

JUL 10 2009

UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION

U.S. DISTRICT COURT
WESTERN DISTRICT OF NC

UNITED STATES OF AMERICA)
)
)
v.)
)
)
SOUTHEASTERN PLASTIC SURGERY, P.C.)
_____)

DOCKET NO. 3:09cr118
BILL OF INFORMATION
Violations:
21 U.S.C. § 331(k)
21 U.S.C. § 333
21 U.S.C. § 352(i)

THE UNITED STATES ATTORNEY CHARGES:

At the specified times and at all relevant times:

Introduction

1. On or about December 9, 1991, the federal Food & Drug Administration (hereafter, "FDA") approved BOTOX[®], a drug derived from Botulinum Toxin Type A and manufactured by Allergan of Irvine, California, for the treatment of cervical dystonia in adults. On or about April 22, 2002, the FDA approved a supplement to the BOTOX[®] license application for use in the treatment of human glabellar lines, also known as wrinkles. Under this latter approval, the supplement is marketed and labeled as BOTOX COSMETIC[®].

2. Toxin Research International, Inc. (hereafter, "TRI") was a corporation formed under the laws of the State of Arizona on or about May 12, 2003, and which maintained its offices in Tucson, Arizona. TRI marketed a Botulinum Toxin Type A product that was not approved by the FDA for use on humans.

3. Defendant SOUTHEASTERN PLASTIC SURGERY, P.C. (hereafter, "SOUTHEASTERN") was a company formed under the laws of the State of North Carolina in or about 1996. SOUTHEASTERN maintained its principal place of business in Gastonia, North Carolina.

Misbranding

4. In or about January of 2004, SOUTHEASTERN received an advertisement from TRI for the company's Botulinum Toxin Type A product. The advertisement stated "not FDA approved."

5. Thereafter, SOUTHEASTERN decided to purchased TRI's Botulinum Toxin Type

A product for use on human patients because, among other things, the product was substantially cheaper than BOTOX COSMETIC[®] and had a longer shelf-life. SOUTHEASTERN then caused four telephone orders to be placed for a total of ten (10) vials of TRI's Botulinum Toxin Type A product. When the product was received, the label on each vial contained the language, "For Research Purposes Only – Not for Human Use."

6. SOUTHEASTERN caused a "Consent for Botulinum Toxin Type A" to be prepared, which consent falsely represented to patients that TRI's Botulinum Toxin Type A product had been "shown to be safe in clinical trials."

7. SOUTHEASTERN administered TRI's Botulinum Toxin Type A product to approximately forty-one (41) individuals. These individuals were charged prices for these treatments comparable to the price charged for treatments with the more expensive BOTOX COSMETIC[®].

COUNT ONE

8. The Government realleges and incorporates by reference herein all of the allegations contained in paragraphs 1 through 7 of the Information, and further alleges that:

9. In or about 2004, in Gaston County, within the Western District of North Carolina, and elsewhere, the defendant,

SOUTHEASTERN PLASTIC SURGERY, P.C.

knowingly did acts with respect to a drug, to wit TRI's Botulinum Toxin Type A product, while such drug was held for sale after shipment in interstate commerce, resulting in such drug being misbranded, in violation of Title 21, United States Code, Sections 331(k), 333(a)(1), and 352(i)(2), (3).

NOTICE OF FORFEITURE AND FINDING OF PROBABLE CAUSE

10. The Government realleges and incorporates by reference herein all of the allegations contained in paragraphs 1 through 9 of the Information, and further alleges that:

11. Notice is hereby given, pursuant to Federal Rule of Criminal Procedure 32.2(a), of the provisions of 18 U.S.C. § 982, 21 U.S.C. §§ 334, 853, and 28 U.S.C. § 2461(c). Under Section 2461(c), criminal forfeiture is applicable to any offenses for which forfeiture is authorized by any other statute, including but not limited to 18 U.S.C. § 981, and all specified unlawful activities listed or referenced in 18 U.S.C. § 1956(c)(7), which are incorporated as to proceeds by 18 U.S.C. § 981(a)(1)(C). The defendants have or had possessory or legal interests in the following property that is subject to forfeiture in accordance with Section 982 and/or Section 2461(c):

- A. All property involved in the violations alleged in this Bill of Indictment, or traceable to such property;
- B. All property which is proceeds of such violations, or traceable to such property; and,
- C. In the event that any property described in (A) or (B) cannot be located or recovered or has been substantially diminished in value or has been commingled with other property which cannot be divided without difficulty, all other property of the defendants, to the extent of the value of the property described in (A) and (B).

12. The Government alleges that the following property is subject to forfeiture on one or more of the grounds stated above:

- A. The sum of approximately \$15,190 in proceeds and funds involved in the alleged violations.

EDWARD R. RYAN
ACTING UNITED STATES ATTORNEY



MATTHEW T. MARTENS
ASSISTANT UNITED STATES ATTORNEY