



**Food and Drug Administration  
OFFICE OF CRIMINAL INVESTIGATIONS  
MEMORANDUM OF INTERVIEW**

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**CASE NUMBER:** 2005-MWM-715-0153  
**CASE TITLE:** ALBERT POET  
**DOCUMENT NUMBER:** 97617  
**PERSON INTERVIEWED:** Laurie Toth  
**PLACE OF INTERVIEW:** Trenton, New Jersey  
**DATE OF INTERVIEW:** 07/18/2006  
**TIME OF INTERVIEW:** 1030 hrs  
**INTERVIEWED BY:** Special Agent Marc Hess

**OTHER PERSONS PRESENT:** Assistant United States Attorney Eugenia Cowles

Laurie Toth appeared with Attorney Robert Stevens at the United States Attorneys Office, 402 East State Street, Trenton, New Jersey. After being advised of the identities of the interviewing agent and Assistant United States Attorney (AUSA) Eugenia Cowles and the nature of the interview, Toth supplied the following information.

Toth is trained as a certified medical assistant. She has been employed at the medical office of Dr. Albert Poet, Manahawkin, New Jersey from approximately 1989 to the present. She worked as a clinical assistant until approximately 2003 and then as office manager up to the present. Toth presently works two days per week at the office.

Toth's duties as a clinical assistant included bringing the patient to the medical treatment section of the office, assisting the doctor and setting up the sterile field. Heather Gifford took this position from approximately September 2003.

Toth's duties as office manager included completing patient insurance forms, issuing pay checks, billing patients, paying bills of Dr. Poet, speaking to patients upon arrival at the office, answering telephones and sometimes making patient appointments. Toth also performed some bookkeeper duties, but the practice also employed an accountant, Mark Ronchetti (ph) of Vineland, New Jersey.

There are three employees of the office besides Toth: Heather Gifford; Jamie Farrow-Krause, and Jennifer (last name unknown/LNU). Farrow-Krause and Jennifer LNU are receptionists and aestheticians.

Dr. Poet determines the duties of employees of the office.

Toth's duties with regard to the office bank account at Commerce Bank include making deposits into the account, cutting checks to pay bills and issuing pay checks from the account. Dr. Poet is the only person authorized to sign checks from the office account. There is no office credit card.

Dr. Poet receives a regular office paycheck.

Dr. Poet sets the office fees. The office fees are updated annually.

Dr. Poet arranges advertising for the office while Toth process bills for this activity. The office advertises in the Long Beach Island (New Jersey) newspaper, the Sand Dollar. Poet may also advertise in a newspaper in the vicinity of Montclair, New Jersey.

The office staff decides what brochures to place in the reception area and may place brochures for a pharmaceutical product if it is received from a pharmaceutical company. Toth did not recall the office ever receiving or displaying any documents for Toxin Research products.

Poet's office offered Botox treatments from approximately 2000. Toth did not know how Poet publicized this treatment but thought that it was probably via advertising or word-of-mouth. Toth believed that most new patients came from these sources.

Toth frequently referred patients with questions to Poet's medical practice website. Toth occasionally printed out a portion of the website to give to a patient. Poet controls and prepares the content of the website. Heather Gifford would sometimes discuss procedures with patients.

When new patients come to the office seeking Botox procedures they ask if the practice "does Botox".

Toth sometimes orders items for the office. Gifford orders basic supplies for medical treatment such as Kleenex and Novocain. Toth recalled ordering pharmaceutical products from Allergan. When Allergan Botox is received at the office the staff usually provides it to Poet and he opens the package. Other types of shipments are opened by the office staff. Poet reconstitutes the Botox product. Gifford does not reconstitute the Botox product.

In approximately 2004 Poet indicated that he intended to acquire a drug described as "purified Botulinum Toxin" to treat patients from a company known as Toxin Research. Poet further indicated that this drug in the "FDA process" for approval. Poet paid for this item using his personal credit card. Toth did not know whether or how Poet compensated himself for this personal credit card payment. Poet tested the Toxin Research drug on himself. Poet also tested the product on the staff after telling them that it was more purified and better than Botox and in the FDA approval process. Toth was treated with this drug by Poet. She and other staff members felt that it was better than Botox because its effect lasted longer.

Following receipt of the Toxin Research drug Poet's office utilized it "interchangeably" with Allergan Botox. Patients were charged approximately \$650.00 for a typical treatment which required approximately two to three vials.

Toth never saw the vials containing the Toxin Research drug and Poet never discussed any warnings associated with the product. AUSA Cowles displayed a copy of a Toxin Research drug brochure previously acquired from Poet's office via subpoena. Toth indicated that she had never seen this brochure and it was never displayed in the office. Toth further indicated that she probably would have wanted to know that the product was indicated as not for human use but she probably would have taken it anyway since she trusted Poet.

Toth had the opportunity as a clinical assistant to observe Poet interact with patients on numerous occasions. Poet would provide patients with a "very thorough" briefing on a procedure before he had the patient sign a consent form and conduct the procedure. This briefing would include a description of the specific drug or other product involved in the procedure including possible side effects, down-time, and after-care. Poet would sometimes speak for one half hour to patients on these topics and they would ask him to stop talking.

As a clinical assistant Toth would co-sign patient consent forms although she frequently "barely read" the content of the forms. Poet produced the forms and would instruct Toth to print additional forms if supplies were low. Toth did not recall whether any form specifically referred to the Botox procedure. Patients usually paid for a Botox procedure with a credit card. Such cosmetic procedures are typically not covered by insurance. Patients sometimes utilized Blue-Cross or Medicare to pay for other procedures.

Poet would record information describing each appointment in patient records. He would make some notes during the appointment and some notes afterwards. The records would be stamped with the date of the procedure and Poet would initial the entry. The patient records contained an illustration of a face. The number of units of Botulinum Toxin used to treat the patient for a particular visit would be noted in this area of the records. The patient records did not specify whether a patient had been treated with Botox or the Botulinum Toxin drug from Toxin Research

Botox treatments usually last from four to six months.

Toth did not recall any complaints from patients or adverse events concerning the Toxin Research products except for incidents typical of Botox treatments such as a bruise from a needle.

Toth advised that a document known in the office as a "super-bill" is utilized mostly to track procedures covered by insurance. AUSA Cowles displayed a copy of a document listing various medical procedures previously acquired from Poet's office via subpoena. Toth advised that the document was in "super-bill" format but she noted that it seemed to cover cosmetic procedures. The "super-bill" with which she is familiar from Poet's office does not cover such procedures. Toth never utilized and was unfamiliar with the document displayed by AUSA Cowles.

Toth did not believe that Poet's office practice was profitable. Her reasons for this were that there were no bonuses or raises given to employees in the recent past and Poet owed many payments on laser equipment which he had purchased for the practice. Toth believed that the business had improved somewhat over the past five years due to Poet focusing it on cosmetic procedures. Revenues from Botox treatments are a significant part of all revenues from cosmetic procedures. One reason that cosmetic procedures are more profitable than other procedures is that it is not necessary to perform insurance paperwork to pay for the cosmetic procedures.

Poet operates a second medical office at a Montclair, New Jersey spa named Peau. Poet opened the spa and began this practice approximately five years ago in partnership with Michele Gurney-Wells, a female age mid 40's, as his partner. Toth believed that Poet and Gurney-Wells met through mutual acquaintances. Toth did not know what function Gurney-Wells performed at Peau. Poet indicated that his function at Peau was to perform laser, filler and Botox treatments. Toth did not believe that Peau was successful until recently. The rent for Peau is paid from the business account of Poet's office practice in Manahawkin.

Toth recalled an incident approximately one to two years ago when patients were injured due to the use of the Toxin Research drug in Florida. At this time Poet conducted a conversation with Toth, and possibly other employees of the office, concerning the Florida incident. Poet indicated that the injuries were caused because the Florida practitioners improperly mixed or diluted the Toxin Research drugs. Poet also indicated that the Florida practitioners were utilizing a different substance which they had acquired from Toxin Research's supplier rather than directly from Toxin Research. Toth did not recall how this conversation began.

At approximately the same time as the Florida incident the office received a recall notice for the Toxin Research Botulinum drug via facsimile. The top of the notice featured the word "Recall" in large black letters. Toth did not know who sent the recall notice. Toth believed that Poet stopped utilizing the Toxin Research drug after receiving the notice. Poet did not notify his patients of the recall or that he had been utilizing this Toxin Research drug.

Poet was generally pleased with the Toxin Research Botulinum toxin drug.

Poet frequently spoke to the staff about various pharmaceutical drugs.

The office was occasionally visited by an Allergan sales representative, although Toth cannot recall the name of this person.

**NAME-TITLE** \_\_\_\_\_ **NAME-TITLE** \_\_\_\_\_

Marc Hess, Special Agent

**DATE** 07/21/2006

**DATE**

**APPROVED:** \_\_\_\_\_

Kim A. Rice, Special Agent in Charge

**DATE:** 07/25/2006

**DISTRIBUTION:** ORIG: MWM  
CC: AD-IOD  
CC: PHP  
CC: MIF, SA KORB

**ATTACHMENTS:** N/A