

IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF VIRGINIA

Alexandria Division

UNITED STATES OF AMERICA

v.

TC MEDICAL GROUP,
SB MEDICAL INC.,
DAVID E. BURKE,
a/k/a "David Johnson,"
TZVI LEXIER,
HANOCH DAVID STEIN,
a/k/a "Albert Simmins,"
ASAF AKIVA IBRAHIMIAN,
a/k/a "Adam Darius," and
REUVEN MIRLIS,
a/k/a "Daniel Mirl,"

Defendants.

UNDER SEAL

Criminal No. 1:14-cr-397

Count 1: 18 U.S.C. § 371
Conspiracy

Counts 2-12: 18 U.S.C. § 545
Importation contrary to law

Counts 13-23: 21 U.S.C. § 331(a)
Introducing misbranded drugs and devices in interstate
commerce

Count 24: 21 U.S.C. § 331(t)
Unlicensed wholesale distribution of prescription drugs

Count 25: 18 U.S.C. § 1956(h)
Conspiracy to commit money laundering

Forfeiture Notice

INDICTMENT

DECEMBER 2014 Term – at Alexandria, Virginia

THE GRAND JURY CHARGES THAT:

GENERAL ALLEGATIONS

At all times relevant to this Indictment:

1. Congress enacted the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"), to protect the public from, among other things, drugs and devices that were misbranded, adulterated, or otherwise unsafe.

2. The Food and Drug Administration ("FDA") was the agency of the United States responsible for enforcing the provisions of the FDCA. The FDA's responsibilities included

regulating the manufacturing and distribution of drugs and devices shipped or received in interstate commerce. Specifically, to protect the public health by assuring the safety, effectiveness, and quality of drugs and devices in the United States, the FDA carried out its government functions by reviewing premarket applications for new drugs and some devices, inspecting both domestic and foreign manufacturing facilities, regulating the labeling and distribution of drugs through proper pharmaceutical supply chain channels, and preventing improperly packaged and labeled products from reaching the United States market.

3. 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 preventing the improper importation into the United States of goods and merchandise, including drugs and devices.

4. A “drug,” among other things, included articles intended for use to diagnose, cure, mitigate, treat, or prevent a disease, or to affect the structure or any function of the body. *See* 21 U.S.C. § 321(g). A “prescription drug,” among other things, was a drug which, because of its toxicity or other potential harmful effect, or because of its method of use, was unsafe except under the supervision of a licensed practitioner. 21 U.S.C. § 353(b)(1)(A).

5. A “device,” among other things, included articles intended to affect the structure or any function of the body, but—unlike drugs—did not achieve its primary intended purposes through chemical action within or on the body, and was not dependent upon being metabolized for the achievement of its primary intended purposes. 21 U.S.C. § 321(h). A device could also be limited to prescription use such that only a licensed practitioner could safely administer or use

it. 21 U.S.C. § 352(f); 21 C.F.R. § 801.109. A Class III device was required to bear the FDA-approved labeling before distribution in interstate commerce in the United States.

6. To carry out their public health and law enforcement functions, and to prevent the introduction and importation of substandard, degraded, or potentially harmful drugs and devices, or drugs whose shipping, storage, and handling history could not be properly accounted for or verified, the FDA, CBP, and ICE-HSI, among other things, sought to (1) prevent the introduction or delivery for introduction into interstate commerce of drugs and devices that were misbranded, 21 U.S.C. § 331(a); and (2) ensure that the wholesale distribution in interstate commerce of prescription drugs was conducted through licensed individuals, entities, and facilities, subject to proper storage and handling requirements, 21 U.S.C. § 353(e)(2)(A).

Misbranded Prescription Drugs and Devices

7. It was prohibited to introduce or deliver for introduction, or to cause the introduction or delivery, into interstate commerce of a misbranded drug or device. 21 U.S.C. § 331(a). The FDCA defined many ways in which a drug or device was misbranded, including if its labeling failed to bear adequate directions for use. 21 U.S.C. § 352(f)(1). Congress authorized the government, by regulation, to exempt certain prescription drugs and devices from this requirement if, among other things, they (1) were in the possession of a person, or his agents or employees, who was regularly and lawfully engaged in the storage or wholesale distribution of prescription drugs or devices, 21 C.F.R. §§ 201.100(a)(1)(i); 801.109; (2) bore a label that contained the required language limiting their use to prescription only, 21 C.F.R. §§ 201.100(b)(1), 801.109(b)(1); and for prescription drugs, (3) bore the FDA-approved labeling, 21 C.F.R. § 201.100(c)(2). Moreover, by statute a prescription drug was deemed to be misbranded if at any time before dispensing its label failed to bear, at a minimum, the “Rx only”

symbol. 21 U.S.C. § 353(b)(4)(A). A drug and device was also deemed to be misbranded if its labeling failed to bear information required under the FDCA, and if this required language was not in the English language. 21 U.S.C. § 352(c); 21 C.F.R. § 201.15(c)(1).

Regulation of Wholesale Distribution of Prescription Drugs

8. In addition, to ensure that prescription drugs in particular move through a proper, safe, and transparent supply chain, the FDCA required that persons engaged in the wholesale distribution in interstate commerce of prescription drugs in a State be licensed by the State. 21 U.S.C. § 353(e)(2)(A). For example, FDA regulations for wholesale distributors – those shipping prescription drugs to other than the consumer or patient – provide:

a. Wholesale distributors are subject to strict storage and handling requirements, and must at a minimum keep records tracking the distribution of prescription drugs. 21 U.S.C. § 353(e)(2)(B). Facilities, for example, must provide adequate lighting, ventilation, temperature, humidity, and security; must quarantine damaged, deteriorated, misbranded, or adulterated prescription drugs; and must store prescription drugs “at appropriate temperatures and under appropriate conditions in accordance with requirements.” 21 C.F.R. § 205.50.

b. To obtain licenses, wholesale distributors must disclose the contact persons for all facilities used for storage, handling, and distribution of prescription drugs. 21 C.F.R. § 205.5.

c. Wholesale distributors who were not the manufacturer or an authorized distributor of record were required to provide to the person who received 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 is known as the “pedigree” requirement.

THE DEFENDANTS

9. Defendants TC MEDICAL GROUP and SB MEDICAL INC. were corporations based in Barbados and Canada, respectively. TC MEDICAL GROUP and SB MEDICAL INC., together with co-conspirators known and unknown to the Grand Jury, specialized in the illegal importation from abroad and wholesale distribution within the United States of misbranded prescription drugs and devices. TC MEDICAL GROUP and SB MEDICAL INC. caused to be shipped from abroad orthopedic injections, rheumatology infusions, cosmetic devices, optomology products, and oncology drugs either directly to customers or to locations, including the personal residences and mailboxes of co-conspirators serving as individual drop shippers located in Maryland, New Jersey, Florida, Connecticut, and Arlington, Virginia, in the Eastern District of Virginia. TC MEDICAL GROUP and SB MEDICAL INC. used these individual drop shippers to receive, repack, and re-send these drugs and devices to customers throughout the United States, including in the Eastern District of Virginia, and to receive check payments by mail, including from the Eastern District of Virginia, all to give the false impression that the drugs and devices were FDA-approved for sale in the United States. TC MEDICAL GROUP and SB MEDICAL INC. operated under other names, including Premium Pharmaceuticals, Clinic Care Direct, Orthodocspharm, and Premium Drug Care, and under websites including www.tcmedicalgroup.com, www.tcmgroup.com, www.ccairect.com, and www.premiumpharmaceuticals.com.

10. Defendant DAVID E. BURKE, a citizen of Canada, oversaw the day-to-day operations of TC MEDICAL GROUP and SB MEDICAL INC. Among other things, BURKE

supervised and managed co-conspirator sales representatives and drop shippers in the United States, tracked and coordinated shipments from overseas into the United States, called United States-based customers to sell prescription drugs and devices from abroad, and engaged in the illegal importation and sales of misbranded drugs and devices. BURKE used the false name “David Johnson” in connection with his activities.

11. Defendant TZVI LEXIER, a citizen of Canada, among other things, was a principal of TC MEDICAL GROUP and SB MEDICAL INC. LEXIER obtained and coordinated the supply of drugs and devices from foreign countries ultimately intended for the illegal importation into and sale inside the United States, and managed the finances and commission payments to co-conspirator sales representatives and drop shippers in the United States on behalf of TC MEDICAL GROUP and SB MEDICAL INC.

12. Defendant HANOCH DAVID STEIN served as an individual drop shipper in the Baltimore, Maryland, area. STEIN’s role was to receive, repack, and re-ship misbranded prescription drugs and devices to customers throughout the United States to give the false impression that TC MEDICAL GROUP and SB MEDICAL INC. were based in the United States. STEIN often used the false name “Albert Simmins” or “Albert Simmons” in connection with his activities.

13. Defendants ASAF AKIVA IBRAHIMIAN and REUVEN MIRLIS were sales representatives for TC MEDICAL GROUP and SB MEDICAL INC. based in New Jersey and responsible for selling misbranded prescription drugs and devices to customers in the United States, including in the Eastern District of Virginia. IBRAHIMIAN, who used the false name “Adam Darius,” and MIRLIS, who used the false name “Daniel Mirl,” co-owned R&A

Consulting Group which received sales commissions from TC MEDICAL GROUP and SB MEDICAL INC. for the illegal sale of misbranded prescription drugs and devices.

14. At no time relevant to this Indictment were any of the defendants licensed wholesale distributors permitted to sell prescription drugs within the United States.

15. The defendants illegally imported into and delivered within the United States at least the following misbranded prescription drugs and devices:

Product	Use
Aclasta	Injectable drug used to treat osteoporosis (bone decay). Not FDA-approved for use in the United States. Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F).
Actemra	Injectable prescription drug used to treat rheumatoid arthritis (joint inflammation). Subject to FDA black-box warning: “[I]ncreased risk for developing serious infections that may lead to hospitalization or death.” Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F), and away from light and moisture.
Artzal	Injectable device used to treat osteoarthritis (joint pain). Not FDA-approved for use in the United States.
Bonviva	Injectable infusion drug used to treat osteoporosis (bone decay). Not FDA-approved for use in the United States.
Botox	Injectable prescription drug used to treat bladder disorders, chronic migraines, muscle spasms, and abnormal head positions. Subject to FDA black-box warning: “Swallowing and breathing difficulties can be life threatening and there have been reports of death.” Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F).
Botox Cosmetic	Injectable prescription drug used to treat forehead wrinkles. Subject to FDA black-box warning: “Swallowing and breathing difficulties can be life threatening and there have been reports of death.” Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F).
Dysport	Injectable prescription drug used to treat abnormal head positions and forehead wrinkles. Subject to FDA black-box warning: “Swallowing and breathing difficulties can be life threatening and there have been reports of death.” Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F), and away from light.
Euflexxa	Injectable Class III prescription device used to treat osteoarthritis (joint pain). Must be kept away from light.
Hyalgan	Injectable Class III prescription device used to treat osteoarthritis (joint pain).
Juvederm	Injectable Class III prescription device used to treat facial wrinkles and folds. Juvederm 2, Juvederm 3, and Juvederm 4 are not FDA-approved

	for use in the United States.
Lucentis	Injectable prescription drug used to treat macular degeneration of the eye. Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F), and away from light.
Mabthera	Injectable prescription chemotherapy drug not FDA-approved for use in the United States. Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F), and away from direct sunlight or shaking.
Macrolane	Injectable Class III device used for body contouring. Not FDA-approved for use in the United States.
Orencia	Injectable prescription drug used to treat rheumatoid arthritis (joint inflammation). Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F), and away from light and freezing.
Orthovisc	Injectable Class III prescription device used to treat osteoarthritis (joint pain).
Prolia	Injectable prescription drug used to treat osteoporosis (bone decay). Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F), and away from light, heat, and vigorous shaking.
Radiesse	Injectable Class III prescription device used to treat facial wrinkles and folds.
Remicade	Injectable prescription drug used to treat rheumatoid arthritis (joint inflammation), bowel inflammation, skeletal inflammation, skin inflammation, and other conditions. Subject to FDA black-box warning: "Increased risk of serious infections leading to hospitalization or death, including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis) and infections due to other opportunistic pathogens." Cold-chain product must be stored at temperatures from 2°C-8°C (36°F-46°F).
Restylane	Injectable Class III prescription device used to treat facial wrinkles and folds, lip-filler.
Supartz	Injectable Class III prescription device used to treat osteoarthritis (joint pain).
Synvisc	Injectable Class III prescription device used to treat osteoarthritis (joint pain).
Zometa	Injectable prescription drug used to treat complications associated with cancer.

16. From approximately April 2011 through the present, the defendants, together with co-conspirators known and unknown to the Grand Jury, illegally imported and distributed misbranded prescription drugs and devices within the United States, amounting to \$18,494,285 in gross proceeds.

17. Specifically, as to the gross proceeds from the illegal importation of misbranded prescription drugs and devices into the United States, defendant SB MEDICAL INC. with the intent to promote further illegal importation, conducted the following financial transfers:

Dates	Amount	Description
6/1/12-1/31/14	\$14,786,900	Transfers from account ending in 4962 held in the name of SB MEDICAL INC. at Chase Paymentech in Canada to account ending in 0915 held in the name of SB MEDICAL INC. at Scotia Bank in Canada
9/8/13-9/20/14	\$3,707,385	Transfers from account ending in 8025 held in the name of SB MEDICAL INC. at American Express in Canada to account ending in 0915 held in the name of SB MEDICAL INC. at Scotia Bank in Canada
3/10/11-1/30/14	\$1,292,650	Commission payment transfers from account ending in 0915 held in the name of SB MEDICAL INC. at Scotia Bank to account ending in 6086 held in the name of 6777538 Canada Inc., O/A TheWeb Guys at the Royal Bank of Canada controlled by defendant DAVID E. BURKE
7/14/11-1/28/14	\$791,732	Salary, check, and other payment transfers from account ending in 0915 held in the name of SB MEDICAL INC. at Scotia Bank to accounts ending in 2185 and 4629 held in the name of defendant TZVI LEXIER at Scotia Bank
2013	\$7,647,512	Payments to foreign co-conspirator suppliers of prescription drugs and devices intended for the illegal importation into the United States from account ending in 0915 held in the name of SB MEDICAL INC., at Scotia Bank to account ending in 4814 held in the name of SB MEDICAL INC. at Cambridge Mercantile Group

18. The above factual allegations are incorporated into each Count of this Indictment as if fully set forth in each Count.

COUNT 1
(Conspiracy)

THE GRAND JURY CHARGES THAT:

19. Beginning in at least April 2011, and continuing until the present, in the Eastern District of Virginia and elsewhere, the defendants,

TC MEDICAL GROUP,
SB MEDICAL INC.,

DAVID E. BURKE,
a/k/a "David Johnson,"
TZVI LEXIER,
HANOCH DAVID STEIN,
a/k/a "Albert Simmins,"
ASAF AKIVA IBRAHIMIAN,
a/k/a "Adam Darius," and
REUVEN MIRLIS,
a/k/a "Daniel Mirl,"

did knowingly and intentionally combine, conspire, confederate, and agree, with each other and with other persons known and unknown to the Grand Jury, to:

- a. Defraud 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 prescription drugs and devices distributed in the United States were safe and effective from the time of manufacturing to the delivery to the entity that sold or dispensed the product to the ultimate consumer or patient; and impeding, impairing, and defeating the lawful functions of CBP and ICE-HSI to protect the public health and safety by governing the importation into the United States of goods and merchandise, including drugs and devices, through deceitful and dishonest means;
- b. Fraudulently and knowingly import and bring into the United States merchandise contrary to law, and receive, conceal, buy, sell, or in any manner facilitate the transportation, concealment, or sale of such merchandise after importation, knowing the same to have been imported or brought into the United States contrary to law, in violation of Title 18, United States Code, Section 545;
- c. Introduce into interstate commerce misbranded prescription drugs and devices, in violation of Title 21, United States Code, Sections 331(a) and 333(a); and

d. Knowingly engage in the wholesale distribution in interstate commerce of prescription drugs in the United States, including to the Commonwealth of Virginia without being licensed to do so, in violation of Title 21, United States Code, Sections 331(t), 333(b)(1)(D), and 353(e)(2)(A).

Manner and Means of the Conspiracy

In furtherance of the conspiracy, the defendants and others known and unknown to the Grand Jury employed, among others, the following manner and means:

20. It was part of the conspiracy that, beginning in or around April 2011, members of the conspiracy purchased from co-conspiring foreign suppliers prescription drugs and devices manufactured and labeled for use in foreign countries, including the Republic of Turkey, Canada, France, Italy, the United Kingdom, and other countries, and caused them to be shipped into the United States.

21. It was a further part of the conspiracy that foreign suppliers, based mostly in the United Kingdom, obtained prescription drugs and devices from yet other foreign countries. Those foreign suppliers in turn forwarded them, at the direction of members of the conspiracy, to doctors and medical practices in the United States, or alternatively to locations including the personal residences and mailboxes of co-conspiring individual drop shippers in Maryland, New Jersey, Florida, Connecticut, and Arlington, Virginia, in the Eastern District of Virginia.

22. It was a further part of the conspiracy that drop shippers in the United States regularly received packages of prescription drugs and devices from abroad, removed labels and other indicia showing that they had been imported from abroad, repacked the orders, and re-shipped them to doctors and medical practices throughout the United States, including to the

Eastern District of Virginia, to give the false impression that the drugs were being distributed domestically and legally.

23. It was further part of the conspiracy that, to impede, impair, and defeat the lawful functions of the FDA, CBP, and ICE-HSI, the defendants, together with co-conspirators known and unknown to the Grand Jury, engaged in deceitful and dishonest means, including:

a. Breaking up large shipments of prescription drugs and devices into smaller separate packages to be sent into the United States to multiple locations, under multiple names, over multiple days, to be consolidated upon arrival after evading border detection;

b. Shipping packages via Royal Mail and Parcelforce Worldwide, which—because they were United Kingdom-based services—allowed packages to be delivered through the United States Postal Service with less scrutiny than would be applied to packages arriving from other countries;

c. Including on customs forms misleading statements about the package contents, weight, and value, and addressing packages to co-conspirators under false names and/or titles;

d. Frequently mishandling prescription drugs subject to strict temperature requirements by failing to keep them at a consistent temperature during shipping and storage as required for the drug's safe and effective use; and

e. Failing to keep and provide the appropriate pedigree records to prove or track the proper shipping, storage, and transaction history of prescription drugs through the supply chain.

24. It was further part of the conspiracy that the defendants, together with co-conspirators known and unknown to the Grand Jury, used the personal residences and mailboxes

of drop shippers in the United States to receive payment checks mailed from United States customers, including from the Eastern District of Virginia, to give the false impression that TC MEDICAL GROUP and SB MEDICAL INC. and their affiliates were based in the United States. Drop shippers in the United States did not cash the payment checks but instead forwarded the checks received to TC MEDICAL GROUP in Canada.

25. It was further part of the conspiracy that the defendants, together with co-conspirators known and unknown to the Grand Jury, internally tracked prescription drugs and devices for sale in the United States by their true origin, by for example, separately tracking the sales of “Botox English” and “Botox, Allergan International”; “Lucentis English” and “Lucentis Turkish”; “Synvisc Classic Turkish” and “Synvisc classic”; “Hyalgan Italian Pack” and “Hyalgan”.

26. It was further part of the conspiracy that defendants, together with co-conspirators known and unknown to the Grand Jury, regularly communicated with each other via email about the foreign acquisition, illegal importation, and sale of misbranded prescription drugs and devices in the United States.

27. It was further part of the conspiracy that defendants, together with co-conspirators known and unknown to the Grand Jury, derived a financial benefit from the illegal importation and sale of misbranded prescription drugs and devices throughout the United States, including in the Eastern District of Virginia.

Overt Acts

It was further part of the conspiracy that the following acts in furtherance of and to effect the objects of the above-described conspiracy were committed in the Eastern District of Virginia and elsewhere:

On or about the following dates, each date being a separate overt act, the following co-conspirators together with defendants TC MEDICAL GROUP and SB MEDICAL INC., caused to be sent to doctors and medical practices in the Eastern District of Virginia the following misbranded prescription drugs and devices:

Para.	Date	Participants Included	Description
28	4/4/12	DAVID E. BURKE HANOCH DAVID STEIN	2 boxes of Botox to Chantilly, Virginia
29	4/10/12	DAVID E. BURKE HANOCH DAVID STEIN	10 boxes of Botox to McLean, Virginia
30	5/1/12	HANOCH DAVID STEIN	5 boxes of Botox to McLean, Virginia
31	5/3/12	HANOCH DAVID STEIN	5 boxes of Radiesse to Vienna, Virginia
32	5/18/12	HANOCH DAVID STEIN	3 boxes of Botox to McLean, Virginia
33	5/30/12	HANOCH DAVID STEIN	5 boxes of Radiesse, 2 boxes of Juvederm, 3 boxes of Botox to Vienna, Virginia
34	6/5/12	HANOCH DAVID STEIN	5 boxes of Botox to McLean, Virginia
35	6/19/12	DAVID E. BURKE HANOCH DAVID STEIN	2 boxes of Botox to Chantilly, Virginia
36	6/20/12	HANOCH DAVID STEIN	10 boxes of Botox to McLean, Virginia
37	7/17/12	HANOCH DAVID STEIN	5 boxes of Botox, 10 boxes of Radiesse to McLean, Virginia
38	8/27/12	DAVID E. BURKE HANOCH DAVID STEIN	2 boxes of Botox to Chantilly, Virginia
39	10/4/12	DAVID E. BURKE	2 boxes of Botox to Chantilly, Virginia
40	10/22/12	DAVID E. BURKE HANOCH DAVID STEIN	5 boxes of Botox to McLean, Virginia
41	7/9/13	ASAF AKIVA IBRAHIMIAN	50 boxes of Synvisc to Fredericksburg, Virginia
42	9/18/13	ASAF AKIVA IBRAHIMIAN REUVEN MIRLIS	50 boxes of Synvisc One to Fredericksburg, Virginia
43	10/30/13	ASAF AKIVA IBRAHIMIAN REUVEN MIRLIS	50 boxes of Synvisc One to Fredericksburg, Virginia
44	2/27/14	DAVID E. BURKE	2 boxes of Botox, 1 box of Juvederm to Leesburg, Virginia
45	3/12/14	DAVID E. BURKE	2 boxes of Botox, 1 box of Juvederm, 1 box of Restylane to Leesburg, Virginia
46	4/2/14	DAVID E. BURKE	3 boxes of Botox to Leesburg, Virginia
47	4/14/14	Co-conspirators	500 boxes of Hyalgan to Virginia Beach, Virginia
48	4/25/14	DAVID E. BURKE	2 boxes of Botox, 1 box of Juvederm to Leesburg, Virginia
49	7/11/14	DAVID E. BURKE	3 boxes of Botox to Leesburg, Virginia

50. On or about April 1, 2011, defendant TZVI LEXIER instructed a drop shipper in the United States to send 10 boxes of Botox to Middleburg, Virginia, in the Eastern District of Virginia by “Overnight Saturday Delivery!!!!”

51. On or about April 11, 2011, defendant TZVI LEXIER instructed a drop shipper in the United States: “40 Botox. The purple Bottom ones that I told Stein to put aside... If we have 60 more that look identical to the 40 then please send 100 Purple bottoms and just mix them around.”

52. On or about April 28, 2011, defendant TZVI LEXIER forwarded to defendant HANOCH DAVID STEIN a customer email which stated: “We received the botox this a.m. at 10:30, my only concern is that the ice packs were completely thawed and it wasn’t even a little cold. I’ve never received a shipment of refrigerated product that warm before and I am concerned whether it is useable. We’ll try it, but in the future will need to be packaged better.”

53. On or about May 31, 2011, defendant HANOCH DAVID STEIN informed defendants TZVI LEXIER and DAVID E. BURKE: “customers have been complaining about the Botox arriving warm. Storing and purchasing dry ice is complicated, also it freezes the good... Up until now I have been using smaller coolers (with a thinner wall) and smaller ice packs (to save on shipping).”

54. On or about June 2, 2011, defendant HANOCH DAVID STEIN informed a co-conspirator and defendant TZVI LEXIER: “We received 30 boxes of Hyalgan. (FYI it is all in Spanish no English) Should I now ship out orders #5 and #6 from yesterday?” The co-conspirator responded: “Let me check David as I don’t know if the all Spanish is an issue.”

55. On or about July 12, 2011, defendant HANOCH DAVID STEIN informed defendant TZVI LEXIER: "I need to order supplies ASAP. I already stopped using the wrap that I use in the coolers to keep the botox cold."

56. On or about September 15, 2011, defendant DAVID E. BURKE instructed defendant HANOCH DAVID STEIN to "ship 6 turkish 8 juvederm" to a doctor in Utah.

57. On or about September 26, 2011, a co-conspirator emailed a customer falsely claiming that "The products we carry are all FDA approved!"

58. On or about December 12, 2011, defendant HANOCH DAVID STEIN informed defendant TZVI LEXIER that: "3 Turkish from [a doctor] FYI They were sent in an envelope (warm) They are taped together. Let me know if you can sell them and who I should send them to." A co-conspirator responded: "david, please put them in the fridge - we are selling them as normal."

59. On or about December 14, 2011, defendant DAVID E. BURKE and a co-conspirator discussed misbranded prescription drugs being imported into the United States under the false name of "Albert Simmins."

Co-conspirator :	botox was shipped to your dad, stein, albert simmins turkey will also shipped today
BURKE:	albert simmins?
Co-conspirator:	steins new name :)
BURKE:	jesus i hope that doesnt present a problem
Co-conspirator:	no he told us a new address
BURKE:	does he have ID for that name to pick up packages
Co-conspirator:	and we can use that name don't know but tzvi also confirmed that name
BURKE:	ok

60. On or about December 22, 2011, defendant DAVID E. BURKE warned a co-conspirator: "you shouldnt advertise macrolane on your site for U.S. customers if its hosted in the u.S. you could have problems product is not FDA approved for use."

61. On or about January 26, 2012, defendant HANOCH DAVID STEIN emailed to defendant TZVI LEXIER photos of drugs and devices including Supartz labeled "INTENDED FOR PHILIPPINE USE ONLY," Aclasta, Bonviva, Orenicia, Remicade, and Zometa boxes labeled in Turkish, and Prolia labeled in French.

62. On or about February 21, 2012, defendant DAVID E. BURKE and a co-conspirator discussed the illegal importation of prescription drugs and devices into the United States:

BURKE: ...please keep what your doing on the down low if possible...
Co-conspirator: ...pharmaceuticals have very very specific laws. be extremely careful with that. I'd check the with the FDA and DOJ sites...
BURKE: importing "medical devices" for sale is against the law as well... the more iv researched the more i realize that it aint so kosher ... there are companies and docotrs losing there licences over "importing" all the time... you shoudl make as much as you can while you can... i go with the thought of every day is my last and make the best of it.

63. On or about April 10, 2012, defendant DAVID E. BURKE falsely represented to a medical practice in McLean, Virginia, in the Eastern District of Virginia that: "Frozen products such as Botox are shipped only by overnight Priority FedEx (medical/frozen special handling) on several kilograms of dry ice... All products are transported and stored in climate controlled environments. Frozen products such, as Botox, are maintained in a cold storage facility at all times and our partner pharmacies are fully licensed t o dispense & ship medication."

64. On or about June 13, 2012, defendant DAVID E. BURKE drafted talking points for selling misbranded prescription drugs and devices in the United States, which stated in part:

I'm sure you know we are all in business to make money... All our products are shipped from within the united states to clinics located in the United States... As well we are a fully licensed pharmaceutical wholesaler... WE SHIPE OUR PRODUCT FROM WITHIN THE US... Now the distributor may tell you it's illegal to order from companies like ours however this is a scare tactic that they utilize on most clients to get them to stop ordering elsewhere... I can Assure you that you will find no evidence that purchasing from a company that operates the way we do is in anyway shape or form Illegal.

65. On or about August 30, 2012, defendant DAVID E. BURKE informed a co-conspirator: “im getting complaints on the turkish botox i dont think its being cooled properly and clients are starting tonotice with this last batch... stein told me this last batch did not come on ice at all ... our inventory is looking kind of low in the US we need more here.”

66. On or about September 10, 2012, defendant DAVID E. BURKE, in an email copying defendant TZVI LEXIER, instructed a drop shipper in the United States that: “The procedure should be as follows: 1. Box comes to you. 2. You open and count the products in each box. 3. You then send an email to accounting@tcmedicalgroup.com and report how many boxes came in and what was in each box. (Example: hello, I received 5 boxes today, box 1 was 20 synvisc, box 2 was 30 euflexxa, box3 was 10 orthovisc etc etc...) 4. You then pack all the stuff into one box and make sure to use packing tape, as well please handle these products with care and then head over to the local shop and ship them to Baltimore.”

67. On or about October 25, 2012, defendant DAVID E. BURKE emailed co-conspirators, including defendant HANOCH DAVID STEIN with instructions to “please make sure that these synvisc ones are clean meaning that they don’t have the Netherlands symbol on it.”

68. On or about October 30, 2012, defendant DAVID E. BURKE and a co-conspirator engaged in the following exchange:

Co-conspirator:	3 Orenca just arrived at the house. Ice was melted, of course, but they weren’t warm.
BURKE:	did you find a cooler for yesterdays botox order?
Co-conspirator:	No, but I used some insulating foil wrap and shrink wrap. Should have been OK and looked pretty good. Sent in a white box which always looks more medically professional too.
BURKE:	perfect. thanks... have another order to go out today, sending it now.

69. On or about November 1, 2012, defendant DAVID E. BURKE emailed a co-conspirator about shipments being sent to Florida: “no more rhemtalogy stuff shipped to my dad im not having him get in toruble over this ok?”

70. On or about November 5, 2012, a co-conspirator informed defendant DAVID E. BURKE that: “Eighteen boxes came today. The following items arrived: 80 Hyalgan, 60 Remcade (put in into the fridge now, were not really cold even though they were packed in nano cools), 195 Juvederm... My office looks like a warehouse and my garage is about to become one.”

71. On or about November 20, 2012, defendant DAVID E. BURKE received an email from a drop shipper in the United States describing shipments of Botox from Turkey instead of the United Kingdom: “1 piece which had previously been taken out of inventory due to being opened; I doctored it to be acceptable in order to get the orders out.”

72. On or about December 4, 2012, defendant DAVID E. BURKE forwarded to defendant TZVI LEXIER a letter from the FDA which had warned doctors that:

Purchasing Unapproved Medications from Foreign or Unlicensed Suppliers Could Result in Serious Harm to Patients... Most, if not all, of the products sold and distributed by these [foreign] suppliers, including versions of Botox, have not been approved by FDA. The manufacture and handling of these products may not be of suitable quality to ensure safety or efficacy, and the products have not been proven to be safe and effective pursuant to FDA standards. FDA is very concerned that products distributed by these suppliers may cause harm to patients, because they may be unsafe or ineffective. Medications obtained from... foreign or unlicensed suppliers may be from unknown sources, may have unknown ingredients, may be counterfeit, or may not have been manufactured, transported or stored under proper conditions as required by US law, regulations, and standards. Such products put patients at risk of exposure to ineffective or dangerous products. In virtually all cases, importing or causing the importation of unapproved prescription medications from foreign sources violates the Federal Food, Drug, and Cosmetic Act and is illegal.

73. On or about December 19, 2012, a co-conspirator instructed a drop shipper in the United States: “I am shipping to you some Synvisc Classic which should arrive in the next few days.... when you receive the package it will come from a Canadian warehouse so any stickers

or anything that says CANADA on it needs to be removed before if you are going to be using the same box that it arrives in.” The response: “Yes I know I will take care of it.”

74. On or about January 3, 2013, a co-conspirator forwarded to defendant DAVID E. BURKE a link from the FDA warning about the dangers and illegality of buying medications, including Botox from foreign and unapproved sources.

75. On or about January 14, 2013, a co-conspirator informed defendant DAVID E. BURKE: “I managed to get the labels off just as the FedEx guys came to the door and resealed the package. I’ve now removed all the stickers on the synevics I have...” BURKE responded: “This is what has to happen with all the Synvisc 1 going forward.”

76. On or about January 15, 2013, defendant TZVI LEXIER forwarded to a co-conspirator an email from defendant DAVID E. BURKE with the headline: “FDA takes action against illegal drug importation of Botox” which noted: “Importation without FDA approval is illegal. According to the United States Federal Food, Drug, and Cosmetic Act (FDCA), unauthorized drugs that are imported are considered unapproved, misbranded, and adulterated (21 U.S.C. 331).”

77. On or about February 28, 2013, defendant TZVI LEXIER received an email from a co-conspirator noting: “Often when items are packed they are wrapped so well that you can’t see the product inside. If the boxes get stopped by customs you are handing them a very easy way to see what is inside and possibly investigate.”

78. On or about March 5, 2013, a co-conspirator notified defendant TZVI LEXIER: “Hi Tzvi, attached is an image I received from [a doctor] with the reaction from the Botox injections from her 2.18.13 order – SO2087 (we spoke about it over the phone. She said 5 out of 10 gave clients side effects. Some clients went to the emergency room because the side effects

were too strong. She has 3 more that I told her not to use. Please look into it and get back to me so I could get back to her with further instructions.”

79. On or about April 5, 2013, a co-conspirator instructed others to “send everything private with value 50 \$.” The response: “what shall i put on the invoice which accompany the parcels is it ok to put cosmetic sample?” The co-conspirator replied: “gift.”

80. On or about April 15, 2013, defendant DAVID E. BURKE told a co-conspirator that: “there is also a pretty big crackdown on the botox... so im hoping this cleint is cool and not a whistlike blower.”

81. On or about April 18, 2013, a co-conspirator informed defendant TZVI LEXIER and other co-conspirators: “I don’t think it is a good idea to send 420 via Royal Mail in one day... it would be prudent to be a little more cautious.... I would then advise we send these out over 2 or 3 days.”

82. On or about May 20, 2013, co-conspirators exchanged the following advice with a drop shipper in the United States: “I f I was shipping this medication from the US I would not put my real return address and I definitely would not leave my number. You obviously know that there is a Shady/Grey aspect in what we are doing. You need to protect yourself for your sake and for ours.” The response: “My address is not on the label as David already instructed me to leave a different address.”

83. On or about May 21, 2013, a co-conspirator emailed a drop shipper in the United States: “Sooo, You are going to be receiving an order shortly for 4 Mabthera. Since this Mabthera Is more expensive and more controlled than the other infusions I want you to be a bit more vigilant with it If Necessary, Please put a different address on the return for this package,

one that is not associated with you or us. And if possible do not put a contact number, if necessary put my number that I gave you.”

84. On or about May 28, 2013, a drop shipper in the United States wrote to defendant DAVID E. BURKE: “Don’t know if this is a problem but one of the boxes of orencia was wet when I took it out of cooler today.” A co-conspirator responded: “please Refrigerate the damaged box of Orencia, but put it separately from the other Orencia. We have one client or two that doesn’t mind taking damaged boxes. When we receive an order from them we will send the damaged Orencia....”

85. On or about June 5, 2013, a drop shipper in the United States and a co-conspirator exchanged the following emails under the subject line “remicade”: “some of the boxes were a little bent today, they might be a bit damp. i just wrapped more cling wrap over them... when medication is delivered on Saturday, I have to pick it up on Monday because they are closed on Sunday, so the medications are not cold anymore, just giving you a heads up.” The response: “often when US customs receives the package and they are backed up or super busy, the delivery date for the package can be postponed a few days, thus resulting in a weekend delivery.”

86. On or about June 10, 2013, defendant TZVI LEXIER emailed a foreign supplier: “I would like to get access to as many Indian generics as possible... Can you please send me the contact details for someone in India who is reliable and can dropship prescriptions for me?”

87. On or about June 10, 2013, a co-conspirator emailed a drop shipper in the United States instructions later forwarded to defendant REUVEN MIRLIS:

my job is to make sure that myself and my co-workers have Enough Infusion medication in New Jersey... The shipping process works like this:

- 1- I arrange for product to be sent from the UK to you guys.
- 2- I will inform you in advance what the parcels are and when you should be expecting them.

3- I will provide you with tracking numbers, so that you will be aware of where the product is, when it should be arriving, and if any parcels are delayed in transit.

4- Once you receive the parcels/medication, you will keep the parcels packaged in the packaging they arrived in, and... Drive the Packages to [another United States-based drop shipper] Home, (Ideally the same day that you received them). Once you move... you will send the parcels on a FedEx overnight delivery service to one of the three addresses I will provide to you.

You will easily get used to scheduling FedEx pickups and printing shipping labels for the Parcels. Once FedEx picks up the medication they will automatically send you an email with the tracking numbers, which you will forward to me.

Please keep in mind that although what we and you are doing is technically completely legal, at the same time it is frowned upon. Therefore to avoid unnecessary attention to our company, you should never tell the FedEx delivery person that you are sending medication!!

Most of the time it will say cosmetics on the box, so as far as you know that is what you are shipping, and if they ask, that is what you will tell them...

88. On or about July 9, 2013, defendant DAVID E. BURKE received an email from a customer stating: "There was an article... pretty blistering regarding ordering from foreign companies. Over the last few months we have been ordering product purchased and shipped from the United States, I want to verify that again, and that verification that you purchase through a state licensed wholesale distributor in the US."

89. On or about July 10, 2013, a co-conspirator forwarded a customer email to defendant DAVID E. BURKE which stated: "We have been contacted by Botox and they are saying that purchasing drugs like Botox, Synvisc, an Hyalgan through other companies such as yours is illegal. Is this true?"

90. On or about July 12, 2013, defendant ASAF AKIVA IBRAHIMIAN emailed to a customer a letter purporting to be from the Chief Operation Office of TC MEDICAL GROUP signed by "Albert Simmons," the false name of HANOCH DAVID STEIN. The letter claimed that: "The Orthovisc we purchase is being manufactured in an FDA approved facility... We have been distributing the Orthovisc for over eight years now..."

91. On or about July 22, 2013, a co-conspirator emailed defendants REUVEN MIRLIS and ASAF AKIVA IBRAHIMIAN: "Orthovisc has just arrived at Yakub chemist. I'm sending 100 to Burke and 100 to Ross today. I'm not sending the 100 to Burke at the Brairwood address because we are sending 100 Synvisc Classic there today. It is too much to send in one day."

92. On or about July 24, 2013, defendant DAVID E. BURKE emailed: "did the botox arrive, or are we goign to flood us customs with 200 botox again."

93. On or about July 26, 2013, defendant DAVID E. BURKE, using the false name "David Johnson" and the false title of "Quality Assurance Specialist" based in New Jersey emailed UPS about a shipment that: "The goods in the shipment (ID# 6R173YCGBP7) are Dermal Filler product used for cosmetic purposes. The country of origin is the United Kingdom. The manufacturing country is France. This shipment is for promotional/sample purposes for the recipient."

94. On or about July 28, 2013, defendant DAVID E. BURKE emailed co-conspirators, including defendant TZVI LEXIER, that: "I do not want us sending lots of Botox into the us at one time."

95. On or about July 29, 2013, a co-conspirator advised a drop shipper in the United States: "we should be repackaging all the meds especially the orthopedics because some of the boxes might say that they are coming from the UK or a location that the customer doesn't know its coming from." The drop shipper responded: "None of the boxes had any indication that they were from the UK. All the labels and packing slips were removed."

96. On or about August 14, 2013, defendants DAVID E. BURKE emailed a co-conspirator noting: "invoices are mislabeled in order to get it into the country. You stand to lose

a lot here if the s--- hits the fan.” BURKE then emailed defendant TZVI LEXIER and a co-conspirator that: “I want to start royal mailing all fillers going forward... Turkish Botox going forward is probably not the best option to be utilizing... Dysport... we only need maximum 100 a month....this can be broken down to small shipments of 20 over a 4 week period... I also recommended to all guys here to stay low for now... tzvi agrees with this.”

97. On or about August 26, 2013, a drop shipper in the United States informed defendant DAVID E. BURKE: “I used up all the ice packs.... I bought a bunch from Walmart last night but they are not as good....”

98. On or about August 30, 2013, defendant DAVID E. BURKE emailed a drop shipper in the United States instructions to send Juvederm, Botox, Restylane, and Radiesse to “Albert Simmons,” the false name used by defendant HANOCH DAVID STEIN. The drop shipper responded: “Should I wait to send the Botox. No FedEx on Monday. Legal holiday. It probably won’t stay cold till Tuesday.” BURKE replied: “Send it out today for Tuesday delivery... it’s fine.”

99. On or about September 9, 2013, defendant REUVEN MIRLIS emailed a co-conspirator: “Please lmk when there’s an update on orthovisc for Europe...” The co-conspirator responded: “The stock situation is going to be a nightmare buddy, be prepared to ship a lot from Europe direct. Royal mail is unpredictable... tzvi refuses to ship parcel force because it passed customs which is mad heat. With Royal Mail I guess it doesn’t but takes so much longer.”

100. On or about September 10, 2013, defendants DAVID E. BURKE, TZVI LEXIER, and a co-conspirator emailed storage requirements for Botox which “requires careful handling during storage, shipping, reconstitution, and use, to ensure that the protein material is not denatured.”

101. On or about September 11, 2013, defendant ASAF AKIVA IBRAHIMIAN circulated a document labeled "Adam and Daniel's list of whats needed for their clinics.docx" listing United States customers and whether they accepted shipments of drugs and devices shipped directly from the United Kingdom or indirectly through a drop location in the United States.

102. On or about September 16, 2013, defendant TZVI LEXIER forwarded a letter of resignation from a former employee, which stated: "I became aware of the serious possibility that the Company may have been engaging in sales activities within the borders of the continental United States which violate the federal laws of the United States relating to the approval for sale and packaging and labeling of prescription drugs and medical devices. I immediately brought this to your attention and told you that I am gravely concerned over this matter and can no longer be a part of an organization that might be engaged in unlawful activities."

103. On or about September 16, 2013, a co-conspirator forwarded to defendant DAVID E. BURKE a letter stating that: "In nearly all instances, drugs and devices purchased from pharmacies are not approved for use within the United States... Given the lack of control over the standards governing the manufacture and distribution of foreign-sourced drugs and devices, it is not difficult to understand the interest federal regulators have in enforcing the prohibitions concerning the importation of such drugs and devices.... The FDCA provides for criminal liability for bringing an adulterated or misbranded drug into interstate commerce..."

104. On or about November 5, 2013, defendant DAVID E. BURKE emailed a co-conspirator: "please check the Lucentis to make sure it is not damaged or marked in any way on the box... also please separate the 5 and the 10 bc I will need to mix it up when we send it out."

105. On or about November 19, 2013, a co-conspirator emailed to defendant DAVID E. BURKE a link to an FDA enforcement letter and noting: "Our website is NOT there" with BURKE warning the co-conspirator not to email such links in subject lines.

106. On or about November 26, 2013, a co-conspirator emailed defendants ASAF AKIVA IBRAHIMIAN and REUVEN MIRLIS:

U want 125 Orthovisc fast? Well let me tell u a trick that might work but doesn't always. I would have 125 Orthovisc Parcel Forced to your client from Europe. Then tell the client, oopps, for some reason a wrong warehouse shipped you instead of our American branch. The client returns the 125 to NJ by UPS overnight. And u go ahead and ship the SAME 125 Orthovisc back to your client on an overnight basis. Tzvi and [a co-conspirator] refuse to Parcel Force anything EXCEPT the client themselves. This is probably the fastest way for you to get all 125 Orthovisc Fast to your client. Your other option is to wait and wait until there are enough and have to ship 3 times to the client until you fill the FULL order. This is crazy enough to just might work! :) ... AND you want to hear a more devious way of getting it there? Well, let's say your client DOESN'T ACCEPT stuff from Europe and it would be heat out to ship to them so.... Well, let's say you have a client who DOES accept Orthovisc from Europe so u send it to them, then apologize to them and say 'Accidently' the WRONG order was shipped to you I will have UPS pick this up from you...you with me so far???? Then u ship it via NJ to the REAL client on UPS. KABOOM!!@! Am I devious or am I devious mr. Darius?!?!?!

IBRAHIMIAN responded: "hahahahaha. i just read this whole thing. genius!"

107. On or about December 4, 2013, a co-conspirator emailed defendants ASAF AKIVA IBRAHIMIAN and REUVEN MIRLIS: "We started removing the NJ warehouse addresses on the invoices to customers, it is heat I probably don't need to explain to you why we shouldn't have Moe R. address on every invoice going out to customers... Please remove all addresses from your invoices going forward. If your client is paying by check then u can call them and tell them orally or email once where they should send the checks but on the invoice itself please remove it. As well, we have removed everyone's names off our website for obvious reasons."

108. On or about December 4, 2013, a drop shipper in the United States emailed to defendant DAVID E. BURKE an FDA letter stating that a shipment had been detained. BURKE responded: "Its OK.... don't worry happens all the time."

109. On or about December 12, 2013, a co-conspirator advised a drop shipper in the United States: "how easy is it for u to switch addresses etc, probably a good idea to do so every year... I think its worth while as we don't know how USPS works and whether certain addresses get flagged or not.... just trying to stay a step ahead :)"

110. On or about January 3, 2014, defendant DAVID E. BURKE emailed defendant TZVI LEXIER and another co-conspirator an email with subject line "Oncology products" and noted: "Please let me know what products we can get our hands on... English Packaging will be an easier and safer sale."

111. On or about January 7, 2014, a drop shipper in the United States emailed defendant DAVID E. BURKE: "shipped radiesse today to baltimore, also, got another letter from the FDA," BURKE responded: "Regarding orthopedic again ?"

112. On or about January 14, 2014, defendant DAVID E. BURKE emailed co-conspirators a draft of a sales pitch with answers to potential customer questions which falsely stated: "we are a licensed medical wholesaler... we buy the product in bulk from the manufacturer direct... I READ SOMEWHERE IT IS ILLEGAL TO PURCHASE: if the product is being sent from medical facility to medical facility there is no issue with legality..."

113. On or about January 15, 2014, a drop shipper in the United States emailed defendant DAVID E. BURKE that "[t]his came to our house" and enclosed a letter from the FDA stating that a shipment of product had been detained. BURKE noted: "It really isn't a big issue at all. Still decreasing isn't a bad idea."

114. On or about February 11, 2014, a co-conspirator informed a drop shipper in the United States: "This customer claims that the 3 Prolia they received came warm from the U.K so they want to return it. Can you please schedule UPS to pick it up TOMORROW...? ... Do the pickup in the morning between 11 and 2pm—whatever it doesn't really matter. And it will go back to you, and we will ship it out as soon as it is cold again."

115. On or about February 19, 2014, defendant DAVID E. BURKE emailed a drop shipper in the United States: "You don't put any ice in the boxes when you ship them to Baltimore right?" The response: "The Botox I do even thought it's not sent with ice packs..." BURKE replied: "You do not need to put ice in anything going forward. It is arriving to Baltimore wet... No reason to put the ice going forward."

116. On or about February 24, 2014, defendant TZVI LEXIER wrote to a co-conspirator: "your new website... displays rheumatology and oncology plus other pharmaceuticals on it. I would highly suggest you pull down these products. The US FDA plus all the big Pharma distributors are on a massive hunt now to destroy and parallel Pharma business and it wouldn't be wise to be advertising to blatantly online. Also the last thing I want is them to come investigate you because of this and then uncover our previous business dealings and then start looking at us."

117. On or about March 6, 2014, defendant ASAF AKIVA IBRAHIMIAN forwarded an email from a customer asking how much Orthovisc was in stock. The email was addressed to "Adam Darius," the false name of defendant IBRAHIMIAN. IBRAHIMIAN forwarding the email stated: "of course this isnt ADAM:)"

118. On or about April 16, 2014, defendant DAVID E. BURKE forwarded a co-conspirator an email from a sales representative who noted: "Jill ordered 35 orencia last week

and only 7 came today and they were warm and all the ice packs melted. she had to cancel a lot of her patients , so as you can imagine she is very upset!”

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

COUNTS 2 THROUGH 12
 (Importation Contrary to Law)

THE GRAND JURY FURTHER CHARGES THAT:

119. The factual allegations contained in Paragraphs 1 through 18 and 20 through 118 are re-alleged and incorporated as if fully set forth here.

120. On or about the following dates, each date constituting a separate count, TC MEDICAL GROUP and SB MEDICAL INC. and other co-conspirators known and unknown to the Grand Jury, together with the following defendants in the Eastern District of Virginia and elsewhere, did fraudulently and knowingly import and bring into the United States merchandise contrary to law, in that the merchandise was: misbranded prescription drugs and devices, in violation of 21 U.S.C. §§ 331(a) and 333(a)(1), and imported by means of a fraudulent and false invoice, declaration, affidavit, letter, paper, and by means of a false statement in a declaration without reasonable cause to believe the truth of such statement, and by means of a false statement procured as to a material matter without reasonable cause to believe the truth of such statement, in violation of 18 U.S.C. § 542, and fraudulently and knowingly did conceal, sell, and facilitate the transportation, concealment, and sale of said merchandise after importation, knowing the same to have been imported and brought into the United States contrary to law.

Count	Date	Defendants	Description
2	4/4/12	DAVID E. BURKE HANOCH DAVID STEIN	2 boxes of Botox sold and transported to Chantilly, Virginia
3	4/10/12	DAVID E. BURKE HANOCH DAVID STEIN	10 boxes of Botox to McLean, Virginia
4	5/30/12	HANOCH DAVID STEIN	5 boxes of Radiesse, 2 boxes of Juvederm, 3 boxes of Botox to Vienna, Virginia
5	7/9/13	ASAF AKIVA IBRAHIMIAN	50 boxes of Synvisc sold and transported to Fredericksburg, Virginia
6	9/18/13	ASAF AKIVA IBRAHIMIAN REUVEN MIRLIS	50 boxes of Synvisc sold and transported to Fredericksburg, Virginia
7	10/30/13	ASAF AKIVA IBRAHIMIAN	50 boxes of Synvisc sold and transported to

		REUVEN MIRLIS	Fredericksburg, Virginia
8	2/27/14	DAVID E. BURKE	2 boxes of Botox and one box of Juvederm sold and transported to Leesburg, Virginia
9	3/12/14	DAVID E. BURKE	2 boxes of Botox, one box of Juvederm, and one box of Restylane sold and transported to Leesburg, Virginia
10	4/2/14	DAVID E. BURKE	3 boxes of Botox sold and transported to Leesburg, Virginia
11	4/25/14	DAVID E. BURKE	2 boxes of Botox and one box of Juvederm sold and transported to Leesburg, Virginia
12	7/11/14	DAVID E. BURKE	3 boxes of Botox sold and transported to Leesburg, Virginia

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

COUNTS 13 THROUGH 23

(Introducing Misbranded Prescription Drugs and Devices in Interstate Commerce)

THE GRAND JURY FURTHER CHARGES THAT:

121. The factual allegations contained in Paragraphs 1 through 18 and 20 through 118 are re-alleged and incorporated as if fully set forth here.

122. On or about the dates listed below, each date being a separate count, in the Eastern District of Virginia and elsewhere, defendants TC MEDICAL GROUP and SB MEDICAL INC. and other co-conspirators known and unknown to the Grand Jury, together with the following defendants, with the intent to defraud and mislead, introduced, delivered for introduction, and caused and aided and abetted the introduction and delivery for introduction into interstate commerce, into the Eastern District of Virginia to the locations listed below, the indicated prescription drugs and devices that were misbranded as defined in Title 21, United States Code, Sections 352 and 353(b)(4)(A), because their labeling did not bear adequate directions for use.

Count	Date	Defendants	Description
13	4/4/12	DAVID E. BURKE HANOCH DAVID STEIN	2 boxes of Botox sold and transported to Chantilly, Virginia
14	4/10/12	DAVID E. BURKE HANOCH DAVID STEIN	10 boxes of Botox to McLean, Virginia
15	5/30/12	HANOCH DAVID STEIN	5 boxes of Radiesse, 2 boxes of Juvederm, 3 boxes of Botox to Vienna, Virginia
16	7/9/13	ASAF AKIVA IBRAHIMIAN	50 boxes of Synvisc sold and transported to Fredericksburg, Virginia
17	9/18/13	ASAF AKIVA IBRAHIMIAN REUVEN MIRLIS	50 boxes of Synvisc sold and transported to Fredericksburg, Virginia
18	10/30/13	ASAF AKIVA IBRAHIMIAN REUVEN MIRLIS	50 boxes of Synvisc sold and transported to Fredericksburg, Virginia
19	2/27/14	DAVID E. BURKE	2 boxes of Botox and one box of Juvederm sold and transported to Leesburg, Virginia
20	3/12/14	DAVID E. BURKE	2 boxes of Botox, one box of Juvederm, and

			one box of Restylane sold and transported to Leesburg, Virginia
21	4/2/14	DAVID E. BURKE	3 boxes of Botox sold and transported to Leesburg, Virginia
22	4/25/14	DAVID E. BURKE	2 boxes of Botox and one box of Juvederm sold and transported to Leesburg, Virginia
23	7/11/14	DAVID E. BURKE	3 boxes of Botox sold and transported to Leesburg, Virginia

(All in violation of Title 21, United States Code, Sections 331(a) and 333(a), and Title 18, United States Code, Section 2)

COUNT 24

(Unlicensed Wholesale Distribution of Prescription Drugs)

THE GRAND JURY FURTHER CHARGES THAT:

123. The factual allegations contained in Paragraphs 1 through 18 and 20 through 118 are re-alleged and incorporated as if fully set forth here.

124. Between in or about April 2011 and the present, in the Eastern District of Virginia and elsewhere, defendants

TC MEDICAL GROUP,
SB MEDICAL INC.,
DAVID E. BURKE,
a/k/a "David Johnson,"
TZVI LEXIER,
HANOCH DAVID STEIN,
a/k/a "Albert Simmins,"
ASAF AKIVA IBRAHIMIAN,
a/k/a "Adam Darius," and
REUVEN MIRLIS,
a/k/a "Daniel Mirl,"

did knowingly engage in, and aid and abet, and attempt, the wholesale distribution in interstate commerce of prescription drugs without being licensed in any State of the United States; specifically, the defendants sent or caused to be sent Botox and Botox Cosmetic from States outside the Commonwealth of Virginia including but not limited to New Jersey and Maryland, into the Commonwealth of Virginia, knowing that those prescription drugs were intended for unlicensed wholesale distribution.

(All in violation of Title 21, United States Code, Sections 331(t), 333(b)(1)(D), 353(e)(2)(A), and 353(e)(3)(B) and Title 18, United States Code, Section 2)

COUNT 25
(Conspiracy to Launder Money)

THE GRAND JURY FURTHER CHARGES THAT:

125. The factual allegations contained in Paragraphs 1 through 18 and 20 through 118 are re-alleged and incorporated as if fully set forth here.

The Conspiracy

126. From at least October 2011 through at least October 2014, in the Eastern District of Virginia and elsewhere, defendants

TC MEDICAL GROUP,
SB MEDICAL INC.,
DAVID E. BURKE,
a/k/a "David Johnson,"
TZVI LEXIER,
HANOCH DAVID STEIN,
a/k/a "Albert Simmins,"
ASAF AKIVA IBRAHIMIAN,
a/k/a "Adam Darius," and
REUVEN MIRLIS,
a/k/a "Daniel Mirl,"

did knowingly combine, conspire, and agree with each other and with other persons known and unknown to the Grand Jury to commit offenses against the United States in violation of Title 18, United States Code, Section 1956, to wit: to transport, transmit and transfer and attempt to transport, transmit and transfer a monetary instrument 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 specified unlawful activity, to wit: fraudulently and knowingly import and bring into the United States merchandise contrary to law, and receive, conceal, buy, sell, or in any manner facilitate the transportation, concealment, or sale of such merchandise after importation, knowing the same to have been imported or brought into the United States contrary to law, in violation of

Title 18, United States Code, Section 545, in violation of Title 18, United States Code, Section 1956(a)(2)(A).

Manner and Means

The manner and means used to accomplish the objectives of the conspiracy included, among others, the following:

127. The defendants moved the proceeds from the sale of misbranded prescription drugs and devices which had been imported contrary to law from the United States to bank accounts in Canada in two main ways. First, the defendants used credit card payment systems and processors to transfer proceeds from the United States to Canada. Second, co-conspirator drop shippers based in the United States received payment checks by mail, bundled them, and forwarded them to Canada to be deposited into bank accounts, all to give the false impression to customers including doctors and medical practices that the defendants operated legally in the United States.

128. The defendants, and together with co-conspirators known and unknown to the Grand Jury, caused at least \$14,786,900 to be transferred from payment card transactions, including VISA and MasterCard into the bank account of defendant SB MEDICAL INC. in Canada. Payment card transactions of VISA were conducted through servers in Ashburn, Virginia, in the Eastern District of Virginia.

129. Once the funds were in the bank account of defendant SB MEDICAL INC., the defendants caused further financial transactions to be made in furtherance of the conspiracy, including:

a. Payments amounting to millions of dollars to foreign co-conspirator suppliers to obtain supplies of prescription drugs and devices intended for the illegal importation into the United States;

b. Payments amounting to millions of dollars to co-conspirator salespersons in the United States and Canada, including defendants ASAF AKIVA IBRAHIMIAN, REUVEN MIRLIS, and DAVID E. BURKE, representing commission payments for the illegal importation and sale of misbranded prescription drugs and devices within the United States on behalf of TC MEDICAL GROUP and SB MEDICAL INC.

c. Payments amounting to hundreds of thousands of dollars to co-conspirator drop shippers in the United States, including defendant HANOCH DAVID STEIN, representing payments for receiving, repacking, and resending misbranded prescription drugs and devices to other customers or locations within the United States.

d. Distributions amounting to hundreds of thousands of dollars to co-conspirator and principal of TC MEDICAL GROUP and SB MEDICAL INC., defendant TZVI LEXIER.

e. In furtherance of the conspiracy, the following financial transactions were also made:

Date	Description	
11/16/12	Transfer of \$3,340.00 from Scotia Bank account ending in 0915 held in the name of defendant SB MEDICAL INC. in Canada to Greater Nevada Credit Union account ending in 8343 held in the name of a co-conspirator in Nevada.	
5/3/13	Transfer of \$800.00 from Scotia Bank account ending in 0915 held in the name of defendant SB MEDICAL INC. in Canada to Susquehanna Bank account ending in 8001 held in the name of a co-conspirator in Maryland.	
6/3/13	Transfer of \$2,459.00 from Scotia Bank account ending in 0915 held in the name of defendant SB MEDICAL INC. in Canada to PNC bank account ending in 1118 held in the name of a co-conspirator in Florida.	
6/27/13	Transfer of \$500.00 from Scotia Bank account ending in 0915 held in the name of	

	defendant SB MEDICAL INC. in Canada to JP Morgan Chase account ending in 2829 held in the name of a co-conspirator in New Jersey.
11/14/13	Transfer of \$18,375.34 from Scotia Bank account ending in 0915 held in the name of defendant SB MEDICAL INC. in Canada to Wells Fargo bank account ending in 2624 held in the name of R&A Consulting Group, an entity owned by defendants ASAF AKIVA IBRAHIMIAN and REUVEN MIRLIS in New Jersey.
12/19/13	Transfer of \$850.00 from Scotia Bank account ending in 0915 held in the name of defendant SB MEDICAL INC. in Canada to Manufacturers & Traders Trust bank account ending in 9117 held in the name of a person affiliated with a co-conspirator in Maryland.
1/9/14	Transfer of \$8,357.50 from Scotia Bank account ending in 0915 held in the name of defendant SB MEDICAL INC. in Canada to JP Morgan Chase account ending in 1790 held in the name of a co-conspirator in New Jersey.

130. In addition, on or about October 5, 2011, a co-conspirator emailed defendant HANOCH DAVID STEIN that defendant TZVI LEXIER “has requested that you ship the check which you received for \$8,114.85 from Southern Orth Ass to the location nin Barbados.”

131. On or about October 16, 2012, a drop shipper in the United States asked defendant DAVID E. BURKE: “I’m creating the shipment for the Botox and checks to Toronto and it asks for me to put in a customs value, what should I put in.”

132. On or about March 6, 2013, defendant DAVID E. BURKE emailed a co-conspirator in Canada copies of checks from customers in the United States sent to a drop location of defendants SB MEDICAL INC. and TC MEDICAL GROUP located in Baltimore, Maryland.

133. On or about the following dates, co-conspirators emailed to each other copies of checks which had been made out to SB MEDICAL INC. and TC MEDICAL GROUP, and had been sent from a medical practice in Fredericksburg, Virginia, in the Eastern District of Virginia, to a drop location in the United States before being mailed abroad:

Date	Description
5/6/13	Check for \$22,720.00 sent to drop location in Lakewood, New Jersey
6/24/13	Check for \$22,275.00 sent to drop location in Lakewood, New Jersey

7/29/13	Check for \$22,275.00 sent to drop location in Lakewood, New Jersey
11/11/13	Check for \$22,275.00 sent to drop location in Lakewood, New Jersey
12/9/13	Check for \$22,275.00 sent to drop location in Lakewood, New Jersey

134. On or about June 24, 2013, defendant ASAF AKIVA IBRAHIMIAN emailed a customer to explain that: “Our accounts receivable has moved to a new location” and provided the location of a house of a co-conspirator living in Lakewood, New Jersey.

135. On or about November 13, 2013, defendant REUVEN MIRLIS emailed defendant TZVI LEXIER: “Ive worked hard to get in payments and over the last week and a half we have gotten between CC and checks over 60k”

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

NOTICE OF FORFEITURE

1. The allegations contained in Counts One through 12 and 25 of this Indictment are hereby alleged and incorporated by reference for the purpose of alleging forfeiture.

2. Pursuant to Federal Rule of Criminal Procedure 32.2(a), the United States of America gives notice to the defenants that, in the event of a conviction of any of the offenses charged in Counts 1 through 12 and 25 of this Indictment, the United States intends to forfeit the property further described in this NOTICE OF FORFEITURE.

3. A defendant who is convicted of an offense in violation of 18 U.S.C. § 545, or a conspiracy to violate 18 U.S.C. § 545, shall forfeit to the United States of America, pursuant to 18 U.S.C. § 981(a)(1)(C) and 28 U.S.C. § 2461(c), any property, real or personal, which constitutes or is derived from proceeds traceable to such violations.

4. A defendant who is convicted of an offense in violation of 18 U.S.C. § 1956(h) shall forfeit to the United States of America, pursuant to 18 U.S.C. § 982(a)(1), any property, real or personal, involved in such violation, or any property traceable to such property.

5. The property to be forfeited includes, but is not limited to, the following:

a. \$18,494,284.73 dollars in United States dollars;

b. Chase Paymentech account ending in 4962 registered to ORTHODOCSPHARM and R.L. located at 258 Wilson Ave., Ste. 200, North York, ON, M3H 1S6;

c. American Express Merchant Service account ending in 8025 registered to SB MEDICAL INC. and TZVI LEXIER located at 258 Wilson Avenue, Ste. 210, North York, ON M3H 1S6;

- d. Scotia Bank account ending in 0915 registered to defendant SB MEDICAL INC. located at 340 College Street, Ste. 210, Toronto, ON M5T 3A9;
- e. Cambridge Mercantile Group account ending in 4814 registered to defendant SB MEDICAL INC., located at 258 Wilson Ave., Toronto, Canada M3H 1S6;
- f. Royal Bank of Canada account ending in 6086 registered to 6777538 Canada Inc., O/A The Web Guys, located at 81 Esther Cres., Thornhill ON L4J 3J8;
- g. Scotia Bank account ending in 2185 and account ending in 4629 registered to defendant TZVI LEXIER;
- h. Web domains: www.tcmedicalgroup.com, www.tcmedgroup.com, www.ccairect.com, and www.premiumpharmaceuticals.com.

6. If any of the property described above, as a result of any act or omission of any 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,

the United States of America shall be entitled to forfeiture of substitute property pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 18, United States Code, Sections 982(b)(1) and Title 28, United States Code, Section 2461(c).

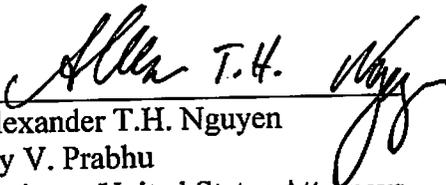
(All pursuant to 18 U.S.C. § 981(a)(1)(C), 28 U.S.C. § 2461(c), § 982(b)(1), and 21 U.S.C. § 853(p))

A TRUE BILL:

Pursuant to the E-Government Act,
the original of this page has been filed
under seal in the Clerk's Office.

Foreperson of the Grand Jury

DANA J. BOENTE
UNITED STATES ATTORNEY



Alexander T.H. Nguyen
Jay V. Prabhu
Assistant United States Attorneys