

**AFFIDAVIT OF SPECIAL AGENT BRIAN HENDRICKS
IN SUPPORT OF AN APPLICATION FOR A SEARCH WARRANT**

I, Brian Hendricks, state:

INTRODUCTION AND AGENT BACKGROUND

1. I have been a Special Agent with the United States Food and Drug Administration's Office of Criminal Investigations ("FDA-OCI") since February 2009. Before joining FDA-OCI, I served for approximately eight years as an Inspector for the U.S. Postal Inspection Service ("USPIS") and as a Special Agent with the Internal Revenue Service's Criminal Investigation Division ("IRS-CID"). During that time, I was responsible for investigating Title 18 and Title 26 violations impacting the interests of those agencies. I have completed several federal agency-sponsored training courses, including FDA-OCI Special Agent Basic Training, the FDA-OCI Federal Food, Drug, and Cosmetic Act Law Class, FDA-OCI Cybercrime Investigations Basic Training and Advanced Training, the USPIS Basic Inspector Training, IRS Special Agent Basic Training, and the Criminal Investigator Training Program at the Federal Law Enforcement Training Center.

2. As a Special Agent with FDA-OCI, I am responsible for conducting criminal investigations involving violations of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, and other federal statutes enforced by the United States Food and Drug Administration ("FDA"). During my employment in federal law enforcement, I have learned various means and methods by which illegal prescription drug traffickers obtain, possess, transport, divert, and distribute counterfeit prescription drugs, misbranded prescription drugs, unapproved new drugs, controlled substances, and the equipment used to manufacture them.

3. I am currently conducting an investigation into the illegal importation and sale of counterfeit and/or misbranded drugs and medical devices by Rebecca Fadanelli ("FADANELLI")

(also known as Rebecca Daley and Rebecca Hawthorne), in violation of 21 U.S.C. § 331(i)(3), 21 U.S.C. § 331(c), 18 U.S.C. § 545, and/or 18 U.S.C. § 2320 (the “TARGET OFFENSES”).

4. I submit this affidavit in support of an application for a warrant under Federal Rule of Criminal Procedure 41 to search and seize certain prescription drugs, medical devices, and business records maintained by FADANELLI at her places of business, known as Skin Beaute Med Spa, located at 247 North Main Street, 4th Floor, Randolph, Massachusetts (the “Randolph Office”) and 690 Washington Street, South Easton, Massachusetts, (the “Easton Office”) (together, the “TARGET LOCATIONS”), as further described in Attachment A-1 and Attachment A-2, respectively.

5. The facts in this affidavit come from my personal observations, my training and experience, other FDA employees, evidence obtained from undercover operations, online open-source data, business records, and information provided by witnesses and other law enforcement officers.

6. This affidavit is submitted for the limited purpose of establishing probable cause in support of the application for the requested search and seizure warrant concerning the TARGET LOCATIONS. Therefore, I have not included every fact known to me or other law enforcement officers relating to this investigation.

RELEVANT LAW

The Federal Food, Drug, and Cosmetic Act and Related Violations

7. The FDA is the federal agency charged with the responsibility of protecting the health and safety of the American public by enforcing the FDCA. Among the purposes of the FDCA is to ensure that drugs and medical devices sold for human use are safe and effective for their intended uses and bear true and accurate labeling.

8. Under the FDCA, a “drug” is, among other things, 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).

9. The term “counterfeit drug” means, in part, 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 to be the product of that drug manufacturer. 21 U.S.C. § 321(g)(2).

10. Under the FDCA, a “device” is defined 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).

11. Under the FDCA, a prescription drug or prescription device is 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. A drug is also a prescription drug under the FDCA if the FDA, when it approved the drug, limited the drug to use under the supervision of a licensed practitioner. 21 U.S.C. § 353(b)(1)(B).

12. A prescription drug may be dispensed only upon the prescription of a licensed practitioner. 21 U.S.C. § 353(b)(1). Dispensing a prescription drug without the prescription of a licensed practitioner causes the drug to be misbranded. *Id.*

13. A drug or device is also misbranded if its labeling lacks adequate directions for its intended use(s). 21 U.S.C. §352(f)(1). “Adequate directions for use” means directions sufficient for a layperson to safely use the drug or device for the purpose(s) for which it is intended. 21 C.F.R. §§ 201.5, 801.5.

14. Because prescription drugs and devices can, by definition, only be used safely at the direction, and under the supervision, of a licensed practitioner, they are exempt from the requirement that their labeling contain adequate directions for use by a layperson. 21 C.F.R. §§ 201.100, 801.109. To qualify for this exemption, among other things, a prescription drug or device must be intended to be dispensed only on the prescription of a practitioner licensed by law to administer prescription drugs and devices. 21 C.F.R. §§ 201.100(a), 801.109(a). Thus, prescription drugs and devices dispensed without the prescription of a licensed practitioner are misbranded under the FDCA because their labeling fails to bear adequate direction for use, and they do not qualify for an exemption.

15. Under the FDCA, a drug or device is also misbranded if its labeling is false or misleading. 21 U.S.C. § 352(a).

16. Under the FDCA, with certain exceptions not applicable here, Class III medical devices, such as the dermal fillers Sculptra and Juvederm, are adulterated if they have not received FDA pre-market approval. 21 U.S.C. § 351(f)(1)(B).

17. The FDCA prohibits doing or causing any of the following:

- a. the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug. 21 U.S.C. § 331(i)(3).
- b. the receipt in interstate commerce of a misbranded drug, misbranded device, or adulterated device, and the delivery or proffered delivery of the misbranded

drug, misbranded device, or adulterated device for pay or otherwise. 21 U.S.C. § 331(c).

Other Relevant Statutes

18. It is a violation of 18 U.S.C. § 545 to fraudulently or knowingly import into the United States any merchandise contrary to law, or to knowingly receive, buy, or sell such merchandise after importation.

19. It is unlawful to intentionally traffic in a drug and knowingly use a counterfeit mark on or in connection with such drug. 18 U.S.C. § 2320(a)(4). It is also unlawful under 18 U.S.C. § 2320(a)(1) to traffic in other counterfeit goods, such as counterfeit medical devices.

INVESTIGATION BACKGROUND

Client 1 Complaint

20. On or about December 15, 2023, I spoke with an individual, referred to herein as “Client 1,” by telephone in response to an electronic complaint Client 1 had filed with the FDA concerning FADANELLI and her business, Skin Beaute Med Spa. During our conversation, Client 1 explained that FADANELLI had performed a “lip filler” procedure¹ on Client 1 at the Randolph Office on or about September 7, 2022.² Client 1 provided the following additional information regarding the procedure.

21. Before beginning the procedure, FADANELLI told Client 1 that she was a nurse. This representation gave Client 1 confidence that FADANELLI was competent to perform the procedure. FADANELLI proceeded to inject Client 1’s lips using a syringe containing an unknown

¹ Based on my training and experience, I believe that “filler” refers to a prescription medical device product that is administered via injection to eliminate skin wrinkles or to enlarge certain areas of the face, for example, the lips.

² Based on her review of a picture of FADANELLI from the Skin Beaute Med Spa website, Client 1 confirmed that it was FADANELLI who performed the procedure.

substance to make them appear fuller. When Client 1 asked FADANELLI what the injected substance was, FADANELLI did not respond directly, stating only that she purchases her products from Brazil and China. After injecting Client 1's lips, FADANELLI also injected Client 1 between her eyebrows using the same syringe, reportedly without Client 1's permission.³

22. At some point after the procedure, Client 1 experienced "bumps" in her lips and tingling in her forehead where FADANELLI had injected her. This caused Client 1 concern that FADANELLI may not have been qualified to conduct the procedure. Client 1 called FADANELLI and requested a copy of the prescription (for the medical device product FADANELLI administered via injection), but FADANELLI never provided her with one. Online research conducted by Client 1 indicated that FADANELLI is not a registered nurse and may not have been certified to conduct the procedure performed on Client 1.

PROBABLE CAUSE TO BELIEVE A FEDERAL CRIME WAS COMMITTED

Parcel Seizures by U.S. Customs and Border Protection

23. After speaking with Client 1, I conducted research into FADANELLI and learned that multiple international parcels addressed to her had been seized by U.S. Customs and Border Protection ("CBP") based on suspicion that the parcels contained misbranded and/or unapproved prescription drugs or devices.

24. Specifically, between approximately November 2023 and March 2024, CBP seized at least six parcels that were addressed to FADANELLI or to individuals who have been identified as employees of Skin Beaute Med Spa. The destination addresses listed on the seized parcels include FADANELLI's personal residence in Stoughton, Massachusetts and both TARGET LOCATIONS. The parcels all originated from China and were sent via UPS, DHL, or FedEx.

³ Client 1 paid \$275 for the procedure (via credit card).

25. The seized parcels contained various products appearing to be prescription drugs or devices intended to be administered via injection for cosmetic purposes. Some of the products were labeled as Botox, Sculptra, and Juvederm. The FDA regulates Botox as a prescription drug, while Sculptra and Juvederm are regulated as prescription Class III medical devices. Botox is FDA-approved to treat, among other things, facial wrinkles. Sculptra and Juvederm are FDA-approved injectable dermal fillers.

26. One of the six parcels discussed above – addressed to Rebecca Dailey at the Skin Beaute Med Spa Randolph Office – was detained by CBP on or about December 5, 2023. The parcel was declared as containing “plastic bottles and plastic container.” Upon inspection, the parcel contents included 20 boxes of a product labeled as Botox. Based on this inspection, an FDA Consumer Safety Officer recommended that the products in the parcel be seized due to suspicion that they were misbranded and unapproved.

27. On or about March 6, 2024, CBP sent a “Notice of Seizure and Information to Claimants” letter to FADANELLI at the Randolph Office.⁴ The letter advised FADANELLI that the above-described parcel had been seized because the products contained therein were suspected of being misbranded and unapproved. The letter advised FADANELLI that she could, among other options, pay to settle the seizure and have the parcel’s contents returned to her (known as an “offer in compromise”).

28. On or about April 9, 2024, CBP received a letter from FADANELLI advising that she had elected to make an offer in compromise for the seized products. FADANELLI wrote, in part, “As a responsible party, I acknowledge the outstanding debts or obligations I have to the

⁴ A “Notice of Seizure and Information to Claimants” letter is a standard form letter sent to recipients of imported goods that cannot be immediately released by CBP without further action and some form of resolution.

United States Customs and Border Protection and am seeking to settle these matters in a timely and efficient manner. I propose to settle the aforementioned debts or obligations for the amount of \$600 . . . ” FADANELLI included with the letter a \$600 check drawn on a Bank of America account in the name of Skin Beaute Inc., signed by FADANELLI.

29. On or about April 11, 2024, CBP sent a letter to FADANELLI, advising her that because the seized products were in violation of FDA regulations, they could not be released to her without prior FDA approval. The letter further advised that any questions could be directed to the FDA’s regulatory office in Stoneham, Massachusetts.

30. On or about May 2, 2024, I spoke with the above-referenced FDA Consumer Safety Officer to inquire whether FADANELLI had contacted him or any other FDA representative about the seized parcel after she was advised that the seized products could not be released without FDA approval. The officer advised that there was no documentation indicating that FADANELLI had contacted the FDA office regarding the parcel.⁵

In-Person Inspection of FADANELLI

31. On or about October 26, 2023, CBP inspected FADANELLI and her belongings at Logan Airport upon FADANELLI’s return from Brazil. CBP found that FADANELLI was in possession of a variety of prescription drugs and devices, including approximately 50 Ozempic⁶ “pens,” tubes and vials of Lidocaine (a numbing agent), several vials containing liquid labeled as Sculptra, vials of bacteriostatic water (sterile water used to inject diluted or dissolved medication

⁵ All of the other parcels addressed to FADANELLI or Skin Beaute Med Spa employees that were seized by CBP have been or will be forfeited based on the FDA’s advice that they should not be released.

⁶ Ozempic is FDA-approved as a prescription drug to improve glycemic control in adults with Type II diabetes. I am aware that Ozempic is also frequently used for weight loss.

into a patient's body), approximately 20 diabetic syringes, and several other vials of liquid with labels in foreign languages.

32. CBP referred these products to the FDA Compliance Branch for review. Based on its determination that all of the products were unapproved or misbranded, the FDA Compliance Branch recommended that they be seized. CBP seized the products on or about March 28, 2024.

Review of Seized Products by Manufacturer Investigators

33. As part of this investigation, FDA-OCI sent photographs of certain products contained in the seized parcels to industry investigators employed by the manufacturers of the legitimate products. Specifically, we contacted AbbVie Inc., the parent company of Allergan, which is the approved manufacturer of both Botox and Juvederm, and Galderma S.A., the manufacturer of Sculptra. As set forth further below, representatives of both companies indicated that they believe the products shipped to FADANELLI and Skin Beaute Med Spa employees, are counterfeit.

34. Based on his examination of photographs of the contents of parcels detained by CBP on or about November 3, 2023, January 26, 2024, and February 6, 2024, the Associate Director of Global Product Protection for AbbVie concluded that the seized products labeled as Botox and Juvederm are counterfeit.

35. Specifically, the seized boxes labeled as Botox have a labeled dosage of 150iu (international units), but AbbVie does not manufacture or distribute a version of Botox at this dosage. Rather, authentic Botox is manufactured in 50iu, 100iu, and 200iu dosages. Additionally, the colors and holograms on some of the boxes are not consistent with authentic Botox boxes,

many do not have tamper indicator seals, and some of the vials are the incorrect shape, have the incorrect color top, or have the incorrect label.⁷

36. With respect to the seized products labeled as Juvederm, the boxes have the incorrect manufacturing years listed for the manufacturing lot numbers. In addition, when the data matrix codes⁸ on the packaging are scanned, the results show different manufacturing lot numbers than those listed on the seized boxes.

37. AbbVie maintains customer shipment records for all Botox and Juvederm sold, whether sold directly or through wholesale distributors. A query of those records identified no customer account for FADANELLI (or Rebecca Daley or Rebecca Hawthorne) or Skin Beaute Med Spa. The query did identify a customer by a different name, “Doctor 1,” using the address of the Skin Beaute Med Spa Randolph Office. The purchase history for Doctor 1’s account shows only one purchase, on May 14, 2021, for various non-prescription skin creams manufactured by AbbVie but no purchases of Botox or Juvederm. In short, there is no indication that FADANELLI has ever purchased authentic Botox or Juvederm from AbbVie.

38. Likewise, the Senior Director of Regulatory Affairs for Galderma examined photographs of the contents of a parcel detained on or about January 30, 2024, and concluded that products labeled as Sculptra are counterfeit. Specifically, the manufacturing lot number on the product labels, “A00203,” is not a lot number that has been used by Galderma. In fact, Galderma does not even use lot numbers that begin with the letter “A.” Galderma has received nearly two dozen documented reports of adverse health events experienced by users of counterfeit Sculptra

⁷ Based on this information, I believe that additional parcel seizures containing vials labeled as Botox with similar characteristics are also counterfeit.

⁸ A data matrix is a two-dimensional code consisting of black and white “cells” or dots arranged in either a square or rectangular pattern, also known as a matrix. The matrix can be used to encode text or numeric data on the labeling of a product.

with the same manufacturing lot number of “A00203” in other countries. These adverse health events include hypotension, injection site reaction, swelling, and dyspnea (shortness of breath).

39. Galderma distributes Sculptra exclusively through McKesson Corporation, a United States-based pharmaceutical distributor. A query of McKesson customer records found no customer account or order history for FADANELLI (or Rebecca Hawthorne or Rebecca Daley) or Skin Beaute Med Spa. There is thus no indication that FADANELLI has ever purchased legitimate prescription drugs or devices from Galderma.

FADANELLI’s Massachusetts Occupational Certifications

40. In connection with this investigation, I have also consulted with the Division of Occupational Licensure for the State of Massachusetts. Public records maintained by the Division of Occupational Licensure show that FADANELLI is a registered aesthetician. Per a representative of the Division of Occupational Licensure, aestheticians are not permitted to administer injections of prescription drugs or devices in Massachusetts.⁹

41. This representative further advised that in or around June 2023, an inspection of Skin Beaute Med Spa’s Easton Office by an inspector with the Division of Occupational Licensure resulted in the issuance of a \$100 fine for having syringes present in the office’s aesthetics room. The inspection report notes that a Skin Beaute Med Spa employee told the inspector that the syringes were related to the administration of Botox in the aesthetics room.

⁹ The Massachusetts Board of Registration of Cosmetology and Barbering has issued a policy (2017-01), most recently amended on March 12, 2019, which states, in part, “Individuals licensed by the Board as cosmetologists, aestheticians, manicurists, barbers or electrologists shall not perform any medical or invasive procedures, as they are beyond the authorized scope of licenses issued by the Board and represent a risk of infection and consumer injury . . . Prohibited medical and invasive procedures include, but are not limited to, A) Any injection of substances, including but not limited to Botox, dermal fillers such as collagen, hyaluronic acid (restylane), and any other injectable substances[.]”

42. In addition, the Bureau of Health Professions Licensure, a component of the Massachusetts Department of Public Health that is responsible for the licensing of health care professionals (including nurses) in Massachusetts, has no record of any licensure or certification for FADANELLI (or Rebecca Hawthorne or Rebecca Daley).

43. There is therefore no indication that FADANELLI possesses any occupational certifications in Massachusetts aside from that of aesthetician. Accordingly, I do not believe that FADANELLI is authorized to prescribe, dispense, or administer prescription drugs or devices, including through injections.

Skin Beaute Med Spa Website and Social Media Accounts

44. The website for Skin Beaute Med Spa – skinbeautemedspa.com – lists both the Randolph Office and the Easton Office as its business locations. The “about” section of the website includes a picture of FADANELLI and a narrative stating that FADANELLI is an aesthetician and has a degree in anatomy from “Havard” [sic]. The narrative claims that FADANELLI specializes in “advanced cosmetic procedures” and is licensed by the Massachusetts “Estate Board.” The narrative goes on to state that “Rebeca [sic] brought to her business . . . spa services provided by a team of estheticians and hardworking nurses,” that “Skin Beaute is dedicated to all aspects of beauty enhancement, including all skincare treatments, laser treatments, Botox and Dermal Fillers,” and that “[t]hroughout her career, Rebeca also qualified as a Licensed Instructor by the Massachusetts State Council[.]”¹⁰

45. The Randolph Office and Easton Office maintain separate Instagram accounts. The business description for both accounts is: “RN/Skin Specialist/Body Art/Aesthetics” and “Botox/fillers.” The feed for the Easton Office Instagram account promotes Botox and lip fillers.

¹⁰ Aestheticians generally provide medical-based facial and beauty treatments, while estheticians offer cosmetic beauty services such as facials, peels, and waxing.

The feed for the Randolph Office Instagram account promotes Botox, lip fillers, Sculptra, dermal fillers, and nose fillers.

Vagaro, Inc.

46. Skin Beaute Med Spa also maintains an online presence through Vagaro, Inc., a business management platform. Vagaro allows its customers (usually small businesses such as spas and salons) to schedule appointments, issue invoices, and accept payments. Vagaro's webpage for Skin Beaute Med Spa indicates that the business offers Botox, dermal fillers, eyebrow microblading, and permanent makeup by "skilled aestheticians and nurse practitioners." Vagaro's scheduling function for Skin Beaute Med Spa allows clients to select, among other products/services, Botox, Sculptra, fillers, and/or Ozempic, and to specifically select FADANELLI as the provider.

47. Business records obtained from Vagaro indicate that the Skin Beaute Med Spa account was created by FADANELLI on or about March 3, 2021, and remained active at the time the records were produced (in or around March 2024). The account lists FADANELLI's cell phone number ending in 7839 as a contact number. It also lists the addresses of both the Randolph Office and the Easton Office of Skin Beaute Med Spa.

48. The Vagaro records include a client list for Skin Beaute Med Spa, along with a list of client appointments. Client 1 is listed as a client, and the list of client appointments indicates that FADANELLI performed a "filler" procedure on Client 1 at the Randolph Office on September 7, 2022, at a cost of \$275. This information corresponds with the information provided by Client 1, indicating that the data contained in the Vagaro records is likely accurate and reliable.

49. The list of client appointments includes details for each appointment, including the client's name, date of service, service status (*e.g.*, completed, canceled, denied, no show), the service provided, the office location where the service was provided, who provided the service,

and the cost of the service. The services listed include (among many others): “Botox,” “fillers,” “Ozempic shot,” and “Sculptra.”

50. I analyzed the data for completed Botox services where FADANELLI is listed as the service provider. That data shows that between approximately June 2021 and March 2024, FADANELLI completed approximately 261 Botox appointments at the Easton Office, and that between approximately March 2021 and March 2024, FADANELLI completed approximately 1,370 Botox appointments at the Randolph Office. The records show that these Botox treatments were provided to hundreds of different clients, and that payments for the services total approximately \$522,869.

51. I also analyzed the data for completed “filler” services where FADANELLI is listed as the service provider. The data shows that between approximately May 2021 and March 2024, FADANELLI completed approximately 181 filler services at the Easton Office, and that between approximately March 2021 and March 2024, FADANELLI completed approximately 809 filler services at the Randolph Office. Payments for these services total approximately \$378,954.

52. The Vagaro list of client appointments for Skin Beaute Med Spa also shows that between approximately March 2022 and March 2024, FADANELLI completed approximately 21 Sculptra appointments at the Easton Office, and that between approximately September 2021 and March 2024, FADANELLI completed approximately 74 Sculptra services at the Randolph Office. Payments for these services total approximately \$31,591.

53. In addition, the records show that between approximately May and November 2023, FADANELLI completed approximately nine “Ozempic shot” appointments at the Easton Office, and that between approximately May 2023 and March 2024, FADANELLI completed approximately 29 Ozempic appointments at the Randolph Office. Payments for these services total approximately \$3,500.

Undercover Operation

54. As part of this investigation, and as set forth further below, a confidential source of information (“SOI”) made consensually recorded phone calls with employees of Skin Beaute Med Spa and also recorded an in-person appointment with FADANELLI.¹¹ These communications were primarily in Portuguese and have since been translated by a translation services company retained by FDA-OCI.

55. On or about March 5, 2024, the SOI made a consensually recorded phone call to the Randolph Office of Skin Beaute Med Spa and spoke to an employee, referred to herein as “Employee 1.” During the call, the SOI told Employee 1 that the SOI was interested in a Botox treatment with “Rebecca.” Employee 1 told the SOI that Rebecca works at both Skin Beaute Med Spa locations and at the time was offering a “deal” for Botox. The SOI asked whether Rebecca could also provide treatment for skin around the neck, and Employee 1 responded that Rebecca could provide a Sculptra treatment.

56. On or about April 3, 2024, the SOI made another consensually recorded phone call to the Randolph Office and spoke with a different employee, referred to herein as “Employee 2.” The SOI told Employee 2 that the SOI wanted to make an appointment with “Rebecca” for a Botox consultation. Employee 2 scheduled the SOI for a Botox consultation on April 9, 2024 at the Randolph Office.

57. On or about April 9, 2024, the SOI visited the Randolph Office of Skin Beaute Med Spa for the above-referenced Botox consultation. The SOI consensually recorded the visit using both a covert camera and audio recording equipment. Upon arriving at the office and checking in

¹¹ FDA-OCI has utilized this SOI in other, similar investigations, and I believe the SOI to be reliable. FDA-OCI provided financial compensation to the SOI for the SOI’s assistance with this investigation.

at reception, an employee asked the SOI to complete a client questionnaire and also provided the SOI with a flyer that contained Botox aftercare instructions. The employee told the SOI that Skin Beaute Med Spa offered Botox treatments at both of its office locations and provided the SOI with a business card listing the address and phone number for each office. After the SOI completed the client questionnaire, the employee escorted the SOI to an examination room, where the SOI was met by a woman who introduced herself as “Rebecca.” Based on my review of the recording and known photographs of FADANELLI, I believe that the woman who met with the SOI was FADANELLI.

58. FADANELLI instructed the SOI to lie down on an examination table in the room and proceeded to examine the SOI’s face. FADANELLI told the SOI that Botox would help with the appearance of wrinkles. FADANELLI also recommended “filling” certain areas on the SOI’s face and advised that she could provide “sculpt” (which I believe to be a reference to Sculptra) to firm the skin on the SOI’s neck. FADANELLI provided the SOI with a quote of \$450 for the Botox treatment. FADANELLI also advised the SOI that the Botox treatment could be provided at the Randolph Office or the Easton Office. When the SOI asked FADANELLI about the authenticity of the Botox she uses on her clients, FADANELLI advised that she uses actual Botox and that its results last for up to four months.

59. Based on the evidence obtained to date, as set forth above, I have probable cause to believe that since at least March 2021, FADANELLI has been illegally importing counterfeit and/or misbranded prescription drugs and devices and illegally selling, dispensing, and/or administering the counterfeit and/or misbranded drugs and devices to hundreds of unknowing clients of Skin Beaute Med Spa.

PROBABLE CAUSE TO BELIEVE THE TARGET LOCATIONS CONTAIN EVIDENCE, FRUITS, AND INSTRUMENTALITIES OF THE TARGET OFFENSES

60. I also have probable cause to believe that the TARGET LOCATIONS, as described in Attachments A-1 and A-2, contain evidence, fruits, and instrumentalities of the TARGET OFFENSES, as described in Attachment B.

61. Specifically, based on, among other things, the information provided by Client 1, the contents and destination addresses of the seized parcels, CBP's in-person inspection of FADANELLI, the inspection conducted by the Massachusetts Division of Occupational Licensure, and the undercover operation, I believe that the TARGET LOCATIONS are likely to contain counterfeit prescription drugs and devices, including but not limited to products labeled as Botox, Juvederm, and Sculptra, and packaging, labeling, and/or containers for those products.

62. In addition, based on my training and experience and the evidence described above, including the Vagaro records, I believe that the TARGET LOCATIONS are likely to contain correspondence, financial, transactional, and other records and/or tangible objects relating to Skin Beaute Med Spa's business. Such records and/or objects may include but are not limited to, general corporate records, occupational certifications and/or licenses for FADANELLI and/or Skin Beaute Med Spa employees (whether legitimate or fabricated), records of client appointments and treatments/services provided, financial records reflecting, for example, client payments and product purchases, and records pertaining to the source and importation of products purchased by the business, including the products contained in the parcels seized by CBP.

Seizure of Computer Equipment and Data

63. Based on my training and experience, and information provided by other law enforcement agents, I am aware that businesses frequently use computers to carry out, communicate about, and store records pertaining to their business operations. These tasks are

frequently accomplished through sending and receiving business-related emails and instant messages; drafting other business documents such as spreadsheets and presentations; scheduling business activities; keeping a calendar of business and other activities; arranging for business travel; storing pictures related to business activities; purchasing and selling inventory and supplies online; researching online; and accessing banking, financial, investment, utility, and other accounts concerning the movement and payment of money online.

64. Based on my training and experience, and information provided by other law enforcement agents, I know that many cell phones (which are included in Attachment B's definition of "hardware") can now function essentially as small computers. Apple iPhones, such as FADANELLI's phone, are such a type of phone.¹² Phones have capabilities that include serving as a wireless telephone to make audio calls, digital camera, portable media player, GPS navigation device, sending and receiving text messages and emails, and storing a range and amount of electronic data. Examining data stored on devices of this type can uncover, among other things, evidence of communications and evidence that reveals or suggests who possessed or used the device.

65. Based on my training and experience, and information provided by other law enforcement agents, I am aware that businesses and individuals commonly store records of the

¹² I am aware that FADANELLI uses an iPhone because digital devices manufactured by Apple, including iPhones, iPads, and Mac computers, are capable of sending data such as texts, photos, and videos to other Apple devices through a function known as iMessage. Apple devices display phone numbers of other Apple devices capable of receiving iMessages in blue when the receiving number is entered to send a message, whereas phone numbers for non-Apple devices are displayed in green when entered. In connection with this investigation, I entered FADANELLI's phone number (ending in 7839) into an Apple iPhone as if to initiate a message. When I did so, FADANELLI's phone number was displayed in blue, indicating that the phone utilized by FADANELLI is likely an Apple iPhone.

type described in Attachment B in computer hardware, computer software, smartphones, and storage media.

66. In addition, based on Skin Beaute Med Spa's online presence, including its website and social media accounts, and its use of Vagaro as a business management platform, I believe that FADANELLI used one or more computers and/or smartphones to commit, communicate about, and/or store records relating to the TARGET OFFENSES.

67. Based on my training and experience, and information provided by other law enforcement agents, I know that computer files or remnants of such files can be recovered months or years after they have been written, downloaded, saved, deleted, or viewed locally or over the internet. This is true because:

- a. Electronic files that have been downloaded to a storage medium can be stored for years at little or no cost. Furthermore, when users replace their computers, they can easily transfer the data from their old computer to their new computer.
- b. Even after files have been deleted, they can be recovered months or years later using forensic tools. This is so because when a person "deletes" a file on a computer, the data contained in the file does not actually disappear; rather, that data remains on the storage medium until it is overwritten by new data, which might not occur for long periods of time. In addition, a computer's operating system may also keep a record of deleted data in a "swap" or "recovery" file.
- c. Wholly apart from user-generated files, computer storage media – in particular, computers' internal hard drives – contain electronic evidence of how the computer has been used, what it has been used for, and who has used it. This evidence can take the form of operating system configurations, artifacts from operating system or application operation, file system data structures, and

virtual memory “swap” or paging files. It is technically possible to delete this information, but computer users typically do not erase or delete this evidence because special software is typically required for that task.

- d. Similarly, files that have been viewed over the internet are sometimes automatically downloaded into a temporary internet directory or “cache.” The browser often maintains a fixed amount of hard drive space devoted to these files, and the files are overwritten only as they are replaced with more recently viewed internet pages or if a user takes steps to delete them.
- e. Data on a storage medium can provide evidence of a file that was once on the storage medium but has since been deleted or edited, or of a deleted portion of a file (such as a paragraph that has been deleted from a word processing file). Virtual memory paging systems can leave traces of information on the storage medium that show what tasks and processes were recently active. Web browsers, email programs, and chat programs store configuration information on the storage medium that can reveal information such as online nicknames and passwords. Operating systems can record additional information, such as the attachment of peripherals, the attachment of USB flash storage devices or other external storage media, and the times the computer was in use. Computer file systems can record information about the dates files created and the sequence in which they were created, although this information can later be falsified.
- f. As explained herein, information stored within a computer and other electronic storage media may provide crucial evidence of the “who, what, why, when, where, and how” of the criminal conduct under investigation, thus enabling law

enforcement to establish and prove each element or, alternatively, to exclude the innocent from further suspicion. In my training and experience, information stored within a computer or storage media (*e.g.*, registry information, communications, images and movies, transactional information, records of session times and durations, internet history, and anti-virus, spyware, and malware detection programs) can indicate who has used or controlled the computer or storage media. This “user attribution” evidence is analogous to the search for “indicia of occupancy” while executing a search warrant at a residence. The existence or absence of anti-virus, spyware, and malware detection programs may indicate whether the computer was remotely accessed, thus inculcating or exculpating the computer owner. Further, computer and storage media activity can indicate how and when the computer or storage media was accessed or used. For example, as described herein, computers typically contain information that log: computer user account session times and durations, computer activity associated with user accounts, electronic storage media that connected with the computer, and the IP addresses through which the computer accessed networks and the internet. Such information allows investigators to understand the chronological context of computer or electronic storage media access, use, and events relating to the crime(s) under investigation. Additionally, some information stored within a computer or electronic storage media may provide crucial evidence relating to the physical location of other evidence and the suspect(s). For example, images stored on a computer may both show a particular location and have geolocation information incorporated into its file data. Such file data typically also contains information

indicating when the file or image was created. The existence of such image files, along with external device connection logs, may also indicate the presence of additional electronic storage media (*e.g.*, a digital camera or cellular phone with an incorporated camera). The geographic and timeline information described herein may either inculcate or exculpate the computer user. Last, information stored within a computer may provide relevant insight into the computer user's state of mind as it relates to the offense(s) under investigation. For example, information within the computer may indicate the owner's motive and intent to commit a crime (*e.g.*, internet searches indicating criminal planning), or consciousness of guilt (*e.g.*, running a "wiping" program to destroy evidence on the computer or password protecting/encrypting such evidence in an effort to conceal it from law enforcement).

- g. A person with appropriate familiarity with how a computer works can, after examining this forensic evidence in its proper context, draw conclusions about how computers were used, the purpose of their use, who used them, and when.
- h. The process of identifying the exact files, blocks, registry entries, logs, or other forms of forensic evidence on a storage medium that are necessary to draw an accurate conclusion is a dynamic process. While it is possible to specify in advance the records to be sought, computer evidence is not always data that can be merely reviewed by a review team and passed along to investigators. Whether data stored on a computer is evidence may depend on other information stored on the computer and the application of knowledge about how a computer behaves. Therefore, contextual information necessary to understand other evidence also falls within the scope of the requested warrant.

- i. Further, in finding evidence of how a computer was used, the purpose of its use, who used it, and when, sometimes it is necessary to establish that a particular thing is not present on a storage medium. For example, the presence or absence of counter-forensic programs or anti-virus programs (and associated data) may be relevant to establishing the user's intent.
- j. In addition, based on my knowledge, training, and experience, I know that businesses and businesspeople often retain correspondence, financial, transactional, and other business records for years to identify past customers/clients and vendors for potential future transactions; keep track of business deals; monitor payments, debts, and expenses; resolve business disputes stemming from past transactions; prepare tax returns and other tax documents; and engage in other business related purposes.

68. Based on my training and experience, and information provided by other law enforcement agents, I am aware that in order to completely and accurately retrieve data maintained in computer hardware, computer software or storage media, to ensure the accuracy and completeness of such data, and to prevent the loss of the data either from accidental or programmed destruction, it is often necessary that computer hardware, computer software, and storage media (computer equipment) be seized and subsequently processed by a computer specialist in a laboratory setting rather than in the location where it is seized. This is true because of:

- a. The volume of evidence – storage media such as hard disks, flash drives, CDs, and DVDs can store the equivalent of thousands or, in some instances, millions of pages of information. Additionally, a user may seek to conceal evidence by storing it in random order or with deceptive file names. Searching authorities may need to examine all the stored data to determine which particular files are

evidence, fruits, or instrumentalities of criminal activity. This process can take weeks or months, depending on the volume of data stored, and it would be impractical to attempt this analysis on site.

- b. Technical requirements – analyzing computer hardware, computer software, or storage media for evidence of criminal activity is a highly technical process requiring expertise and a properly controlled environment. The vast array of computer hardware and software available requires even computer experts to specialize in some systems and applications. Thus, it is difficult to know, before the search, which expert possesses sufficient specialized skill to best analyze the system and its data. Furthermore, data analysis protocols are exacting procedures, designed to protect the integrity of the evidence and to recover even “hidden,” deleted, compressed, or encrypted files. Many commercial computer software programs also save data in unique formats that are not conducive to standard data searches. Additionally, computer evidence is extremely vulnerable to tampering or destruction, both from external sources and destructive code imbedded in the system as a “booby trap.”

Consequently, law enforcement agents may either copy the data at the premises to be searched or seize the computer equipment for subsequent processing elsewhere.

69. The premises may contain computer equipment whose use in the crime(s) or storage of the things described in this warrant is impractical to determine at the scene. Computer equipment and data can be disguised, mislabeled, or used without the owner’s knowledge. In addition, technical, time, safety, or other constraints can prevent definitive determination of their ownership at the premises during the execution of the requested warrant. If the items described in Attachment B are of the type that might be found on any of the computer equipment, this application seeks

permission to search and seize it in order to determine their true use or contents, regardless of how the contents or ownership appear or are described by people at the scene of the search.

70. Law enforcement agents will endeavor to search and seize only the computer equipment which, upon reasonable inspection and/or investigation conducted during the execution of the search, reasonably appear to contain the evidence described in Attachment B. If, however, law enforcement agents cannot make a determination as to use or ownership regarding any particular device, the law enforcement agents will seize and search that device pursuant to the probable cause established herein.

71. In this case, I recognize that Skin Beaute Med Spa is a functioning business that performs some legitimate functions, and that seizing computer equipment may have the unintended and undesired effect of limiting the business's ability to function.

- a. As stated above, there are a variety of reasons why law enforcement agents might need to seize computer equipment for subsequent processing elsewhere. If Skin Beaute Med Spa requires access to data that is not evidence of a crime, law enforcement will work with the business after the search to copy this data onto storage media provided by the business for the business's use.
- b. If the search team determines that there is no reason to seize certain of Skin Beaute Med Spa's computer equipment during the execution of the requested warrant, the team will create an onsite electronic "image" of those parts that are likely to store data specified in the warrant, if imaging is practical. Generally speaking, imaging is the taking of a complete electronic picture of the data, including all hidden sectors and deleted files. Imaging permits agents to obtain an exact copy of the computer's stored data without actually seizing the computer equipment. However, imaging at the premises can often be

impractical, because imaging is resource-intensive: it can take hours or days, thus requiring law enforcement agents to remain at the premises for much longer than they would remain if they seized the items, and it can require personnel with specialized experience and specialized equipment, both of which might be unavailable. If law enforcement personnel do create an image at the premises, they will then search for the records and data specified in the warrant from the image copy at a later date off site.

72. This warrant authorizes a review of electronic storage media seized, electronically stored information, communications, other records and information seized, copied or disclosed pursuant to this warrant in order to locate evidence, fruits, and instrumentalities described in this warrant. The review of this electronic data may be conducted by any government personnel assisting in the investigation, who may include, in addition to law enforcement officers and agents, attorneys for the government, attorney support staff, and technical experts. Pursuant to this warrant, the FDA may deliver a complete copy of the seized, copied, or disclosed electronic data to the custody and control of attorneys for the government and their support staff for their independent review.

Unlocking a Device Using Biometric Features

73. I know from my training and experience, my own personal and professional use of cell phones, and information found in publicly available materials, that some models of cell phones made by Apple and other manufacturers offer their users the ability to unlock a device via the use of a fingerprint or through facial recognition, in lieu of a numeric or alphanumeric passcode or password.

74. On the Apple devices that have this feature, the fingerprint unlocking feature is called Touch ID. If a user enables Touch ID on a given Apple device, he or she can register up to

five fingerprints that can be used to unlock that device. The user can then use any of the registered fingerprints to unlock the device by pressing the relevant finger(s) to the device's Touch ID sensor. In some circumstances, a fingerprint cannot be used to unlock a device that has Touch ID enabled, and a passcode must be used instead, such as: (1) when more than 48 hours has passed since the last time the device was unlocked or (2) when the device has not been unlocked via Touch ID in eight hours and the passcode or password has not been entered in the last six days. Thus, in the event law enforcement agents encounter a locked Apple device, the opportunity to unlock the device via Touch ID exists only for a short time. Touch ID also will not work to unlock the device if (1) the device has been turned off or restarted; (2) the device has received a remote lock command; or (3) five unsuccessful attempts to unlock the device via Touch ID are made.

75. The passcode that would unlock any device(s) found during the search of the TARGET LOCATIONS is not currently known to law enforcement. Thus, it may be useful to press the finger(s) of the user(s) of the device(s) found during the search of the TARGET LOCATIONS to the device's fingerprint sensor or to hold the device up to the face of the owner in an attempt to unlock the device for the purpose of executing the search authorized by this warrant. The government may not otherwise be able to access the data contained on those devices for the purpose of executing the search authorized by this warrant.

76. In my training and experience, the person who is in possession of a device or has the device among his or her belongings at the time the device is found is likely a user of the device. However, in my training and experience, that person may not be the only user of the device whose fingerprints are among those that will unlock the device and it is also possible that the person in whose possession the device is found is not actually a user of that device at all. Furthermore, in my training and experience, I know that in some cases it may not be possible to know with certainty who is the user of a given device, such as if the device is found in a common area of a premises

without any identifying information on the exterior of the device. Thus, it may be necessary for law enforcement to have the ability to require any occupant of the TARGET LOCATIONS to press their finger(s) against the sensor of the locked device(s) or place the devices in front of their faces in order to attempt to identify the device's user(s) and unlock the device(s).

77. For these reasons, I request that the Court authorize law enforcement to press the fingers (including thumbs) of individuals found at the TARGET LOCATIONS to the sensor of the device(s) or place the device(s) in front of their faces for the purpose of attempting to unlock the device(s) in order to search the contents as authorized by this warrant.

CONCLUSION

78. Based on the information described above, I have probable cause to believe that FADANELLI has violated 21 U.S.C. § 331(i)(3), 21 U.S.C. § 331(c), 18 U.S.C. § 545, and/or 18 U.S.C. § 2320.

79. Based on the information described above, I also have probable cause to believe that evidence, fruits, and instrumentalities of these crimes, as described in Attachment B, are contained within the premises described in Attachments A-1 and A-2.

Subscribed and sworn to,

Brian Hendricks
 Brian Hendricks
 Special Agent
 U.S. Food and Drug Administration

Attested to by the applicant in accordance with the requirements of Fed. R. Crim. P. 4.1 by telephone on June 25, 2024

David H. Kennedy
 HONORABLE DAVID H. KENNEDY
 UNITED STATES MAGISTRATE JUDGE
 DISTRICT OF MASSACHUSETTS



5:18 p.m.