UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
SOUTHERN DIVISION
LONDON

UNITED STATES OF AMERICA

V. **INFORMATION NO.** 6:25-CR-47-REW

FACIAL EXPRESSIONS **DEFENDANT**

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THE UNITED STATES ATTORNEY CHARGES:

Background

At all relevant times:

1. **FACIAL EXPRESSIONS** was a business entity owned and operated by Dr. Paula Gill in Laurel County, in the Eastern District of Kentucky.

2. **FACIAL EXPRESSIONS** offered facial treatments and filler injections of various Botulinum toxins for a fee to various customers primarily in Laurel County, Kentucky. **FACIAL EXPRESSIONS** also offered chemical peels, microdermabrasion, and Vitamin B12 shots.

3. Gill was a dentist licensed by the Kentucky Board of Dentistry, and she practiced dentistry in Laurel and Pulaski Counties, in the Eastern District of Kentucky.

4. The Food and Drug Administration ("FDA") of the United States Department of Health and Human Services regulated the manufacture, distribution, and marketing of all drugs shipped or received in interstate commerce through enforcement of

the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. § 301, et seq. ("FDCA") and the Public Health Service Act, 42 U.S.C. §§ 201 et seq. ("PHSA"). The requirements of the FDCA, in part, were meant to ensure that drugs sold for human use were safe and effective and bear labeling that contained accurate and adequate information.

5. The FDCA defined a "drug" in relevant part, as (1) any article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animal; (2) any article (other than food) intended to affect the structure or any function of the body; or (3) any article used as a component of either. 21 U.S.C. § 321(g).

6. Some drugs were also biological products, which were defined by the PHSA as a "therapeutic serum, toxin, antitoxin . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings." 42 U.S.C. § 262(i)(1).

7. The FDCA defined a "new drug" as, with limited exceptions, any drug that was not generally recognized as safe and effective among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs for use under the conditions prescribed, recommended, or suggested in its labeling. *See* 21 U.S.C. § 321(p).

8. The FDCA defined "label" to include a display of written, printed, or graphic matter upon the immediate container of a drug. 21 U.S.C. § 321(k). The FDCA defined "labeling" to include all labels as well as other written, printed, or graphic matter upon a drug, or any of its containers or wrappers, or otherwise accompanying such drug. 21 U.S.C. § 321(m).

9. Unless there was in effect with the FDA a new drug application ("NDA") or an abbreviated new drug application ("ANDA"), a new drug was unapproved and could

not lawfully enter into interstate commerce. *See* 21 U.S.C. §§ 355(a); 331(d).

10. Under the PHSA, a biological drug was required to have an FDA-approved Biologics License Application ("BLA") before it could be introduced into interstate commerce. 42 U.S.C. §262(a)(1)(a). Biological drugs were subject to all requirements of the FDCA, but if they had an FDA-approved license they did not also have to be the subject of an approved NDA or ANDA. *See* 42 U.S.C. § 262(j).

11. Some of the drugs regulated under the FDCA were "prescription drugs." "Prescription drugs" were those drugs which, because of their toxicity or other potential harmful effects, or the method of their use, or the collateral measures necessary to their use, were not safe for use except under the supervision of a practitioner licensed by law to administer such drugs, or which were required by FDA to be administered under the professional supervision of a practitioner licensed by law to administer such drugs. 21 U.S.C. § 353(b)(l)(A) and (B).

12. The FDCA prohibited the receipt in interstate commerce of any drug that was misbranded and prohibited the delivery or proffered delivery of such drug for pay or otherwise, or the causing thereof. 21 U.S.C. § 331(c).

13. A drug was misbranded if it was a "prescription drug" and at any time prior to dispensing the label of the drug failed to bear the symbol "Rx only." 21 U.S.C. § 353(b)(4)(A).

14. A drug was also misbranded if its labeling did not bear adequate directions for its use. 21 U.S.C. § 352(f)(1). "Adequate directions for use" meant directions adequate for a "layman" to use the "drug safely and for the purpose for which it was intended." 21

C.F.R. § 201.5. Prescription drugs, by definition, were not safe for use except under the supervision of a practitioner licensed by law to administer such drugs or were required by the FDA to be administered under the professional supervision of a practitioner licensed by law to administer such drugs and were therefore misbranded unless they qualified for an exemption.

15. A prescription drug was exempt from 21 U.S.C. § 352(f)(1) only if *all* of the listed conditions were met, including that: (1) the label bore the statement "Rx only"; (2) the label bore adequate information for its use, including any relevant hazards, side effects, and precautions under which medical practitioners could use the drug safely and was the labeling authorized by the FDA-approved new drug application. 21 C.F.R. §§ 201.100(b)(1), (c).

16. In 1989, the FDA approved a biologics license application ("BLA") for BOTOX® ("BOTOX"), the brand name of a drug manufactured by Allergan Inc.,[1] for the treatment of crossed eyes and spasm of the eyelids. BOTOX was manufactured from onabotulinumtoxinA, the Botulinum Type A toxin produced by the bacteria Clostridium botulinum. The Type A toxin was a highly potent and potentially dangerous toxin and could cause the disease botulism when present in human beings in a sufficient amount.

17. In 2002, the FDA approved a supplement to Allergan's BOTOX BLA for the temporary improvement in the appearance of glabellar lines, commonly referred to as wrinkles. Under this FDA approval, Allergan's Type A toxin product was marketed and

[1] In May 2020, Allergan was acquired by AbbVie, Inc.

labeled for this supplemental usage as "BOTOX® Cosmetic." FDA's approvals for BOTOX and BOTOX Cosmetic limited them to use under the supervision of a licensed practitioner and required that their labels bear the symbol "Rx only."

18. FDA has approved several other botulinum toxin type A prescription drug products for various medical and cosmetic uses, to include abobotulinumtoxinA (Dysport®), incobotulinumtoxinA (Xeomin®), prabotulinumtoxinA (Jeuveau®), and daxbotulinumtoxinA (Daxxify®). The different botulinum toxin products were not interchangeable with BOTOX® or each other because, among other things, the units used to measure the products were different.

19. BOTOX®, BOTOX® Cosmetic and all the other botulinum type A drugs carry a "boxed warning" (sometimes referred to as a "black box warning") under 21 C.F.R. § 201.57(c)(1) cautioning that the effects of all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulism and can appear hours to weeks after injection. The label warns that swallowing and breathing difficulties can be life threatening and there have been reports of death.

FACIAL EXPRESSIONS' Purchase and Use of Foreign Unapproved Botox

20. Beginning at least as early as 2019, **FACIAL EXPRESSIONS** purchased botulinum toxin type A drugs that were manufactured, packaged, and labeled for sale in Korea and/or Turkey and other foreign countries and not licensed or approved for sale or distribution in the United States. From in or around August 2019 through in or about August 2023, Facial Expressions purchased unlicensed and unapproved botulinum toxin products from several different sources – but none of it was authorized for use inside the

United States.

21. **FACIAL EXPRESSIONS** purchased unlicensed and unapproved botulinum toxin drugs at prices significantly below the price that Allergan and its authorized distributors charged for BOTOX® and BOTOX® Cosmetic that were manufactured and labeled for sale in the United States.

22. The clients of **FACIAL EXPRESSIONS** were treated for wrinkles, facial lines, and other cosmetic purposes, but the drugs being administered to those clients came from outside the legal supply chain for prescription drugs and were not licensed, approved, or labeled for distribution or use in the United States.

COUNT ONE
Receipt of Misbranded Drugs
21 U.S.C. §§ 331(c), 333(a)(1)

23. The allegations set forth in Paragraphs 1–22 of this Information are incorporated and re-alleged as if set forth in full herein.

24. From in or around August 2019 to August 2023, in the Eastern District of Kentucky, defendant,

FACIAL EXPRESSIONS

received and caused the receipt of prescription drugs – specifically unlicensed and unapproved botulinum toxin drugs – in interstate commerce that were misbranded within the meaning of: (1) 21 U.S.C. § 352(f)(1) in that their labeling failed to bear adequate directions for use, and (2) 21 U.S.C. § 353(b)(4)(A) in that their labels failed to bear the symbol "Rx only" and delivered and proffered delivery of such misbranded drugs for pay and otherwise.

In violation of 21 §§ U.S.C. 331(c) and 333(a)(1).

FORFEITURE ALLEGATION
21 U.S.C. § 334
28 U.S.C. § 2461

25. Upon conviction of a violation of 21 U.S.C. §§ 331(c), 331(a)(1), as set forth in this Information, the defendant,

FACIAL EXPRESSIONS

shall forfeit to the United States any property, real or personal, that constitutes or is derived, directly or indirectly, from proceeds traceable to the commission of the offense and all right, title, and interest in any prescription drug that is misbranded when introduced into or while in interstate commerce or which may not, under the provisions of 21 U.S.C. § 331, be introduced into interstate commerce, pursuant to 18 U.S.C. § 982(a)(7), 21 U.S.C. § 334, and 28 U.S.C. § 2461(c).

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

MONEY JUDGMENT:

A forfeiture money judgment in the amount of $10,911 obtained by **FACIAL EXPRESSIONS** as a result of the violation alleged in this Information.

27. If any of the property listed above, 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, the United States shall be entitled to forfeit substitute property pursuant to 21 U.S.C. § 853(p).

PAUL C. McCAFFREY
ACTING UNITED STATES ATTORNEY

MAXIMUM ORGANIZATIONAL PENALTIES

COUNT 1: Probation for not more than 5 years and a fine of not more than $200,000.

PLUS: Mandatory special assessment of $125 per count.

PLUS: Restitution, if applicable.

PLUS: Forfeiture, if applicable.