UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA v. REBECCA FADANELLI, Defendant	Criminal No. 24cr10352 Violations: Counts One–Four: Importing Merchandise Contrary to Law; Aiding and Abetting (18 U.S.C. §§ 545 and 2) Counts Five–Six: Sale/Dispensing of Counterfeit Drugs (21 U.S.C. §§ 331(i)(3) and 333(b)(8)) Counts Seven–Eight: Sale/Dispensing of Counterfeit Devices (21 U.S.C. §§ 331(fff)(3) and 333(b)(8)) Import Violation Forfeiture Allegation: (18 U.S.C. § 982(a)(2)(B)) FDCA Violation Forfeiture Allegation: (21 U.S.C. § 334 and 28 U.S.C. § 2461(c))

INDICTMENT

At all times relevant to this Indictment:

General Allegations

1. Defendant REBECCA FADANELLI ("FADANELLI") resided in Stoughton, Massachusetts.

2. FADANELLI owned and operated Skin Beaute, Inc., doing business as Skin Beaute Med Spa, with locations in Randolph and South Easton, Massachusetts.

3. FADANELLI offered various spa services and cosmetic procedures to Skin Beaute Med Spa clients.

4. FADANELLI was an aesthetician. She was not a licensed nurse or other medical practitioner.

5. FADANELLI was also the Vice President and Director of Linda Concept Inc., a clothing store in Weymouth, Massachusetts.

The Federal Food, Drug, and Cosmetic Act

6. The United States Food and Drug Administration ("FDA") regulated, among other things, the manufacture and distribution of drugs and medical devices in the United States according to the provisions of the Federal Food, Drug, and Cosmetic Act, Title 21, United States Code, Section 301 *et seq.* ("FDCA").

7. The FDCA defined a "drug," in relevant part, as any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and any article (other than food) intended to affect the structure or any function of the human body. 21 U.S.C. § 321(g)(1).

8. The FDCA defined a "device," in relevant part, as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article intended to affect the structure or any function of the human body, and which does not achieve its primary intended purposes through chemical action within or on the human body and which is not dependent upon being metabolized for the achievement of its primary intended purposes. 21 U.S.C. § 321(h).

9. Under the FDCA, a prescription drug or prescription device was one that, because of its toxicity, other potential harmful effects, the methods of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by

law to administer the prescription drug or prescription device. 21 U.S.C. § 353(b)(1)(A); 21 C.F.R. § 801.109.

10. Botox, manufactured by Allergan, was FDA-approved to treat, among other things, facial wrinkles.

11. Sculptra and Restylane, manufactured by Galderma, and Juvederm, manufactured by Allergan, were FDA-approved injectable dermal fillers.

12. The FDA regulated Botox as a prescription drug.

13. The FDA regulated Sculptra, Restylane, and Juvederm as prescription medical devices.

14. The FDCA defined a "counterfeit drug," in relevant part, as a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, or any likeness thereof, of a drug manufacturer, and which thereby falsely purports or is represented to be the product of that drug manufacturer. 21 U.S.C. § 321(g)(2).

15. The FDCA defined a "counterfeit device," in relevant part, as a device which, or the container, packaging, or labeling of which, without authorization, bears a trademark, trade name, or other identifying mark, or any likeness thereof, of a device manufacturer, and which thereby falsely purports or is represented to be the product of that device manufacturer. 21 U.S.C. § 321(h)(2).

Importation and Sale/Dispensing of Counterfeit Prescription Drugs and Devices

16. Beginning in at least March 2021 and continuing through approximately in or about November 2024, FADANELLI offered Botox and dermal filler injections to Skin Beaute Med Spa clients.

17. FADANELLI falsely represented to Skin Beaute Med Spa clients and employees that she was a nurse licensed to perform injections.

18. For example, in or about September 2022, FADANELLI told a Skin Beaute Med Spa client ("Client 1") that she was a nurse before performing a filler procedure on Client 1. Client 1 paid Skin Beaute Med Spa approximately $275 for this procedure.

19. FADANELLI also made false statements to Skin Beaute Med Spa clients regarding the identity and safety of the substances she was injecting into the clients.

20. The products FADANELLI injected into her clients included counterfeit Botox, Sculptra, Restylane, and Juvederm.

21. FADANELLI imported counterfeit prescription drugs and devices, including counterfeit Botox, Sculptra, and Juvederm, from China and Brazil.

22. For example, on or about October 26, 2023, FADANELLI returned to the United States from Brazil carrying, among other things, products labeled as Sculptra which Galderma has since identified as counterfeit.

23. In addition, between approximately in or about November 2023 and in or about March 2024, FADANELLI caused at least six parcels, originating from China and sent via UPS, DHL, or FedEx, to be shipped to FADANELLI's home and to both Skin Beaute Med Spa locations that contained, among other things, products labeled as Botox, Sculptra, and Juvederm which Allergan and Galderma have since identified as counterfeit.

24. For example, on or about December 5, 2023, law enforcement detained a parcel, addressed to FADANELLI's attention at the Skin Beaute Med Spa location in Randolph, that contained, among other things, products labeled as Botox which Allergan has since identified as counterfeit.

25. After law enforcement seized certain parcels referenced in paragraph 23 above that were addressed to Skin Beaute Med Spa, FADANELLI caused a Chinese supplier of counterfeit prescription drugs and devices to use different delivery addresses for the shipments, including FADANELLI's home address and the address of Linda Concept Inc., FADANELLI's clothing store in Weymouth.

26. On or about June 28, 2024, law enforcement found various injectable prescription drugs and devices at both Skin Beaute Med Spa locations, including products labeled as Botox, Sculptra, Restylane, and Juvederm which Allergan and Galderma have since identified as counterfeit.

27. Customer records reflect that FADANELLI has never purchased authentic prescription drugs or devices from Allergan or Galderma.

28. From approximately in or about March 2021 through in or about March 2024, FADANELLI performed approximately 1,631 Botox injection procedures and approximately 1,085 filler injection procedures using counterfeit prescription drugs and devices, resulting in payments from Skin Beaute Med Spa clients totaling approximately $933,414.

29. For example, on or about January 31, 2022, a Skin Beaute Med Spa client ("Client 2") paid Skin Beaute Med Spa approximately $350 for a purported Botox injection procedure performed by FADANELLI.

30. On or about March 9, 2024, FADANELLI injected purported Botox and purported Restylane into another Skin Beaute Med Spa client ("Client 3") in exchange for payment.

31. In addition, on or about October 18, 2024, FADANELLI performed a filler injection procedure on another Skin Beaute Med Spa client ("Client 4"), using purported Restylane, in exchange for payment.

COUNTS ONE–FOUR
Importing Merchandise Contrary to Law; Aiding and Abetting
(18 U.S.C. §§ 545 and 2)

The Grand Jury charges:

32. The Grand Jury re-alleges and incorporates by reference paragraphs 1 through 31 of this Indictment.

33. On or about the dates listed below, in the District of Massachusetts and elsewhere, the defendant,

REBECCA FADANELLI,

did fraudulently and knowingly import and bring into the United States merchandise contrary to law and receive, conceal, buy, sell, and facilitate the transportation, concealment, and sale of such merchandise after importation, knowing the same to have been imported and brought into the United States contrary to law, as set forth below:

Count	Approximate Date	Merchandise
1	10/26/2023	Products labeled as "Sculptra"
2	11/21/2023	Products labeled as "Juvederm"
3	12/5/2023	Products labeled as "Botox"
4	2/6/2024	Products labeled as "Botox"

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

COUNTS FIVE–SIX
Sale/Dispensing of Counterfeit Drugs
(21 U.S.C. §§ 331(i)(3) and 333(b)(8))

The Grand Jury further charges:

34. The Grand Jury re-alleges and incorporates by reference paragraphs 1 through 31 of this Indictment.

35. On or about the dates set forth below, in the District of Massachusetts and elsewhere, the defendant,

REBECCA FADANELLI,

knowingly sold and dispensed counterfeit drugs, to wit products labeled as "Botox" but not manufactured by Allergan, as set forth below:

Count	Approximate Date	Description
5	1/31/2022	Injection of counterfeit Botox to Client 2
6	3/9/2024	Injection of counterfeit Botox to Client 3

All in violation of Title 21, United States Code, Sections 331(i)(3) and 333(b)(8).

COUNTS SEVEN–EIGHT
Sale/Dispensing of Counterfeit Devices
(21 U.S.C. §§ 331(fff)(3) and 333(b)(8))

The Grand Jury further charges:

36. The Grand Jury re-alleges and incorporates by reference paragraphs 1 through 31 of this Indictment.

37. On or about the dates set forth below, in the District of Massachusetts and elsewhere, the defendant,

REBECCA FADANELLI,

knowingly sold and dispensed counterfeit devices, to wit products labeled as "Restylane" but not manufactured by Galderma, as set forth below:

Count	Approximate Date	Description
7	3/9/2024	Injection of counterfeit Restylane to Client 3
8	10/18/2024	Injection of counterfeit Restylane to Client 4

All in violation of Title 21, United States Code, Sections 331(fff)(3) and 333(b)(8).

IMPORT VIOLATION FORFEITURE ALLEGATION
(18 U.S.C. § 982(a)(2)(B))

The Grand Jury further finds:

38. Upon conviction of one or more of the offenses in violation of Title 18, United States Code, Section 545, as set forth in Counts One through Four, the defendant,

REBECCA FADANELLI,

shall forfeit to the United States pursuant to Title 18, United States Code, Section 982(a)(2)(B), any property constituting, or derived from, proceeds obtained, directly or indirectly, as the result of such offenses. The property to be forfeited includes, but is not limited to, the following:

a. $933,414, to be entered in the form of a forfeiture money judgment.

39. If any of the property described in Paragraph 38 above as being forfeitable, as a result of any act or omission of the defendant:

a. cannot be located upon the exercise of due diligence;

b. has been transferred or sold to, or deposited with, a third party;

c. has been placed beyond the jurisdiction of the Court;

d. has been substantially diminished in value; or

e. has been commingled with other property which cannot be divided without difficulty;

it is the intention of the United States, pursuant to Title 18, United States Code, Section 982(b), incorporating Title 21, United States Code, Section 853(p), to seek forfeiture of any other property of the defendant up to the value of the property described in Paragraph 38 above.

All pursuant to Title 18, United States Code, Section 982(a)(2)(B).

FDCA VIOLATION FORFEITURE ALLEGATION
(21 U.S.C. § 334 and 28 U.S.C. § 2461(c))

40. Upon conviction of one or more of the offenses in violation of Title 21, United States Code, Sections 331(i)(3) or 331(fff)(3), as set forth in Counts Five through Eight, the defendant,

REBECCA FADANELLI,

shall forfeit to the United States, pursuant to Title 21, United States Code, Section 334, and Title 28, United States Code, Section 2461(c), any property constituting: (a) any drug that is a counterfeit drug, (b) any container of a counterfeit drug, (c) any punch, die, plate, stone, labeling, container, or other thing used or designed for use in making a counterfeit drug or drugs, (d) any adulterated or misbranded device, (e) any adulterated or misbranded tobacco product, (f) any device that is a counterfeit device, (g) any container, packaging, or labeling of a counterfeit device, and (h) any punch, die, plate, stone, labeling, container, or other thing used or designed for use in making a counterfeit device or devices.

41. If any of the property described in Paragraph 40 above as being forfeitable pursuant to Title 21, United States Code, Section 334, and Title 28, United States Code, Section 2461(c), as a result of any act or omission of the defendant:

a. cannot be located upon the exercise of due diligence;

b. has been transferred or sold to, or deposited with, a third party;

c. has been placed beyond the jurisdiction of the Court;

d. has been substantially diminished in value; or

e. has been commingled with other property which cannot be divided without difficulty;

it is the intention of the United States, pursuant to Title 28, United States Code, Section 2461(c), incorporating Title 21, United States Code, Section 853(p), to seek forfeiture of any other property of the defendant up to the value of the property described in Paragraph 40 above.

All pursuant to Title 21, United States Code, Section 334, and Title 28, United States Code, Section 2461(c).

A TRUE BILL

FOREPERSON

LESLIE A. WRIGHT
SARAH B. HOEFLE
ASSISTANT UNITED STATES ATTORNEYS
DISTRICT OF MASSACHUSETTS

District of Massachusetts: November 20, 2024
Returned into the District Court by the Grand Jurors and filed.

/s/Thomas F. Quinn 11/20/24 @ 5:18pm
DEPUTY CLERK