

**FILED**

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SUSAN Y. SOONG  
CLERK, U.S. DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN FRANCISCO

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8 UNITED STATES DISTRICT COURT  
9 NORTHERN DISTRICT OF CALIFORNIA  
10 SAN FRANCISCO DIVISION

11 UNITED STATES OF AMERICA, ) CASE NO. 3:21-cr-00132 SI  
12 Plaintiff, )  
13 v. ) VIOLATION:  
14 LINDSAY MARIE CLARK, ) 21 U.S.C. §§ 331(c), 333(a)(2) – Receipt in interstate  
15 Defendant. ) commerce of a drug that is misbranded, and a device  
16 ) that is adulterated and misbranded, and the delivery or  
17 ) proffered delivery thereof for pay or otherwise, with  
18 ) intent to defraud and mislead  
19 )  
20 ) SAN FRANCISCO  
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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.

INDICTMENT

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

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

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

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

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

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

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

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

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

7 10. A drug or device was “misbranded” if its labeling lacked “adequate directions for use.”  
8 21 U.S.C § 352(f)(1). “Adequate directions for use” meant directions under which a layperson could use  
9 a drug or device safely and for the purposes for which it was intended. 21 C.F.R. §§ 201.5, 801.5.  
10 Directions under which a layperson can use a prescription drug or device safely could not be written  
11 because such drugs and devices could, by definition, only be used safely at the direction, and under the  
12 supervision, of a licensed practitioner. FDA-approved prescription drugs and devices with their  
13 approved labeling were exempt from having adequate directions for use by a layperson under specific  
14 circumstances. 21 C.F.R. §§ 201.100 and 801.109. But unapproved prescription drugs and devices that  
15 did not meet all the conditions for an exemption from the requirement of having adequate directions for  
16 use were per se misbranded.

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

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

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

## 24 **2. Botox® and Juvederm®**

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

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

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

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

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

### 15 **3. Conduct of CLARK**

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

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

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

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

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

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

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

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

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

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

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

20 28. CLARK’s business website contained misleading statements that these products, as used  
21 by CLARK, were “approved” by the FDA.

22 29. “Consent” forms signed by CLARK’s patients were misleading in that the forms referred  
23 only to products approved by the FDA, rather than informing patients that they were receiving products  
24 that were unlicensed and unapproved.

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

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

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

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

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

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

12 LINDSAY MARIE CLARK

13 with intent to defraud and mislead, received and caused the receipt of drugs (injectable botulinum toxin)  
14 and devices (injectable hyaluronic acid dermal fillers), in interstate commerce, from foreign countries  
15 including the United Kingdom, to San Mateo, California, which drugs and devices were misbranded as  
16 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. §  
17 351(f)(1), and delivered and proffered for delivery these adulterated and misbranded drugs and devices  
18 for pay and otherwise, all in violation of 21 U.S.C. §§ 331(c) and 333(a)(2), and 18 U.S.C. § 2.

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

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

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

23 LINDSAY MARIE CLARK

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

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

LINDSAY MARIE CLARK

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

5 37. If any property described above, as a result of any act or omission of defendant:

- 6 a. cannot be located upon the exercise of due diligence;
- 7 b. has been transferred or sold to, or deposited with, a third party;
- 8 c. has been placed beyond the jurisdiction of the court;
- 9 d. has been substantially diminished in value; or
- 10 e. has been commingled with other property which cannot be divided without  
11 difficulty,

12 the United States shall be entitled to forfeiture of substitute property pursuant to 21 U.S.C. § 853(p), as  
13 incorporated by 18 U.S.C. § 982(b).

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

17 DATED: April 1, 2021

A TRUE BILL.

18 /s/ Foreperson  
19 FOREPERSON

20 STEPHANIE M. HINDS  
21 Acting United States Attorney

22 /s/ Joseph Tartakovsky  
23 JOSEPH TARTAKOVSKY  
24 Assistant United States Attorney