UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

18-20640-CR-SCOLA/TORRES

CASE NO. _____

21 U.S.C. §331(c)
21 U.S.C. §333(a)(2)
18 U.S.C. §2
21 U.S.C. §334
18 U.S.C. §982(a)(7)

UNITED STATES OF AMERICA

vs.

KERLYS MERCEDES CHAPARRO,

Defendant.
_____/

INDICTMENT

The Grand Jury charges that:

GENERAL ALLEGATIONS

At all times relevant to this Indictment:

1. The Food and Drug Administration ("FDA") was an agency of the Government of the United States within the Department of Health and Human Services and was responsible for oversight and enforcement concerning the provisions of Title 21, United States Code, Section 301 *et seq.,* also known as the Federal Food, Drug and Cosmetic Act ("FDCA").

Medical Devices

2. Under the FDCA, the term "device" (commonly referred to as a "medical device") was defined in relevant part as an "instrument, apparatus, implement . . . implant . . . or similar or related article, including any component, part, or accessory, which is intended to affect the

structure or any function of the [human body], and which does not achieve its primary intended purpose through chemical action within or on the [human body] and which is not dependent on being metabolized for achievement of its primary purpose." 21 U.S.C. § 321(h). Included in the term "device" was any substance intended to be injected into a portion of the human body for the purpose of affecting its size, contour or structure for aesthetic purposes (a process commonly referred to as "body contouring").

3. Polydimethylsiloxane, or any compound or mixture containing polydimethylsiloxane (also known as "silicone"), and hyaluronic acid, or any compound or mixture containing hyaluronic acid (frequently referred to as a "hydrogel" substance), as well as any other injectable substance of any type, including oils, gels or other such materials, amounted to "devices" within the meaning of the FDCA when these substances were intended to be injected into the human body for the purpose of body contouring and would achieve this purpose without chemical action within the body and without being dependent upon being metabolized.

4. As "devices," silicone, hyaluronic acid, hydrogel, and any other such substance as described above, would have required an FDA-approved pre-market application ("PMA") in which the FDA specifically authorized its intended use as a "Class III Medical Device" for the purpose of body contouring. 21 U.S.C. § 360c(f)(1) & 360e(a).

5. FDA has never approved a PMA for injectable silicone for the purpose of body contouring. Injections of silicone for body contouring purposes, especially deep tissue injections into the buttocks of the large amounts of silicone that would be required to achieve visible buttocks augmentation and enhancement, presented serious risks and dangers. Included among the risks of such injections were the potential of injection into a blood vessel resulting in embolism, migration of injected silicone to other bodily regions and resultant interference with organs and bodily

systems, serious sepsis infection and infection-related disorders, silicone-filled scar tissue formations ("granulomas"), necrosis, skin discoloration, immune system hyperactivity and related adverse systemic conditions, disfigurement, discomfort, and pain.

6. Due to the serious health risks set forth above, it had not been demonstrated to the satisfaction of the FDA that silicone could ever be safely injected into the human body for the purpose of body contouring even by a licensed medical practitioner.

7. In addition to silicone, the FDA had never approved a PMA for any other substance, including hyaluronic acid or "hydrogel," for injection into the buttocks region for the purpose of body contouring, even by a licensed medical practitioner, due to the risks associated with deep tissue injection of the large amounts of such substances necessary to achieve visible body contouring, including certain injection-related risks uniquely present in that particular region of the body due such factors as the presence of multiple blood vessels and the proximity of the sciatic nerve.

Adulteration of Medical Devices

8. With certain exceptions not applicable here, under the FDCA, a Class III Medical Device was deemed "adulterated" if it had not received PMA approval from the FDA. 21 U.S.C. § 351(f)(1)(B). Any substance intended for injection into the buttocks for body contouring purposes, regardless of whether such injection was dispensed and administered by a licensed medical practitioner, amounted to a Class III device requiring FDA PMA approval and any such substance was an "adulterated" device because no such approval had been granted by the FDA.

Prescription Drugs

9. Under the FDCA, a category of drug commonly referred to as a "prescription drug" was subject to certain dispensing and use restrictions and requirements. A prescription drug was

a drug which: (1) because of its toxicity or other potentiality for harmful effect, or 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 such drug (a "licensed medical practitioner") or (2) the FDA had limited approval of the drug to use only under the supervision of a licensed medical practitioner. 21 U.S.C. § 353(b)(1)(A) & (B).

10. As mandated by the FDCA, prescription drugs could be dispensed only: (a) upon a written prescription of a licensed medical practitioner; or (b) upon an oral prescription of such licensed medical practitioner reduced promptly to writing and filed by a pharmacist. 21 U.S.C. § 353(b) (1)(A) & (B) (*i*) & (*ii*). Similar restrictions applied to the refilling of prescription drugs. 21 U.S.C. § 353(b) (1)(A) & (B) (*iii*).

11. Injectable lidocaine, as well as any other injectable substance which functioned as a local anesthetic, were prescription drugs commonly used to block pain associated with medical procedures which, in the absence of such an anesthetic, would be prohibitively painful.

Misbranding Prescription Drugs Due to Dispensing Without Prescription

12. The act of dispensing prescription drugs such as injectable lidocaine contrary to the above provisions of the FDCA resulted in this prescription drug being "misbranded" while held for sale within the meaning of the FDCA. 21 U.S.C. § 353(b)(1).

Misbranding Prescription Drugs and Devices Due to False or Misleading Labeling and Lack of Adequate Directions for Use

13. Under the FDCA, drugs and devices were deemed to be "misbranded" if their labeling was "false or misleading in any particular." 21 U.S.C. § 352(a).

14. Drugs and devices were also deemed to be "misbranded" under the FDCA if their labelling did not bear "(1) adequate directions for use; and (2) such adequate warnings against use

in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, [and] in such manner and form, as are necessary for the protection of users . . ." 21 U.S.C. § 352(f).

15. Under Title 21, Code of Federal Regulations, Sections 201.5 and 801.5, "adequate directions for use" with respect to a drug or device meant directions under which a layman could use a drug or device safely and for the purposes for which it was intended.

16. Silicone, hyaluronic acid, hydrogel or any other such injectable substance amounting to a "device," when intended to be unlawfully injected into the buttocks for body contouring purposes, could not have adequate directions that would allow a layman to use such devices safely for such purposes, and were thus "misbranded" when used or intended to be used in this manner without such directions and warnings. 21 U.S.C. § 352(f).

Unlawful Conduct Concerning Misbranded or Adulterated Drugs and Devices

17. The FDCA made it unlawful to: (a) cause the introduction and delivery for introduction into interstate commerce of a misbranded or adulterated drug or device (21 U.S.C. § 331(a)); (b) to receive in interstate commerce any misbranded or adulterated drug or device and to deliver or proffer the delivery thereof for pay or otherwise (21 U.S.C. § 331(c)); and (c) do any act with respect to a drug or device if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded. 21 U.S.C. § 331(k).

18. Under the FDCA, the term "interstate commerce" included "commerce between any State or Territory and any place outside thereof" and included in its definition international commerce between the United States and any foreign country. 21 U.S.C. § 321(b).

The Defendant

19. Defendant **KERLYS MERCEDES CHAPARRO** was a resident of Miami-Dade County, Florida and was not a "practitioner licensed by law" ("licensed medical practitioners") within the meaning of the aforementioned provisions of the FDCA.

Delivery for Pay of an Adulterated and Misbranded Device Received in Interstate Commerce With Intent to Defraud and Mislead (21 U.S.C. §§331(c) and 333(a)(2))

On or about July 27, 2016, in Miami-Dade County, in the Southern District of Florida, and elsewhere, the defendant,

KERLYS MERCEDES CHAPARRO,

did knowingly, with the intent to defraud and mislead, having received in interstate commerce a device which the defendant intended to be injected into the human body for body contouring purposes and which was: (a) adulterated within the meaning of Title 21, United States Code, Section 351(f)(1)(B), in that the FDA had neither approved it nor cleared it for marketing for such use; and (b) misbranded within the meaning of Title 21, United States Code, Section 352(a), in that its labeling was false and misleading, and within the meaning of Title 21, United States Code, Section 352(f)(1), in that its labeling did not bear adequate directions for use, deliver and proffer the delivery of said device for pay and otherwise, by injection and offering the injection of said device into S.R. for body contouring purposes in exchange for payment of money.

In violation of Title 21, United States Code, Sections 331(c) and 333(a)(2), and Title 18, United States Code, Section 2.

FORFEITURE
(21 U.S.C. §334 and 18 U.S.C. §982(a)(7))

1. The General Allegations section of this Indictment are realleged and incorporated by reference as though fully set forth herein, for the purpose of alleging forfeiture to the United States of certain property in which the defendant, **KERLYS MERCEDES CHAPARRO** has an interest.

2. Upon conviction of any violation of Title 21, United States Code, Sections 331(c) or 333(a) alleged in this Indictment, the defendant so convicted shall forfeit to the United States, pursuant to Title 18, United States Code, Section 982(a)(7), any property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of such violation.

3. Upon conviction of any violation of Title 21, United States Code, Sections 331(c) or 333(a) as alleged in this Indictment, the defendant so convicted shall forfeit to the United States, pursuant to Title 21, United States Code, Section 334: (A) Any drug that is a counterfeit drug, (B) Any container of a counterfeit drug, (C) Any punch, die, plate, stone, labeling, container, or other thing used or designed for use in making a counterfeit drug or drugs, and (D) Any adulterated or misbranded device.

All pursuant to Title 21, United States Code, Section 334, and Title 18, United States Code, Section 982(a)(7), and the procedures set forth in Title 21, United States Code, Section 853 made applicable by Title 18, United States Code, Section 982(b) and Title 28, United States Code, Section 2461(c).

A TRUE BILL

FOREPERSON

for BENJAMIN G. GREENBERG
UNITED STATES ATTORNEY

MIESHA SHONTA DARROUGH
ASSISTANT UNITED STATES ATTORNEY

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

UNITED STATES OF AMERICA

v.

KERLYS MERCEDES CHAPARRO,

Defendant.

_____ /

CASE NO. _____

CERTIFICATE OF TRIAL ATTORNEY*

Superseding Case Information:

Court Division: (Select One)

_X_ Miami _____ Key West
___ FTL _____ WPB ___ FTP

New Defendant(s) Yes ____ No ___
Number of New Defendants ____
Total number of counts ____

I do hereby certify that:

1. I have carefully considered the allegations of the indictment, the number of defendants, the number of probable witnesses and the legal complexities of the Indictment/Information attached hereto.

2. I am aware that the information supplied on this statement will be relied upon by the Judges of this Court in setting their calendars and scheduling criminal trials under the mandate of the Speedy Trial Act, Title 28 U.S.C. Section 3161.

3. Interpreter: (Yes or No) Yes
List language and/or dialect Spanish

4. This case will take 3 days for the parties to try.

5. Please check appropriate category and type of offense listed below:

	(Check only one)		(Check only one)	
I	0 to 5 days	X	Petty	
II	6 to 10 days		Minor	
III	11 to 20 days		Misdem.	
IV	21 to 60 days		Felony	X
V	61 days and over			

6. Has this case been previously filed in this District Court? (Yes or No) No
If yes:
Judge: Case No. _____
(Attach copy of dispositive order)
Has a complaint been filed in this matter? (Yes or No) No
If yes:
Magistrate Case No.
Related Miscellaneous numbers:
Defendant(s) in federal custody as of
Defendant(s) in state custody as of
Rule 20 from the District of
Is this a potential death penalty case? (Yes or No) No

7. Does this case originate from a matter pending in the Northern Region of the U.S. Attorney's Office prior to October 14, 2003? Yes _____ No X

Miesha S Darrough

MIESHA SHONTA DARROUGH
ASSISTANT UNITED STATES ATTORNEY
FL Bar No. / Court I.D. No. 17238

*Penalty Sheet(s) attached

REV 5/3/17

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

PENALTY SHEET

Defendant's Name: KERLYS MERCEDES CHAPARRO

Case No: _____

Count #: 1

Delivery for Pay of an Adulterated and Misbranded Device Received in Interstate Commerce With Intent to Defraud and Mislead

Title 21, United States Code, Sections 331(c) and 333(a)(2)

***Max. Penalty:** 3 Years' Imprisonment

***Refers only to possible term of incarceration, does not include possible fines, restitution, special assessments, parole terms, or forfeitures that may be applicable.**