ORIGINAL

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

UNITED STATES OF AMERICA

v.

DEANNA M. ROBERTS

Criminal Indictment

No. 1 16-CR-171

UNDER SEAL

THE GRAND JURY CHARGES THAT:

Introduction

1. The Food and Drug Administration ("FDA") is an agency of the United States Government charged with the responsibility of protecting the health and safety of the public by enforcing the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-399f, to ensure that, among other things, devices sold for use by or upon humans are safe and effective. The FDA's responsibilities under the FDCA included regulating the manufacture, labeling, and distribution of devices introduced into interstate commerce.

2. The FDCA defines a "device" as, among other things, "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is ... intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical

action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. § 321 (h)(2)(3).

3. With certain exceptions not applicable here, under the FDCA, a Class III device is adulterated if it has not received FDA pre-market approval nor was it exempt from the requirement to obtain FDA pre-market approval.

4. The FDCA prohibits the introduction or delivery for introduction into interstate commerce (or the causing thereof) of any device that is adulterated.

5. The only injectable silicone products approved or cleared for marketing by FDA are ophthalmic devices for the treatment of eye injuries, such as, detached retinas. These products are regulated by FDA as prescription medical devices.

6. Factor II, Inc., located in Lakeside, Arizona is a wholesale supplier of silicone to various industries. Factor II, Inc., does not produce medical grade silicone for injection into the human body. The liquid silicone that is distributed by Factor II, Inc., has not obtained FDA approval or clearance for injection into the human body.

The Defendant

7. DEANNA M. ROBERTS, the defendant herein, is a resident of Sanford, Florida, and travels frequently to the Northern District of Georgia and elsewhere, to inject liquid silicone obtained from Factor II, Inc., into the buttocks, hips, lips, and other body parts of customers for enhancement of those areas in exchange for money. When liquid silicone is used in this fashion, liquid silicone is a device subject to regulation by the FDA.

8. From at least April 1, 2004, the defendant purportedly operated a business called D & D Distributing located in Orlando, Florida.

9. On or about April 2, 2004, the defendant sought to purchase liquid silicone from Factor II, Inc. Before Factor II, Inc. would sell liquid silicone to the defendant, Factor II, Inc., required that the defendant submit an affidavit in which the defendant certified that "I will not knowingly use, in either its pure state or as a component of some other material, any of the aforementioned products (liquid silicone) hereafter received by me from Factor II, Inc. into humans for injection into any areas of the body, or onto any areas of the body in an uncured state, nor will I supply the aforementioned product(s) to others for such purposes." The defendant falsely and with intent to defraud submitted the required affidavit to Factor II, Inc., when in truth and in fact, the defendant well knew that she intended to inject the liquid silicone that she received from Factor II, Inc. into the bodies of humans.

10. On or about April 3, 2004, the defendant falsely and with intent to defraud advised Factor II, Inc., that she wanted to purchase liquid silicone for resale to a client to use to lubricate the client's medical equipment.

11. From April 5, 2004 through December 3, 2015, based upon the defendant's false and fraudulent affidavit and representations, Factor II, Inc., sold the defendant approximately 178 gallons of liquid silicone. Factor II, Inc., employees shipped the liquid silicone from Lakeside, Arizona to addresses the defendant controlled in Florida and Virginia.

12. The defendant transported the liquid silicone to the Northern District of Georgia for the purpose of injecting liquid silicone into the buttocks, lips, and other body parts of the victims identified herein.

13. The defendant falsely and with intent to defraud claimed to the victims and others that she was a licensed medical practitioner, when in truth and in fact, she was not a licensed medical practitioner.

14. The grand jury incorporates each and every allegation contained in paragraphs 1-13 into each count of this Indictment.

Count One

On or about November 16, 2015, in the Northern District of Georgia, the defendant, DEANNA M. ROBERTS, in and using a means and facility of interstate commerce, did knowingly possess and transport a pre-retail medical product, that is, liquid silicone, that was involved in a violation of Title 18, United States Code, Section 670(a)(1), that is, the defendant in and using a means and facility of interstate commerce, did by fraud and deception obtain liquid silicone which the defendant injected into the buttocks of L.H., and said violation did result in the death of L.H., in that the death of L.H. resulted from the use of the liquid silicone obtained by the defendant by means of fraud and deception, in violation of Title 18, United States Code, Sections 670(a)(3), (b)(2)(C), and (c)(1).

Count Two

On or about November 16, 2015, in the Northern District of Georgia, the defendant, DEANNA M. ROBERTS, in and using a means and facility of

interstate commerce, did knowingly possess and transport a pre-retail medical product, that is, liquid silicone, that was involved in a violation of Title 18, United States Code, Section 670(a)(1), that is, the defendant in and using a means and facility of interstate commerce, did by fraud and deception obtain liquid silicone which the defendant injected into the hips and buttocks of J.T., in violation of Title 18, United States Code, Sections 670(a)(3) and (c)(3).

Count Three

On or about November 2014, the exact date being unknown to the grand jury, in the Northern District of Georgia, the defendant, DEANNA M. ROBERTS, in and using a means and facility of interstate commerce, did knowingly possess and transport a pre-retail medical product, that is, liquid silicone, that was involved in a violation of Title 18, United States Code, Section 670(a)(1), that is, the defendant in and using a means and facility of interstate commerce, did by fraud and deception obtain liquid silicone which the defendant injected into the hips and buttocks of V.M., in violation of Title 18, United States Code, Sections 670(a)(3) and (c)(3).

Count Four

On or about October 2014, the exact date being unknown to the grand jury, in the Northern District of Georgia, the defendant, DEANNA M. ROBERTS, in and using a means and facility of interstate commerce, did knowingly possess and transport a pre-retail medical product, that is, liquid silicone, that was involved in a violation of Title 18, United States Code, Section 670(a)(1), that is, the

defendant in and using a means and facility of interstate commerce, did by fraud and deception obtain liquid silicone which the defendant injected into the face of S.P., in violation of Title 18, United States Code, Sections 670(a)(3) and (c)(3).

Count Five

On or about November 16, 2015, in the Northern District of Georgia, the defendant, DEANNA M. ROBERTS, with intent to defraud and mislead, introduced into interstate commerce, a medical device, namely polydimethylsiloxane fluid, a/k/a, liquid silicone, which was adulterated within the meaning of Title 21, United States Code, Section 351(f)(1)(B) in that it was a Class III device that had not received FDA pre-market approval nor was it exempt from the requirement to obtain FDA pre-market approval, and the defendant did inject said adulterated device into the buttocks of L.H., in violation of Title 21, United States Code, Sections 331(a), 333(a)(2), and 351(f)(1)(B).

Count Six

On or about November 16, 2015, in the Northern District of Georgia, the defendant, DEANNA M. ROBERTS, with intent to defraud and mislead, introduced into interstate commerce, a medical device, namely polydimethylsiloxane fluid, a/k/a, liquid silicone, which was adulterated within the meaning of Title 21, United States Code, Section 351(f)(1)(B) in that it was a Class III device that had not received FDA pre-market approval nor was it exempt from the requirement to obtain FDA pre-market approval, and the defendant did inject said adulterated device into the hips and buttocks of J.T., in

violation of Title 21, United States Code, Sections 331(a), 333(a)(2), and 351(f)(1)(B).

Count Seven

On or about November 2014, the exact date being unknown to the grand jury, in the Northern District of Georgia, the defendant, DEANNA M. ROBERTS, with intent to defraud and mislead, introduced into interstate commerce, a medical device, namely polydimethylsiloxane fluid, a/k/a liquid silicone, which was adulterated within the meaning of Title 21, United States Code, Section 351(f)(1)(B) in that it was a Class III device that had not received FDA pre-market approval nor was it exempt from the requirement to obtain FDA pre-market approval, and did inject said adulterated device into the hips and buttocks of V.M., in violation of Title 21, United States Code, Sections 331(a), 333(a)(2), and 351(f)(1)(B).

Count Eight

On or about October 2014, the exact date being unknown to the grand jury, in the Northern District of Georgia, the defendant, DEANNA M. ROBERTS, with intent to defraud and mislead, introduced into interstate commerce, a medical device, namely polydimethylsiloxane fluid, a/k/a liquid silicone, which was adulterated within the meaning of Title 21, United States Code, Section 351(f)(1)(B) in that it was a Class III device that had not received FDA pre-market approval nor was it exempt from the requirement to obtain FDA pre-market approval, and did inject said adulterated medical device into the face of S.P., in

violation of Title 21, United States Code, Sections 331(a), 333(a)(2), and 351(f)(1)(B).

A TRUE BILL

FOREPERSON

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