



Food and Drug Administration  
OFFICE OF CRIMINAL INVESTIGATIONS  
MEMORANDUM OF INTERVIEW

CASE NUMBER: 2005-MWM-715-0153  
CASE TITLE: ALBERT POET  
DOCUMENT NUMBER: 87049  
PERSON INTERVIEWED: ALBERT POET  
PLACE OF INTERVIEW: TRENTON, NEW JERSEY  
DATE OF INTERVIEW: 06/08/2005  
TIME OF INTERVIEW: 10:30 a.m.  
INTERVIEWED BY: SAs CRAIG VERKERKE and MARC HESS

OTHER PERSONS PRESENT: See Narrative

On June 6, 2005, Dr. ALBERT POET appeared at the offices of the United States Attorney, District of New Jersey, Trenton, New Jersey and participated in a proffer session. Poet was accompanied by his attorneys, Patrick Collins and Julian Wiley. AUSAs Michael Guadagno and Hope Olds and FDA SAs Craig Verkerke and Marc Hess represented the government at the session. AUSA Olds reviewed a Kastigar letter with POET and his attorneys and POET executed the letter. Poet then provided the following information.

ALBERT POET, M.D. conducts his medical practices from two offices, SHORE LASER (SL), at 96 East Bay Avenue, Manahawick, New Jersey and PEAU, 44 Fairfield Street, Montclair, New Jersey. POET described his practice as primarily oriented to facial plastic surgery and aesthetic surgery, along with dermatologic and reconstructive surgery, laser hair removal/tattoo removal/skin rejuvenation. POET is a State of New Jersey certified medical doctor. The treatment of patients with Botulinum Toxin Type A (BTXA) is also a significant part of POET's practice. For the years 2003 and 2004 approximately 95% of BTXA treatments were "aesthetic", to reduce or prevent wrinkles, while the remaining 5% were intended to reduce facial spasms, relax areas of the face after other medical treatments and reduce excessive underarm sweating.

POET does not conduct medical research and last published in a scholarly journal approximately 20 years ago. POET considers himself to be involved in informal medical research because he observes and makes logical conclusions from medical activity at his practice.

Approximately 95% of the practice at PEAU is aesthetic BTXA. Approximately 60% of the practice at SL is aesthetic BTXA and 20% to 30% involves reconstructive treatment.

POET provided a "wild guess" concerning financial statistics of his practice as described below:

1. Gross income from aesthetic BTXA procedures was \$25,000 in 2002, \$50,000 in 2003, and \$100,000 in 2004;
2. Total gross income POET's practice was \$350,000 in 2002, \$375,000 in 2003, and \$525,000 in 2004;
3. Total Gross income at SL was \$320,000 in 2002, \$310,000 in 2003, and \$405,000 in 2004;
4. Total Gross income at PEAU was \$30,000 in 2002, \$60,000 to \$80,000 in 2003, and \$120,000 in 2004; and,
5. The salary paid to POET by the practice was \$8,000 in 2002, \$8,000 to \$8,000 in 2003, and \$8,000 in 2004.

For the past several years POET has mostly lived off of his savings and utilized the practice's proceeds to

purchase new equipment and establish the PEAU/Montclair location.

For BTTA treatment, POET's practice charges patients \$300.00 per anatomic area/muscle group treated and \$600.00 if two or more areas are treated on the same visit. In 2005 the price rose to \$350 for a single anatomic area/muscle group and \$700 for two or more anatomic area/muscle groups.

POET prepares BTTA treatments by mixing the freeze dried substance with a sterile saline solution to a concentration of .025 cc, equal to one unit. Other doctors may prepare a more diluted solution to .02 cc.

There are no other M.D.s or D.O.s associated with POET's practice. POET's practice employs the following additional employees:

1. HEATHER GIFFORD, a white female, approximately 28 years old, residing in Forked River, New Jersey (NJ). GIFFORD is employed as a licensed surgical assistant and her duties include "fetching" instruments and escorting patients. GIFFORD works at the S.L. location and has been employed by POET for approximately 1.5 years;
2. LAURIE TOTH, a white female, approximately 35 years old, residing in Forked River, NJ. TOTH is a licensed medical assistant (LMA) and office manager. As a LMA, TOTH's duties are similar to GIFFORD's but she does not assist in surgical procedures. GIFFORD works at the S.L. location and has been employed by POET for approximately 15 years;
3. JAMIE KRAUSS, a white female, approximately 28 years old, residing in Tuckerton, NJ. KRAUSS is a trained aesthetician and works as a receptionist at SL. KRAUSS works at the S.L. location and has been employed by POET for approximately 3 years;
4. JENIFER BRAZILL, a white female, approximately 35 years old, residing in Barnegat, NJ. BRAZILL works at the S.L. location and has been employed by POET as a receptionist for approximately 8 months; and,
5. MICHELLE GURNEY WELLS, a white female, approximately 48 years old, residing in West Orange, NJ. WELLS is POET's business partner at PEAU and acts as receptionist and patient escort. WELLS also conducts skin care treatments at PEAU. POET met WELLS as a friend of his former girlfriend and they agreed to open PEAU together as a salon/cosmetic surgery center. PEAU was opened in or about June 2002 with 75% of the expenses provided by POET.

POET first learned of TOXIN RESEARCH INTER-NATIONAL (TRI) when he received a brochure in or about November 2003 advertising their BTTA product in the mail. At the proffer session POET displayed an original TRI brochure which was identical to the one he received initially. POET advised that the brochure he displayed at the proffer was received in a subsequent mailing from TRI but identical to the original except that POET's name and address were only on the original. SA Hess received the brochure from POET as evidence.

Prior to this and related investigations becoming public POET had never heard of POWDERZ, THE COSMETIC PHARMACY, Z SPA, ZAHRA KARIM or DR. ROBERT BAKER. POET has subsequently read in the media of suspicious activity by POWDERZ involving homeopathic products. If POET had heard of that activity prior to ordering from TRI he would not have ordered from them.

The TRI brochure attracted POET because it seemed to advertise a very stable form of BTTA. POET was aware of research which indicated that complex free forms of BTTA were being developed. POET acknowledged that the brochure did not state that TRI was marketing complex free BTTA but noted that it did state that it was a "very stable" form of BTTA.

In or about December 2003 POET telephonically contacted TRI through a number provided on the brochure and spoke to a female receptionist who advised that the medical director of TRI was CHAD LIVDAHL. LIVDAHL and POET discussed the composition of the BTTA product that TRI was marketing. LIVDAHL advised that it was a "complex free neurotoxin". POET thought that this "complex free neurotoxin" represented a trend in research. For example, the original Allergan Botox product featured 25 nanograms (ng) of BTTA per 100 units. The present Botox features 5 ng per 100 units. POET spoke with LIVDAHL for approximately 1.5 to 2 minutes. POET's primary concern was that the units of measurement mentioned in the brochure were "international units" LIVDAHL replied affirmatively to this query.

POET advised that "complexing" proteins can make up 80% of the weight of BTTA products and "complex free" BTTA products, in comparison with conventional BTTA products, are considered to possibly have the following characteristics: act more rapidly, diffuse less after treatment, and last longer.

In or about December 2003 POET, was familiar with other innovations in BTTA products. NT201 was introduced by BiotechCon/Merz in scientific literature Europe in or about 2000. POET advised that NT201 is a complex free Botulinum product that will be approved and sold in Germany as Xeomin. POET further advised that NT201/Xeomin was in phase III testing but should have been approved in March 2005. POET speculated that final release of the product could be delayed because Allergan has a financial interest in Merz and wished to delay the product so as to delay competition to Botox. POET also referred to a U.S. company known as Mentor which had a complex free Botulinum product in Phase I testing in or around December 2003 and an unknown Japanese company which had a similar product in Phase I testing.

Aside from the one brochure which he received from TRI and the conversation with LIVSDAHL, POET was unaware of any other information or references from colleagues concerning TRI BTTA. Nevertheless, POET assumed that it was a legitimate product due to the above referenced developments in BTTA products of which he was aware.

When POET initially contacted TRI he asked the receptionist whether the TRI BTTA product was FDA approved. The receptionist advised that FDA approval was pending. POET did not discuss FDA approval with LIVDAHL. POET subsequently advised that he should have referred to the receptionist as, a "person who answered the phone" and who "spoke well" and in a competent manner like a "public relations" specialist. POET advised that the "receptionist" was a female and her first name could have been SHANNON, although POET believed he spoke with two different women in this position. Neither woman indicated that she had professional medical or technical knowledge. LIVDAHL did seem to POET to possess professional medical knowledge based on his discussion of BTTA.

POET conducted three telephone calls to TRI and spoke to the "receptionist" concerning orders in December 2003, Summer 2004 and Fall 2004.

POET believed that the TRI BTTA brochure and product had a warning against use in humans because FDA approval was pending. POET never asked TRI personnel, medical colleagues or authorities, or anyone else about the warning. POET did look at the FDA website but found no mention of the TRI BTTA product.

POET opined that the FDA website should be modified to present information about which products have approval pending.

POET advised that the price of Botox was \$440 per vial while TRI BTTA was \$1,250, but that the contents of one vial of TRI BTTA product could be substituted for five vials of BOTOX due to the purity of the TRI BTTA.

POET modified his recitation of the facts of his telephone conversation with LIVDAHL to indicate that he did ask LIVDAHL whether the TRI BTTA product was safe for use in humans and prepared under GMP conditions. LIVDAHL replied affirmatively.

POET never asked LIVDAHL or the "receptionist" about possible side effects or contra indications for the use of TRI BTTA. POET indicated that this was not necessary as utilizing Botox vs. TRI BTTA was comparable to utilizing Tylenol vs. generic Acetaminophen.

Starting in or about December 2003 POET began to order TRI BTTA product from TRI by contacting them by telephone and utilizing his MasterCard.

POET had no other contacts with TRI.

TRI shipped the BTTA product to POET's SL location and POET would transport any product he needed to the PEAU location. POET would use Allergan product when he only planned to use a few units or treat a few

patients. POET would utilize the TRI BTTA product if he was expecting to use many units or treat many patients.

POET's practice would charge patients the same price whether they were treated with TRI BTTA or Botox.

In response to a question POET acknowledged that the purchase of Botox by his practice dropped significantly once they began to purchase TRI BTTA.

POET observed no significant difference in patients regardless of whether they were treated with BOTOX or TRI BTTA, but noted that TRI product was easier to utilize since a larger quantity in the vial could be mixed and utilized.

POET prepared the TRI BTTA at double strength and then diluted it for use. POET noted that the TRI BTTA had a shelf life of one month once it was mixed.

POET advised that he did not require instructions from the manufacturer to prepare the solution due to his expertise in utilizing such substances. POET acknowledge that, aside from BOTOX and TRI BTTA he had never utilized any other BTTA product.

POET agreed that he relied upon the representation by the "receptionist" that the TRI BTTA product was pending FDA approval. POET decided that TRI BTTA was a safe, effective and good quality product based on his medical training, his 16 years utilizing BTTA related products, his review of the TRI brochure, his telephone conversation with LIVDAHL and the "receptionist", and his "logical" conclusion that, since other companies were attempting to research and seek approval for purer and complex-free BTTA products, the TRI BTTA product must have been an example of these new products.

POET only discussed the price of TRI BTTA in relation to ordering. He never discussed the comparative price of BTTA versus Botox with TRI officials.

POET never heard of TRI prior to receiving the brochure from them. POET utilized the Google search engine and found only the TRI website and a few other references.

POET only utilized a non-FDA approved product on one other occasion. He utilized Restylane, a QMED Hyaluronic Acid Jell. POET received references for Restylane from colleagues, heard about it at medical conferences, and read about it in medical trade journals.

POET opined that there is no law or regulation which prevents him, as a medical doctor, from treating patients with non-FDA approved products.

The Botox product which POET utilized in his practice contained an FDA approved insert with instructions for use. The TRI BTTA did not contain a FDA approved insert. It did contain a material safety data sheet (MSDS) with instructions for disposal of the product. POET noted that an almost identical document was presently displayed on the LISTLABS.COM website. The MSDS in the TRI BTTA did not mention that spilled BTTA should be boiled.

Upon receiving the first shipment of TRI BTTA POET first administered it to himself, applying 20 to 30 units to his glabella and forehead. One and one half or two weeks later POET began to give the TRI BTTA to his patients.

POET never attended any TRI sponsored seminars or conferences.

The TRI BTTA product was shipped to Shore Laser, POET's practice at Manahawkin, via UPS. POET was responsible for opening and storing the products. Although other practice employees might receive the packages from UPS, only POET would open them and store the contents. POET described the typical package as 8" x 8" x 6" containing two BTTA vials secured by styro-foam and "blue-ice" cold packs. POET

did not recall whether there was a label on the box. There were no inserts or outserts or other documents related to the BTA except for the MSDS. The vials were labeled with the same warnings as the TRI brochure indicating that the substance was for research and not for human use. Each vial was 10 cc and 1 and 1/4".

The documents from POET's practices provided in the subpoena return accurately describe the extent and nature of his purchases from TRI.

POET conducted the purchases by telephoning TRI. POET did not recall the number he called but indicated that it was the same as the telephone number on the TRI brochure (866/306-0874).

POET paid for the TRI product with his MasterCard as indicated in the subpoenaed documents.

POET did not recall with whom he spoke at TRI concerning the orders, but noted that it was a female.

Upon opening the packages, POET placed the vials in the office freezer.

POET would reconstitute the vials shortly before use and store unused portions of the vials in the refrigerator. POET would never re-freeze the BTTA product. POET is aware that TRI instructions indicate that the reconstituted BTTA product could be stored in the refrigerator for up to four weeks while the Allergan instructions indicated that reconstituted Botox could be stored in the refrigerator for several hours. POET stored both reconstituted TRI BTTA and reconstituted Botox products in the refrigerator for up to two weeks. POET advised that his long experience in handling proteins gave him the expertise to determine that storage for this length of time was safe.

POET would prepare the BTA for use in the following manner. POET would add 6.25 cc's of chilled sterile saline preservative solution to the BTTA vial, rotate gently and refrigerate.

If Botox is reconstituted and then not refrigerated for a period of more than four hours the product decreases in potency. POET noted that the primary risk of reconstituted, un-refrigerated Botox in the period of four to eight hours concerns sterility and that contamination could occur. POET noted that this risk is significantly reduced due to his practice of employing refrigeration and other proper handling/preparation procedures.

POET stored reconstituted Botox and TRI BTTA in the practice's refrigerator for up to two weeks. POET acknowledged that Allergan guidelines indicate that Botox should not be stored in the refrigerator for such a lengthy period of time after reconstitution.

POET never told his patients he was treating them with TRI BTTA product. POET said to his patients that he was treating them with "Botulinum Toxin". POET never told or specified to his patients that he was not treating them with Allergan Botox.

POET acknowledged that when patients ask for treatment they request "Botox". POET believes that when patients ask for "Botox" they are requesting wrinkle treatment with BTTA to muscle groups. POET believes that the word "Botox" has been used since 1985, prior to its use as a trademark product by Allergan, and can be used to signify any BTTA product. POET acknowledged that most patients do specifically use the word, "Botox" in their requests, rather than BTTA.

POET said that it is possible that some brochures for Allergan Botox might find their way into his waiting room. There is no system or office policy as to what brochures are placed in the waiting room. POET does not pay attention to what brochures his employees place in the waiting room and if there were Allergan Botox brochures in the waiting room his employees placed these on their own initiative.

POET has used a variety of patient consent forms at his practice for patients receiving BTTA treatments. During the period 1990 to December 2003 the form only mentioned Botox. Starting in or about December 2003 the form was changed to mention both BTTA and Botox. In or January or February 2005 the form was modified to mention only BTTA. POET only provided the consent form to patients at the beginning of their

treatment with him. POET did not provide a consent form to patients if they indicated that they had received Botox at another practice.

POET acknowledged that neither his consent forms nor his counseling of patients who were treated with TRI BTTA would have communicated to them that they were not receiving Allergan Botox and that the product utilized to treat them was "for research purposes only", "not for human use", and not an FDA approved product. POET agreed that the patients would not have consented to be treated with TRI BTTA if they were aware of the product's restrictions and lack of FDA approval.

POET acknowledged that he charged patients the same price whether they were treated with TRI BTTA or Botox, but that it was cheaper for his practice to purchase the TRI BTTA in comparison with the Botox.

POET utilized the TRI BTTA in "exactly" the same way he utilized Botox.

POET is aware of medical literature and other doctors who believe that it is appropriate to store these products in this manner for up to four weeks after which time they will gradually decay. POET is aware that ALLERGAN guidelines indicate that BOTOX should not be stored in the refrigerator for such a lengthy period of time after reconstitution.

POET was never asked by TRI to be a paid participant or presenter in a seminar or workshop or paid to test TRI BTTA.

POET developed the website for his practice himself approximately five years ago. The host is XO Concentric/9 Net Avenue. The website was initially Windows NT based and is currently Unix or Linux based. The name of the website is www.Shorelaser.com. The website mentioned both Botox specifically and BTTA generally. POET agreed that the content of the website, until in or about January 2005, was an implied offer for treatments with Botox and a person viewing the website would not have understood that he also treated patients with other types of BTTA.

In January 2005, in response to a complaint from Allergan Corporation, POET removed references to BOTOX from the website. POET prepares and maintains the site primarily as a reference for medical practitioners and has received many laudatory comments from colleagues concerning the site. POET denied that the removal of references to BOTOX from the site was motivated by any intent to hide any previous misrepresentation to potential patients that they would receive BOTOX in treatments.

POET's practice, Albert Poet, MDPA, utilizes a checking account at Commerce Bank on Bay Avenue, Manahawkin, New Jersey to deposit payments for treatments from patients. Payments are received in cash, check and credit card. Some payments are made to PEAU. Cash and check payments to PEAU for services by POET are deposited directly into the Albert Poet, MDPA account. Credit card payments to PEAU for services by POET are made to an account at Chase Manhattan Bank/Chase Merchant Services and then transferred to the Albert Poet, MDPA account.

POET paid for the TRI BTTA purchases with a MasterCard as indicated on the subpoenaed documents (CFTI World MC#5468 1602 2269 1816, in name of Albert Poet).

POET's accountant is Mark Ronchetti, Vineland, New Jersey.

POET utilized the proceeds from his TRI BTTA treatments to purchase new BTTA and medical equipment for his practice. POET did not deposit any proceeds into investments, real estate or property. POET's vehicle is a 2003 Ford Van with \$8,000 paid off.

POET is unaware of any ill effect experienced by any BTTA patient except for injection related matters.

In response to specific questions, POET stated that he knew that TRI BTTA was not for use on humans and was for research purposes only. POET further stated that he was aware, at the time that he utilized the TRI BTTA on patients, that the only approved Botulinum Toxin Type A is Allergan's Botox® and the only approved

Botulinum Toxin Type B is Elan's Myoblock. POET further stated that he utilized the TRI BTTA on patients instead of Botox because the TRI BTTA was easier to use and purer (five times the concentration of BTTA compared with Botox). POET acknowledged that during the period when he was ordering and utilizing TRI BTTA, his orders of Allergan Botox dropped dramatically.

POET advised that he does not believe that there is any prohibition on a physician utilizing a drug not approved by the FDA to treat a patient. POET further advised that he believed that a physician's decision to use a particular drug should be based on the nature of the drug and the patient's particular situation.

POET stated that it was a "bad error in judgment" for him to have utilized TRI BTTA on his patients.

POET never kept a portion of the TRI BTTA vial frozen and then utilized the remainder separately. It is not possible to remove a portion of BTTA from the frozen vial, reconstitute the removed portion and return the remainder to the freezer.

The standard dose of BTTA is 20 to 70 units. A fatal overdose would involve 3500 to 7000 units, according to information on the Allergan inserts.

It is possible that a person who was injected with an overdose of BTTA could become paralyzed. POET is aware of a total of 4 such cases nationwide.

It is possible to purchase significantly cheaper BTTA from overseas, for example from China, or from the internet.

POET modified the receipts/billing statements utilized by his practice in January 2005 to refer to BTTA rather than BOTOX to reflect the increasing number of BTTA products which were being developed.

NAME-TITLE *Craig Verlenke*  
CRAIG VERLENKE, SPECIAL AGENT  
DATE 07/08/2005

NAME-TITLE *Marc Hepp* 8/4/05  
MARC HEPPE, SPECIAL AGENT  
DATE 07/08/2005

APPROVED: *Thomas A. Ricci*  
DATE: 8/4/05

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CC: MIA (SAs KORB AND LEEDS)  
CC: PHP

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