

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA : Criminal No. 06-
:
v. :
:
ALBERT POET : 18 U.S.C. §§ 1341 and 2;
: 21 U.S.C. §§ 331(k);
: 333(a)(2); and 352(i)(3).
:
: I N D I C T M E N T

The Grand Jury in and for the District of New Jersey,
sitting in Trenton, charges:

COUNTS 1-13
(Mail Fraud)

The Defendant

1. At all times relevant to this Indictment:
 - a. Defendant ALBERT POET was a physician licensed to practice medicine in the state of New Jersey;
 - b. Defendant ALBERT POET offered medical cosmetic services to his patients;
 - c. Defendant ALBERT POET owned and operated the Shore Laser Center (hereinafter "SLC") located at 96 Bay Avenue, Manahawkin, New Jersey, and "PEAU," located at 44 Fairfield Street, Montclair, New Jersey.

The Food and Drug Administration

2. At all times relevant to this Indictment:
 - a. The United States Food and Drug Administration ("FDA") was the federal agency within the United States

Department of Health and Human Services charged with the responsibility of protecting the health and safety of the American public by assuring that drugs are safe and effective for their intended uses before they may be legally introduced into interstate commerce. The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 321, et seq., and its implementing regulations, provided guidance for the legal introduction of drugs into interstate commerce.

b. The FDCA defined drugs to include any articles, or any components thereof, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans, and articles intended to affect the structure or any function of the human body.

c. The FDCA defined new drugs as drugs 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 their labeling.

d. The FDCA defined "biological product" as a toxin applicable to the prevention, treatment, or cure of a disease or condition of human beings. A biological product was also a drug if it was intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans, or was intended to affect the structure or any function of the human body.

e. A new drug which was also a biological product could not lawfully enter interstate commerce unless there was a biological license, new drug application, abbreviated new drug application, or notice of claimed exemption for an investigational new drug in effect with the FDA.

f. The FDA enforced drug safety and effectiveness standards by guarding against the misbranding of drugs. A drug was misbranded if, among other things, it was offered for sale under the name of another drug.

Federal Regulation of Botulinium Toxin Type A

3. At all times relevant to this Indictment:

a. The bacterium *Clostridium Botulinum* produced Botulinum Toxin Type A, a highly potent toxin. When present in sufficient amount in humans, Botulinum Toxin Type A caused botulism.

b. Botulism was a muscle-paralyzing condition in which Botulinum Toxin Type A prevented the nerves from signaling the muscles to contract.

c. Botulinum Toxin Type A was both a drug and a biological product subject to regulation by the FDA when the product was intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans, or to affect the structure or function of the human body. Therefore, before any form of Botulinum Toxin Type A could be distributed legally in

interstate commerce for use in humans, the FDA must have approved the Botulinum Toxin Type A as a new drug or licensed it as a biological product.

d. On December 9, 1991, the FDA approved a biological products license for Botox®, the brand name of a drug derived from Botulinum Toxin Type A and for the treatment of certain muscle disorders of the eye that was manufactured by Allergan, Inc., of Irvine, California.

e. On or about April 12, 2002, the FDA approved a supplement to Allergan's Botox® license application for the treatment of glabellar lines, commonly referred to as forehead wrinkles. Allergan marketed the product manufactured pursuant to this supplemental license as Botox® Cosmetic.

f. No other drug or biological product containing Botulinum Toxin Type A has been approved or licensed by the FDA for use in humans.

TRI's Botulinum Toxin Type A

4. At all times relevant to this Indictment:

a. Toxin Research International, Incorporated ("TRI") was an Arizona corporation with its principal place of business at 3280 East Hemisphere Loop, Tucson, Arizona.

b. From in or about December 2003 through in or about December 2004, TRI marketed and sold a Botulinum Toxin Type A product that was neither approved nor licensed by the FDA. For

purposes of this Indictment, this product is referred to as "Tritox."

c. Although TRI marketed its product to physicians, Tritox was sold in injectable vials which were labeled "For Research Purposes Only" and "Not for Human Use." TRI claimed that the "international units" in which its product was measured were equivalent to the "units" in which Allergan measured Botox® and Botox® Cosmetic.

The Scheme to Defraud

5. From on or about December 4, 2003, through in or about December 2004, in the District of New Jersey and elsewhere, the defendant

ALBERT POET

did knowingly and willfully devise a scheme and artifice to defraud, which scheme and artifice was in substance as set forth below, and to obtain money and property by means of false and fraudulent pretenses, representations, and promises, and for the purpose of executing such scheme and artifice knowingly caused to be delivered by private and commercial interstate carrier according to the direction thereon, matters and things, as more fully described below.

6. It was the purpose of the scheme and artifice to defraud that defendant ALBERT POET would obtain money or profit by purchasing less expensive, unapproved Tritox, and selling it to

patients as, and at the price of, more expensive, FDA-approved Botox® made by Allergan.

7. It was part of the scheme and artifice to defraud that defendant ALBERT POET offered medical cosmetic services at his offices at SLC in Manahawkin, New Jersey and "PEAU" in Montclair, New Jersey.

8. It was further a part of the scheme and artifice to defraud that between January 2004 and February 2005, defendant ALBERT POET placed regular advertisements in local newspapers offering "Botox" treatments at his offices.

9. It was further a part of the scheme and artifice to defraud that defendant ALBERT POET maintained a website, www.shorelaser.com, that provided information for potential clients about services offered at his offices. From on or about May 4, 2004 through on or about January 18, 2005, ALBERT POET advertised "Botox" treatments on his website.

10. It was further a part of the scheme and artifice to defraud that on or about December 4, 2003, defendant ALBERT POET ordered 1 vial of Tritox from TRI for \$1,294.00. ALBERT POET charged this expense to his personal Mastercard credit card.

11. It was further a part of the scheme and artifice to defraud that between December 4, 2003 and November 8, 2004, defendant ALBERT POET placed 13 orders for a total of 26 vials of Tritox from TRI at a total cost of \$ 26,559.00. TRI claimed that

one vial of Tritox contained 500 "International Units" of Tritox. All payments for Tritox were made on ALBERT POET's personal Mastercard credit card.

12. It was further a part of the scheme and artifice to defraud that defendant ALBERT POET received the 26 vials of Tritox at SLC; each vial was marked "FOR RESEARCH PURPOSES ONLY NOT FOR HUMAN USE."

13. It was further a part of the scheme and artifice to defraud that during 2004, defendant ALBERT POET purchased 21 vials of Allergan's Botox® Cosmetic for a total cost of \$9,346.00. Each vial of Botox® Cosmetic contained 100 of Allergan's "units" of Botox® Cosmetic. During the year 2003, ALBERT POET had purchased 81 vials of Allergan's Botox® Cosmetic.

14. It was further a part of the scheme and artifice to defraud that defendant ALBERT POET injected many of the approximately 130 patients who sought Botox® treatments at his offices between January 1, 2004 and December 1, 2004 with Tritox.

15. It was further a part of the scheme and artifice to defraud that defendant ALBERT POET provided consent forms to most new patients seeking Botox® injections that specifically advised the patients of the risks of injection with "Botox."

16. It was further a part of the scheme and artifice to defraud that defendant ALBERT POET did not inform most patients receiving Tritox injections that they were receiving injections

of a product not approved by the FDA.

17. It was further a part of the scheme and artifice to defraud that defendant ALBERT POET did not inform those patients receiving Tritox injections that Tritox was packaged in vials labeled "For research purposes only" and "Not for human use."

18. It was further a part of the scheme and artifice to defraud that defendant ALBERT POET did not inform most of the patients receiving Tritox injections that they were not receiving Allergan's Botox®.

19. It was further a part of the scheme and artifice to defraud that defendant ALBERT POET charged his patients the same price for Tritox and Botox® injections during 2004.

20. It was further a part of the scheme and artifice to defraud that defendant ALBERT POET did not note in patient records which patients received Botox® and which patients received Tritox.

21. For the purpose of executing the aforesaid scheme and artifice, in the District of New Jersey and elsewhere, defendant

ALBERT POET

did knowingly and willfully cause to be delivered by private and commercial interstate carrier, namely United Parcel Service ("UPS"), on or about the dates listed, as described below, according to the direction thereon the following:

Count	Date	To	From	Item
1	12/4/03	Poet, Manahawkin, NJ	TRI, Tucson, AZ	1 vial Tritox
2	12/17/03	Poet, Manahawkin, NJ	TRI, Tucson, AZ	2 vials Tritox
3	1/22/04	Poet, Manahawkin, NJ	TRI, Tucson, AZ	2 vials Tritox
4	3/1/04	Poet, Manahawkin, NJ	TRI, Tucson, AZ	2 vials Tritox
5	4/6/04	Poet, Manahawkin, NJ	TRI, Tucson, AZ	2 vials Tritox
6	4/29/04	Poet, Manahawkin, NJ	TRI, Tucson, AZ	2 vials Tritox
7	6/2/04	Poet, Manahawkin, NJ	TRI, Tucson, AZ	2 vials Tritox
8	7/1/04	Poet, Manahawkin, NJ	TRI, Tucson, AZ	2 vials Tritox
9	8/2/04	Poet, Manahawkin, NJ	TRI, Tucson, AZ	2 vials Tritox
10	8/26/04	Poet, Manahawkin, NJ	TRI, Tucson, AZ	2 vials Tritox
11	10/4/04	Poet, Manahawkin, NJ	TRI, Tucson, AZ	2 vials Tritox
12	10/20/04	Poet, Manahawkin, NJ	TRI, Tucson, AZ	2 vials Tritox
13	11/8/04	Poet, Manahawkin, NJ	TRI, Tucson, AZ	3 vials Tritox

In violation of Title 18, United States Code, Sections 1341 and 2.

COUNT 14
(Misbranding a Drug While Held for Sale)

1. Paragraphs 1 through 4 and 6 through 20 of Counts 1 through 13 of this Indictment are hereby realleged and incorporated as though set forth in full herein.

2. From on or about December 17, 2003, to on or about January 1, 2005, in Manahawkin, New Jersey and Montclair, New Jersey, in the District of New Jersey and elsewhere, the defendant

ALBERT POET

with the intent to defraud and mislead, did an act that caused a drug, namely Botulinium Toxin Type A distributed by Toxin Research International, Inc., to be misbranded while it was held for sale and after shipment in interstate commerce, in that defendant ALBERT POET offered the TRI Botulinium Toxin Type A ("Tritox") for sale by injection to patients under the name of another drug, namely, Botox® and Botox® Cosmetic, Allergan's FDA-approved Botulinium Toxin Type A products.

In violation of Title 21, United States Code, Sections 331(k), 333(a)(2), 352(i)(3), and Title 18, United States Code, Section 2.

A TRUE BILL

FOREPERSON

CHRISTOPHER J. CHRISTIE
UNITED STATES ATTORNEY

