

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO.
04-61717 CIV-COHN

**MAGISTRATE JUDGE
SNOW**

UNITED STATES OF AMERICA

Plaintiff.

vs.

DR. CHAD LIVDAHL, N.D., DR. ZARAH
KARIM, N.D., TOXIN RESEARCH
INTERNATIONAL, INC., POWDERZ,
INC., THE COSMETIC PHARMACY,
INC., and Z SPA INC.,

Defendants.

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Ex Parte **COMPLAINT FOR EMERGENCY TEMPORARY RESTRAINING ORDER,
PRELIMINARY AND PERMANENT INJUNCTION**

The United States of America, plaintiff, by and through the undersigned Assistant United States Attorney, respectfully present to the Honorable Court as follows:

Introductory Allegations:

1. This statutory injunction is brought under the Federal Food, Drug and Cosmetic Act (the "FDCA"), 21 U.S.C. § 332(a), and the Fraud Injunction Statute, 18 U.S.C. § 1345, to enjoin Dr. Chad Livdahl N.D., Dr. Zarah Karim, N.D., Toxin Research International, Inc., Powderz, Inc., The Cosmetic Pharmacy, Inc., Z Spa, Inc., and all those in active concert and participation with any of them from violating:

a. 21 U.S.C. § 331(a) and by the introduction or delivery for introduction into interstate commerce of Botulinum Type A (Botulinum), a drug, as defined in 21 U.S.C. § 321(g), that is

but each unit is equivalent, and we will be submitting studies to demonstrate that 1 unit of their [sp] is equal to 1 unit of ours. . . . Thanks, CHad.” (sic).

- g. Copies of five (5) invoices, dated December 1 and 2, 2004, and completed order forms for TRI’s Botulinum Neurotoxin type A, reflecting sales to: Richard Allen, whose order form includes a copy of a physician’s assistant license in his name; Dr. Robert West at the Almos Heights Skin Clinic in San Antonio, Texas; Dr. Martha Gonzalez, Physician and Surgeon, Ventura California; Dr. Kreg Jenson, Physician and Surgeon, Oren, Utah; and Dr. Herbert Smyczek, Newark, New Jersey.

Powderz’ and the Cosmetic Pharmacy’s Marketing, Promotion, and Instructions For Use

22. Powderz, Inc., (“Powderz”) was incorporated in Arizona on June 12, 2001, by Chad Livdahl, N.D., and its registered agent was listed as Zahra Karim, N.D. Powderz’s Articles of Incorporation list Livdahl as the sole member of the company’s initial Board of Directors. The most currently available filings with the Arizona Corporation Commission, dated June 3, 2004, list Chad Livdahl as the President of the company and the company’s principal place of business as 3280 E. Hemisphere Loop, # 116-A, Tucson, Arizona 85706.

23. The Cosmetic Pharmacy was incorporated in Arizona on June 8, 2004, and its statutory agent of record is Chad Livdahl. The company’s principal place of business is listed as 3280 E. Hemisphere Loop, # 112, Tucson, Arizona 85706.

24. During service of the December 4, 2004, warrant, there were seized numerous marketing and registration materials relating to seminars held by the principals of TRI and Powderz, Chad Livdahl and Zahra Karim. These documents reflect Powderz conducted the

seminars in July 2003 and October 2003, and prepared materials for another in September 2004.

Included among these documents were:

a. A registration brochure for the July 19-20, 2003, seminar, titled "The Physician's Approach to Compounding for Aesthetic Enhancement 'Hands-On' Workshop and Demonstration." which advertises a block of instruction from 3:00 p.m. to 4:00 p.m. on July 19, 2003 titled "Botulinum Toxin Type A," and a block of instruction from 8:00 a.m. to 1:00 p.m. on July 20, 2003, called "Demo/Tutorial Course Botulinum toxin type A, Hyaluronic acid." One of the presenters listed in the July 2003 brochure was Bach McComb, D.O., N.D., Ph.D., whose license to practice medicine was suspended by the Florida Department of Health in April 2003 for having allegedly prescribed excessive amounts of controlled substances.

b. Handwritten consent forms, titled "Botulinum Toxin Type A Consent Form and Cross Linked Hyaluronic Acid for Injection," which appear to be signed by participants at the July seminar, and state as their purpose, "Educational Demonstration." Several also include in the purpose statement the following: "This is not to be construed to be the practice of medicine." The consent form lists possible side effects, to include: bruising, redness, droopy eyelid, double vision, pain, and need for more treatment; more or less effect than desired / lumpy appearance, and concludes with the statement, "I agree I have had the opportunity to ask questions." On a majority of these signed forms, the sentence continues with, ". . . and am having this treatment voluntarily." Also, blank, unexecuted copies of the handwritten consent form were also located and seized. A typewritten version of a consent form, called "Patient Informed Consent," unsigned, was seized. It stated: "This consent form is intended to provide (Name) with the information needed to make an informed decision as to whether or not to undergo Botulinum

Toxin Type A (AKA: Botox®, Dysport®, Botulinum Toxin) injection therapy for the treatment of wrinkles, forehead furrowing, frown lines, wrinkling around the eyes, and/or eyelid twitching.”

c. Single-page disclaimers which appear to be signed by participants of the July 2003 seminar, which state, in part:

“Powderz disclaims any and all liability for injury or other damages resulting to any individuals attending a session for all claims which may arise out of the use of the techniques demonstrated or discussed therein . . . Some drugs or medical devices demonstrated in Powderz courses or described in print or electronic publications have not been cleared by the FDA or have been cleared by the FDA for specific uses only. The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or device he or she wishes to use in clinical practice.”

d. An agenda for the October 18, 2003, “Powderz Cosmetic Compounding” seminar, which included a 30-minute instruction block called “Botulinum Toxin Type A & Discussion.”

Notably, a warning regarding Photography/Audio/Visual Taping Restrictions is included in this agenda which reads: “There is strictly no photography, audio, or visual taping allowed. Anyone found photographing or taping without authorization will be required to immediately surrender the film or tape, subject to expulsion, with no reimbursement or further recourse.”

e. Copies of materials for a presentation by The Cosmetic Pharmacy, for a September 18, 2004 seminar labeled “Hands-On Mesotherapy and Cosmetic Techniques Advanced Course.” Dr. Zahra Karim, NMD is one of three individuals listed on the first page as an instructor. The materials include a section titled “Botulinum Toxin Type A” and state, “Botulinum Toxin Type A was recently approved for cosmetic use to soften the effects of stress, pollution and aging. It is simply another weapon in our arsenal to significantly enhance a person’s appearance thereby boosting their self-image, confidence, satisfaction, & enjoyment of life.” There is no mention of

BOTOX® or BOTOX® COSMETIC as the only FDA-approved drug derivations of Botulinum Toxin Type A. Several pages with instructions and diagrams for properly injecting the toxin into humans follow. Details as to the amount of units and the amount of injections recommended for each site on the human body are included. Injection points for the upper brow, medial brow, the forehead, area surrounding the eyes (crow's feet), below the eyes, mouth area, chin, and neck are all diagramed and explained.

Physician Testimonials:

25. In December 2004, officials of the New Jersey Department of Health interviewed Dr. Herbert Smyczek, who stated that he had used the TRI Botulinum toxin on patients. Dr. Smyczek said he knew the product was not approved for human use, but used it on them anyway.

26. Dr. Martin Blau, a plastic surgeon in New York said he believed he purchased Botulinum Toxin Type A from TRI approximately 6 months ago. Dr. Blau stated he received a fax from TRI and called the company. TRI told Dr. Blau that hundreds of physicians were using this product. Dr. Blau said he did not remember seeing the wording "NOT FOR HUMAN USE". He stated he purchased several vials of the product, and used it on himself and his patients. Dr. Blau said he did not experience any problems after using the product and received no complaints from patients who received the injections.

27. Dr. Herve Gentile, a plastic surgeon in Corpus Christi, Texas, said he purchased four vials of the Botulinum Toxin Type A from TRI and had received a great deal of literature from the company. Dr. Gentile stated he also received small cards from Powderz. Dr. Gentile said he used the vials on his wife and two sisters weeks ago and they did not experience any problems, nor did he notice any difference between the Allergan product and that of TRI. Dr. Gentile stated