United States District Court

FOR THE
NORTHERN DISTRICT OF CALIFORNIA

VENUE: SAN FRANCISCO

[redacted]

UNITED STATES OF AMERICA,

V.

LINDSAY MARIE CLARK

DEFENDANT(S).

INDICTMENT

21 U.S.C. §§ 331(c), 333(a)(2) –
Receipt in interstate commerce of a drug that is misbranded, and a device that is adulterated and misbranded, and the delivery or proffered delivery thereof for pay or otherwise, with intent to defraud and mislead

A true bill.

/s/ Foreperson of the Grand Jury

Foreman

Filed in open court this 1st day of

April, 2021.

Ada Means

Clerk

Bail, $0

Hon. Jacqueline Scott Corley

STEPHANIE M. HINDS (CABN 154284)
Acting United States Attorney

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. LINDSAY MARIE CLARK, Defendant.	CASE NO. 3:21-cr-00132 SI VIOLATION: 21 U.S.C. §§ 331(c), 333(a)(2) – Receipt in interstate commerce of a drug that is misbranded, and a device that is adulterated and misbranded, and the delivery or proffered delivery thereof for pay or otherwise, with intent to defraud and mislead SAN FRANCISCO

INDICTMENT

The Grand Jury charges:

BACKGROUND

1. The U.S. Food and Drug Administration's Regulation of Injectable Botulinum Toxins and Hyaluronic Acid Fillers

At times relevant to this Indictment:

1. The United States Food and Drug Administration ("FDA") was the federal agency charged with protecting the health and safety of the American public by enforcing the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 et. seq. The FDA regulated, among other things, the manufacture, labeling, distribution, and administration of biologics, drugs, and devices shipped or received in interstate commerce.

2. Under the FDCA, a "drug" was defined as an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, or an article, other than food, intended to affect the structure or any function of the body. 21 U.S.C. § 321(g)(1)(B), (C), and (D).

3. A "prescription" drug was, among other things, a drug that, because of its toxicity or other potential harmful effects, the method of its use, or the collateral measures necessary to its use, was not safe for use except under the supervision of a practitioner licensed by law to administer the drug. 21 U.S.C. § 353(b)(1).

4. A "biological product" was a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings. 42 U.S.C. § 262(i). No person could introduce or deliver for introduction into interstate commerce any biological product unless a biologics license was in effect for the biological product. 42 U.S.C. § 262(a).

5. Many products met the definitions of both drugs and biological products. The FDCA applied to a biological product subject to regulation under Title 42, except that a product for which a biological license has been approved under subsection 42 U.S.C. § 262(a) was not required to have an approved new drug application under 21 U.S.C. § 355. 42 U.S.C. § 262(j).

6. The FDCA defined a "device" as, among other things, an instrument, apparatus, implement, machine, contrivance, or implant intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or intended to affect the structure or any function of the body, and which did not achieve its primary intended purposes through chemical action within or on the body, and which was not dependent upon being metabolized for the achievement of its primary intended purposes. 21 U.S.C. § 321(h)(1)(B) & (C).

7. A "prescription device" was a device that, because of any potential for harmful effect, or the method of its use, or the collateral measures necessary for its use, was not safe except under the supervision of a practitioner licensed by law to direct the use of such device. 21 C.F.R. § 801.109.

8. With the exception of certain devices that were exempt (by statute or regulation) from any premarket review, all "new" devices (those not in existence before 1976) were automatically

classified as "Class III devices" as a matter of law, and required full premarket approval from the FDA before they could be lawfully marketed. 21 U.S.C. §§ 360c(f)(1) and 360e(a).

9. The term "label" meant a display of written, printed, or graphic matter upon the immediate container of any article. 21 U.S.C. § 321(k). The term "labeling" was broader, and included all labels, as well as other printed or graphic matter upon any article or any of its containers or wrappers, or accompanying such article. 21 U.S.C. § 321(m).

10. A drug or device was "misbranded" if its labeling lacked "adequate directions for use." 21 U.S.C § 352(f)(1). "Adequate directions for use" meant directions under which a layperson could use a drug or device safely and for the purposes for which it was intended. 21 C.F.R. §§ 201.5, 801.5. Directions under which a layperson can use a prescription drug or device safely could not be written because such drugs and devices could, by definition, only be used safely at the direction, and under the supervision, of a licensed practitioner. FDA-approved prescription drugs and devices with their approved labeling were exempt from having adequate directions for use by a layperson under specific circumstances. 21 C.F.R. §§ 201.100 and 801.109. But unapproved prescription drugs and devices that did not meet all the conditions for an exemption from the requirement of having adequate directions for use were per se misbranded.

11. A drug or device was also misbranded if the labeling was false or misleading in any particular. 21 U.S.C. § 352(a)(1).

12. A prescription drug was also misbranded if its labels lacked the symbol "Rx only." 21 U.S.C. § 353(b)(4)(A).

13. A device was "adulterated" if it was a class III device pursuant to 21 U.S.C. § 360c(f), and was required under 21 U.S.C. § 360e(a) to have in effect an approved Pre-Market Application for Approval, and lacked that FDA approval. 21 U.S.C. § 351(f)(1).

2. Botox® and Juvederm®

14. Botulinum Toxin Type A was a highly potent toxin which can cause the disease botulism when present in human beings in a sufficient amount.

15. The FDA approved a biological products license for Botox®, the brand name of a drug derived from Botulinum Toxin Type A and manufactured by Allergan, Inc. The FDA approved a

supplement to Allergan's Botox® license application for the treatment of wrinkles. Under this FDA approval, Allergan's Botulinum Toxin Type A product was marketed and labeled for this supplemental usage as "Botox® Cosmetic." Both FDA approved licenses for Allergan Botox® products limited them to use pursuant to a prescription from a licensed practitioner.

16. Injectable botulinum toxins used in these ways also met the definition of a "drug" under the FDCA, and any such products that were not the subject of an approved biological license would require approval. Such products also met the definition of a prescription drug under the FDCA.

17. Allergan received FDA approval for Juvederm Voluma™ XC for injection for purposes that include cheek augmentation and lip injections in adults. FDA-approved Juvederm® products, lawfully marketed in the U.S. under the names Juvederm, Juvederm XC, Juvederm Ultra, Juvederm Ultra XC, Juvederm Ultra Plus, Juvederm Ultra Plus XC, Juvederm Vollure XC, Juvederm Vobella XC, and Juvederm Voluma XC were dermal fillers made from hyaluronic acid, and Class III medical devices. Their approvals limited them to prescription use only. Any similar injectable product with similar intended use would also have been Class III medical devices, requiring its own FDA premarket approval.

3. Conduct of CLARK

18. Dr. Lindsay Marie CLARK was an internal-medicine physician, licensed by California since 2006, who specialized in procedures using injectable drugs and devices for cosmetic or aesthetic purposes. She had maintained practices in San Francisco and San Mateo since at least 2015. She served as medical director of Entrada Medical Group. Her practices had previously been called "Physicians' Youthful Resolutions" and "Enhance Medical Group."

19. From at least April 1, 2016 until no earlier than February 2020, CLARK obtained drugs and devices, represented to be foreign versions of Botox® and Juvederm®, that were not the subject of an FDA biologics license, drug approval, or Class III device approval, from foreign unknown sources, primarily by ordering the drugs and devices over the phone and internet.

20. CLARK ordered these unauthorized products from online "pharmacies" that bore names such as "Inject Medical," "Rose Pharmacy," "Filler Depot," "Medica Depot," "Knightsbridge Cosmetics," "Team Medical," and "Ritz Pharmacy."

21. CLARK received, from foreign countries, shipments of these unapproved and unlicensed

injectable botulinum toxin drugs and hyaluronic acid Class III devices manufactured for intended distribution in foreign countries that included Argentina, France, the United Kingdom, Austria, and India.

22. CLARK purchased at least $270,951 in product from these online "pharmacies" and "depots," among other titles. Revenue to CLARK from services rendered in connection with these products may have exceeded $1,069,880.

23. The botulinum drugs received by the CLARK from these online "pharmacies" and "depots," among other titles (and located outside of California), and delivered and proffered for delivery to patients by CLARK, were misbranded within the meaning of the FDCA.

24. The injectable hyaluronic acid devices received by CLARK from online "pharmacies" and "depots," among other titles (and located outside of California), and delivered and proffered for delivery to patients by CLARK, were adulterated and misbranded within the meaning of the FDCA.

25. These foreign unauthorized products were purchased at a steep discount, at times approaching 40% of the price CLARK would have paid for the approved or licensed Botox® and Juvederm® medical products.

26. Patients of CLARK were charged the same price for the "Botox" and "Juvederm" products whether the products were FDA-licensed and approved, or unlicensed and unapproved.

27. CLARK instructed staff to conceal the true identity, name, and source of these products from patients.

28. CLARK's business website contained misleading statements that these products, as used by CLARK, were "approved" by the FDA.

29. "Consent" forms signed by CLARK's patients were misleading in that the forms referred only to products approved by the FDA, rather than informing patients that they were receiving products that were unlicensed and unapproved.

30. CLARK concealed their purchases of unapproved and unlicensed products from Allergan, the manufacturer of FDA-licensed and approved Botox® and Juvederm®.

31. CLARK persisted in this scheme despite written notices issued by the FDA that informed CLARK that shipments of foreign unauthorized "Botox" and "Juvederm" ordered by CLARK were

detained by U.S. Customs and Border Protection because they were adulterated and unapproved new drugs and devices.

32. Misbranded and adulterated botulinum drugs and hyaluronic acid devices were injected into CLARK's patients by CLARK.

COUNT ONE: (21 U.S.C. §§ 331(c), 333(a)(2) – Receipt in interstate commerce of drugs that are misbranded, and devices that are misbranded and adulterated, and the delivery and proffered delivery thereof for pay or otherwise, with intent to defraud and mislead)

33. Beginning at a time unknown to the Grand Jury but no later than April 1, 2016, and continuing to a time unknown to the Grand Jury but no earlier than February 2020, in the Northern District of California, the defendant,

LINDSAY MARIE CLARK

with intent to defraud and mislead, received and caused the receipt of drugs (injectable botulinum toxin) and devices (injectable hyaluronic acid dermal fillers), in interstate commerce, from foreign countries including the United Kingdom, to San Mateo, California, which drugs and devices were misbranded as defined at 21 U.S.C. §§ 352(a), 352(f)(1) and 353(b)(4)(A), and adulterated as defined at 21 U.S.C. § 351(f)(1), and delivered and proffered for delivery these adulterated and misbranded drugs and devices for pay and otherwise, all in violation of 21 U.S.C. §§ 331(c) and 333(a)(2), and 18 U.S.C. § 2.

FORFEITURE ALLEGATION: (18 U.S.C. § 982(a)(7); 21 U.S.C. § 334; and 28 U.S.C. § 2461(c))

34. The allegations contained in Count One of this Indictment are hereby realleged and incorporated by reference for the purpose of alleging forfeiture, and providing notice of such.

35. Upon conviction of the offense alleged in Count One, the defendant,

LINDSAY MARIE CLARK

shall forfeit to the United States, any property, real or personal, that constitutes or is or derived, directly or indirectly, from gross proceeds traceable to the offense, proceeds the person obtained, directly or indirectly, traceable to the commission of the offense, including but not limited to a forfeiture money judgment.

36. Upon conviction of the offense alleged in Count One, the defendant,

LINDSAY MARIE CLARK

shall forfeit to the United States any article of food, drug, or cosmetic that was adulterated or misbranded when introduced into or while in interstate commerce, or while held for sale after shipment in interstate commerce, including but not limited to any adulterated or misbranded drugs represented to be Botox® and Juvederm®.

37. If any property described above, as a result of any act or omission of 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 shall be entitled to forfeiture of substitute property pursuant to 21 U.S.C. § 853(p), as incorporated by 18 U.S.C. § 982(b).

All pursuant to Title 18, United States Code, Section 982(a)(7); Title 21, United States Code, Section 334; Title 28, United States Code, Section 2461(c); and the rules and procedures described in Title 21, United States Code, Section 853 and Federal Rule of Criminal Procedure 32.2.

DATED: April 1, 2021

A TRUE BILL.

/s/ Foreperson
FOREPERSON

STEPHANIE M. HINDS
Acting United States Attorney

/s/ Joseph Tartakovsky
JOSEPH TARTAKOVSKY
Assistant United States Attorney