUR

Mail Fraud

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

21. From on or about December 31, 2010, through on or about January 14, 2013, in the Eastern Division of the Eastern District of Missouri and elsewhere, the Defendant, NIKHIL BUHECHA, aided and abetted by others, and aiding and abetting others, with the intent to defraud, devised a scheme and artifice to defraud and obtain money by materially false and fraudulent pretenses, representations, and promises.

THE SCHEME AND ARTIFICE

22. It was part of the scheme and artifice to defraud and to obtain money and property by false and fraudulent pretenses, representations and promises and in furtherance of it that the defendant knowingly and intentionally engaged in and caused the following activities:

23. Defendant and others obtained prescription drugs from Turkey and other countries from outside the United States, and shipped them to commercial post office boxes located in the State of Washington, near the Canadian border. Defendant and others 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 "gift" or "healthcare items and remedies for personal use" with low declared monetary values. Defendant directed others to stockpile the drugs from these smuggled shipments at a private residence, and pack and ship smaller quantities to individual doctors throughout the United States as drug orders were placed. Defendant did not store or ship the drugs at the cold temperatures required by the drugs' labeling. Defendant did not inform either the doctors who purchased his drugs or the doctors' patients that he was smuggling drugs into the United States using packages without any temperature protection, storing some of the drugs at a private residence in Washington before shipment, and shipping drugs in the United States without adequate temperature protection.

THE MAILINGS

24. In the Eastern Division of the Eastern District of Missouri, for the purpose of executing or attempting to execute the above-described scheme and artifice to defraud and deprive, Defendant knowingly deposited and caused to be deposited to be sent and delivered by a private and commercial interstate carrier the following matter, with each mailing being a separate count of this Indictment:

Count	Date	Item/Carrier
3	July 23, 2012	Approximately four 100 I.U. vials of drugs labeled as "Botox®" via a federal express package to a doctor's office in St. Louis County
4	December 20, 2012	Approximately two 100 I.U. vials of drugs labeled as "Botox®" via a federal express package to an address in St. Louis County

All in violation of Sections 1341 and 2 of Title 18 of the United States Code.

A TRUE BILL.

_____
FOREPERSON

CARRIE COSTANTIN
Acting United States Attorney

_____
ANDREW J. LAY, #39937MO
Assistant United States Attorney