

Patrick Bitter

On March 14, 2005, SA Ottaviano interviewed DR. PATRICK BITTER, JR., M.D. at his office, 14651 South Bascom Avenue, Suite 200, Los Gatos, California

The pertinent information from the interview is as follows:

DR. PATRICK BITTER JR., maintains a Dermatology and Cosmetic Dermatology practice in Los Gatos, California. DR. BITTER is a board certified Dermatologist. DR. BITTER stated that he is engaged in research with Syneron of Toronto in the use of the dermatology product, VelasMOOTH.

DR. BITTER had received mailers from TRI and POWDERZ. The mailer from TRI was offering Botulinum Neurotoxin Type A, and the mailer from POWDERZ was offering raw materials and instruction on topical and injectable products.

DR. BITTER claimed he never attended any conferences or workshops sponsored by TRI or POWDERZ, and was never a presenter for TRI or POWDERZ.

DR. BITTER stated that he did purchase Botulinum Neurotoxin Type A from TRI by credit card after discussing the product with TRI representatives. DR. BITTER said he bought the TRI product, because it had a lower price than Allergan's product. DR. BITTER admitted that he saw "Research Purposes Only" and "Not for Human Use" on the label.

DR. BITTER said he injected himself, members of his staff, and about six to twelve patients. DR. BITTER claimed that he told his patients that this was a less expensive source of Botox®. He claimed that he told his patients that it was like Botox®. DR. BITTER said he did not tell the patients that the TRI Botulinum Neurotoxin Type A had not been approved by the FDA. He also said he did not routinely get a written consent from patients he injected. DR. BITTER stated that he charged about \$150 per injection site for the TRI product and \$250 to \$300 per site with Botox®.

DR. BITTER said that his patients did not get the same results as they did with Botox® and that the effects didn't last as long. DR. BITTER claimed that he did see the "Not for Human Use" on the flyer. He said that he called TRI inquiring about the labeling. He said he was told that it was legal to use and that other doctors were using it in place of Botox®. DR. BITTER said that he was not aware that Allergan's Botox® and Elan's Myoblock were the only FDA-approved Botulinum Neurotoxin products.

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EX 2

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

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**DOCUMENT NUMBER:** 85112

**PERSON INTERVIEWED:** DR. GILBERT LEE

**PLACE OF INTERVIEW:** San Diego, CA

**DATE OF INTERVIEW:** 03/30/2005

**TIME OF INTERVIEW:** 2:15pm - 3:00pm

**INTERVIEWED BY:** SAs Lisa Hartsell and Lisa L. Malinowski

**OTHER PERSONS PRESENT:** N/A

On 03/30/05, SA's Hartsell and Malinowski interviewed DR. GILBERT LEE regarding his purchase of five (5) vials of BOTULINUM NEUROTOXIN TYPE A from TRI. DR. LEE agreed to speak with SA's Hartsell and Malinowski and voluntarily provided the following information:

DR. GILBERT WESLEY LEE provided his valid [REDACTED] drivers license that showed his date of birth as [REDACTED] and his [REDACTED] drivers license number as [REDACTED]. DR. LEE is a Plastic Surgeon, certified with the American Board of Plastic Surgery. Additionally, DR. LEE is a voluntary Assistant Clinical Professor at the University of California San Diego where he occasionally teaches and conducts research concerning anatomy and nerve sensitivity of the hands.

DR. LEE stated he received an advertisement for the BOTULINUM NEUROTOXIN TYPE A from TRI via fax in approximately July or August 2004. Approximately one month after receiving the fax, DR. LEE contacted TRI to inquire about the product. He spoke with a woman by the name of Sandra (LNU) who answered DR. LEE's questions regarding the purity and safety of the product. Sandra told DR. LEE that the TRI product was more pure than the Allergan Botox product and that TRI was awaiting FDA approval for their BOTULINUM NEUROTOXIN TYPE A product. DR. LEE recalled Sandra stating that the TRI BOTULINUM NEUROTOXIN TYPE A could be used in humans. Based on the information provided by Sandra, DR. LEE purchased one (1) vial of TRI's BOTULINUM NEUROTOXIN TYPE A with his VISA credit card. DR. LEE had the product shipped to his office, however he could not recall what parcel service delivered the product.

DR. LEE explained that he ordered the vial to use on himself, since his body had built up a resistance to the Allergan Botox product. DR. LEE admitted that he did get better, longer lasting results with the TRI BOTULINUM NEUROTOXIN TYPE A product. DR. LEE did not recall if reconstitution instructions accompanied his order, however he used the reconstitution directions on TRI's website. DR. LEE injected himself in the forehead and eye area and then placed the vial in the refrigerator. DR. LEE stated that he threw the first vial and its contents away shortly after injecting himself because it was his understanding that it would not last long once it was reconstituted.

DR. LEE admitted to purchasing two (2) additional vials of BOTULINUM NEUROTOXIN TYPE A from TRI in approximately late October or early November of 2004. DR. LEE stated he really only wanted one (1) vial, however TRI was offering a special. He recalled TRI was selling one (1) vial for \$1,250.00 or two (2) vials for \$2,000.00. Like his first order, DR. LEE purchased the two (2) vials of TRI's BOTULINUM NEUROTOXIN TYPE A with his VISA credit card. DR. LEE had the vials shipped to his office, however he could not recall

what parcel service delivered the product. DR. LEE used one of the vials on himself again, and put the other in the refrigerator. DR. LEE did not use the second vial of BOTULINUM NEUROTOXIN TYPE A at all because he later heard of the TRI investigation and threw any remaining bottles of the BOTULINUM NEUROTOXIN TYPE A away in the office bio-hazard bag.

DR. LEE explained that he did read on both the fax, as well as on the BOTULINUM NEUROTOXIN TYPE A vials he ordered from TRI that the TRI BOTULINUM NEUROTOXIN TYPE A was for research purposes only and not for human use, however, it was DR. LEE's understanding and experience that any research grade product usually means that it is a better, more pure product than what is commonly available. DR. LEE thought that the TRI product was like a generic form of the Allergan Botox product and that TRI put "not for human use" on their product because they were in the process of getting FDA approval and had technically not received the approval yet. DR. LEE could not recall any other details about the labeling of the BOTULINUM NEUROTOXIN TYPE A vials he purchased from TRI.

Regarding the other two (2) vials of BOTULINUM NEUROTOXIN TYPE A that TRI has record of DR. LEE purchasing, DR. LEE stated he never ordered these vials, never received these vials and believes he was double billed. DR. LEE was very cooperative and produced all pertinent paperwork regarding his purchases of BOTULINUM NEUROTOXIN TYPE A from TRI. DR. LEE again stated that he only used the BOTULINUM NEUROTOXIN TYPE A from TRI on himself.

NAME-TITLE	<u>Lisa L. Mallnowski</u>	NAME-TITLE	_____
	Lisa L. Mallnowski		

DATE	06/09/2005	DATE	_____
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APPROVED: [Signature]

DATE: 6/20/05



ATTACHMENTS: None

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Food and Drug Administration  
OFFICE OF CRIMINAL INVESTIGATIONS  
MEMORANDUM OF INTERVIEW

[REDACTED]

[REDACTED]

DOCUMENT NUMBER: 86829  
PERSON INTERVIEWED: DR. F. DON PARSA and Touri Parsa  
PLACE OF INTERVIEW: 1329 Lusitana St., Ste 807, Honolulu, HI  
DATE OF INTERVIEW: 07/21/2005  
TIME OF INTERVIEW: Approx. 5:30 pm  
INTERVIEWED BY: SA's William T. Leitner and Lori B. Janosko  
OTHER PERSONS PRESENT: None.

On July 21, 2005, SA's Leitner and Janosko traveled to the office of DR. F. DON PARSA (DR. PARSA) located at 1329 Lusitana Street, Suite 807, Honolulu, HI. Upon arrival at the office, agents were met by Touri Parsa, DR. PARSA's wife. Agents were escorted into DR. PARSA's office.

At approximately 5:30 pm., DR. PARSA came into his office. Agents identified themselves and advised DR. PARSA on the purpose of their visit. DR. PARSA stated he understood and wanted to speak freely with agents regarding his purchases from TOXIN RESEARCH INTERNATIONAL (TRI) of Botulinum Neurotoxin Type A (TRI Toxin).

DR. PARSA stated that he administers "Botox" to 2-4 patients per day on an average. Per DR. PARSA, most of his "Botox" patients are return clients.

DR. PARSA began using "BRI Botox" late in 2003 or at the beginning of 2004. DR. PARSA believed that "BRI" was "Botox Research International." When SA Janosko inquired if he was sure of the name of the company, DR. PARSA recalled the company name to be TOXIN RESEARCH INTERNATIONAL and corrected himself by saying the company was "TRI," not "BRI."

DR. PARSA said that, in late 2003, he was invited to attend a "Society of Plastic Surgeons" meeting, which was where he first heard about TRI's "Botox."

DR. PARSA said TRI's "Botox" was "marvelous" and that "it worked fine." DR. PARSA said that TRI's "Botox" was "less expensive" and "exactly the same as Allergan's Botox® Cosmetic."

SA Janosko inquired if DR. PARSA, or his staff, had been advised that TRI's Toxin was FDA approved. DR. PARSA said he knew the product was not approved by the FDA. DR. PARSA said that both he and his wife, Touri, had ordered TRI Toxin from TRI via telephone. DR. PARSA said he had several conversations with a man (later recalled to be CHAD LIVDAHL), who told him that the product was "the same as Botox® Cosmetic." DR. PARSA thought of the TRI Toxin as a "generic Botox." When asked, DR. PARSA said he was not aware of any FDA-approved "generic Botox."

DR. PARSA recalled receiving countless pamphlets and facsimiles from TRI regarding their TRI Toxin. DR. PARSA said the pamphlets always "talked about the safety of their product." DR. PARSA said that he was

"fool enough to use it (TRI Toxin)." DR. PARSA said that one of the letters he received from TRI was from a professor in Kentucky (NFI). DR. PARSA said this professor was well known in the academic community, which validated the TRI Toxin in his mind.

DR. PARSA said that "everyone was using it (TRI Toxin)," so he believed it to be reputable and good. When asked, he could not provide the names of doctors who told them they were using TRI Toxin.

DR. PARSA stated that he quit using the TRI Toxin around November or December 2004, when all the media attention started in Florida. DR. PARSA said he could not recall how many vials he ordered, but recalled discarding approximately 1/4 of a vial of TRI Toxin. DR. PARSA recalled ordering ten (10) vials of TRI Toxin. DR. PARSA claimed to be "very concerned" when he first heard of the problems in Florida. DR. PARSA told agents that he personally contacted each of his patients when he learned of the Florida incident and found "zero patients with problems."

DR. PARSA claimed to have reviewed all the charts of patients who might have been injected with TRI Toxin. DR. PARSA showed agents a handwritten list of patient names. DR. PARSA said he believed these were the patients who received TRI Toxin injections. SA Janosko asked DR. PARSA if he made a note of the contact in each patient file to which he replied, "No, I did not make a note in the patient files." SA Janosko asked DR. PARSA if he told the patients the reason for the contact, and he again said no.

SA Janosko asked if DR. PARSA advised his patients that they were being injected with TRI Toxin. DR. PARSA said that he always told his patients that they were getting injections of Botox® Cosmetic. DR. PARSA showed agents a copy of a "Botox Patient Waiver," which he required all patients to sign before receiving "Botox" injections. DR. PARSA said he did not make any special note on patient charts when they received the TRI Toxin. He advised that all patient records would reflect that he injected "Botox."

Touri Parsa advised SA Janosko that, when she spoke to TRI she talked to a man. When asked if she spoke with CHAD LIVDAHL, Touri Parsa said that the name sounded correct. LIVDAHL advised Touri Parsa and DR. PARSA that "all plastic surgeons in Florida were using it (TRI Toxin)" and that TRI's product was "generic Botox." DR. PARSA recalled hearing that TRI's product was "not approved" and that it was intended for "animal use only."

DR. PARSA said he never attended any seminars hosted by TRI. He did not recognize the names, The Cosmetic Pharmacy, Powderz, or Zahra Karim.

DR. PARSA said that there was "no better way to mislead doctors than by having testimonials."

DR. PARSA admitted that TRI Toxin was a "cheaper alternative" to authentic Botox® Cosmetic and that was why he purchased it. He never conducted any clinical research with the product, nor was that his intent. DR. PARSA stated that he also injected the TRI Toxin into his wife, Touri.

Touri Parsa said that she considered TRI Toxin to be "like a generic Botox," as that was what she was told by TRI. Touri Parsa said she ordered the product from TRI and always dealt with a man who she recalled to be CHAD LIVDAHL. LIVDAHL introduced the product to Touri Parsa as "generic Botox." DR. PARSA recalled speaking to LIVDAHL as well.

SA Janosko requested to view the Botox® Cosmetic on the premises. Touri Parsa escorted SA Janosko to the refrigerator, where two (2) boxes of what appeared to be authentic Botox® Cosmetic were observed. No other forms of "Botox" were present in the refrigerator.

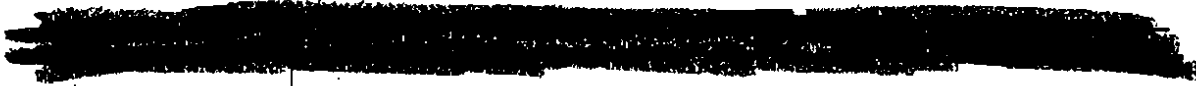
DR. PARSA provided the following local plastic surgeons that might have also used TRI Toxin: Dr. Carl De Los Reyes, Dr. Marco Rizzo, Dr. Vincent Yip, and Dr. Clyde Ishi. DR. PARSA said they were all on staff at Queen's Hospital.

DR. PARSA said that he "had a little product (TRI Toxin) left in one (1) vial," which he destroyed. Prior to

destruction, he contacted the Center for Infectious Disease to determine how to properly destroy the TRI Toxin. DR. PARSA then said he used six (6) vials of TRI Toxin (minus the 1/4 of a vial he claimed to have destroyed).

SA Janosko inquired if there were any differences in TRI Toxin versus authentic Botox® Cosmetic. DR. PARSA said TRI's vials were bigger; that he had to draw and mix the TRI product differently; and that he had to add "more dilution to it than Botox."

DR. PARSA provided a copy of his medical license and controlled substances licenses to SA Janosko (Attachment 1).



At approximately 6:30 pm, the interview with DR. PARSA and Touri Parsa was concluded.

NAME-TITLE *William T. Leitner*  
William T. Leitner, Special Agent

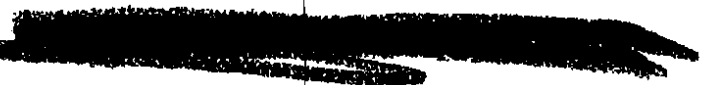
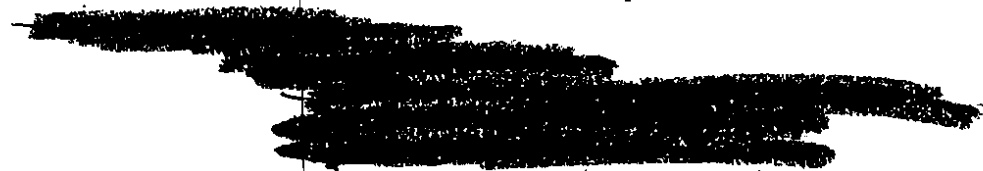
NAME-TITLE *Lori B. Janosko*  
Lori B. Janosko, Special Agent

DATE *8/2/05*

DATE *8/2/05*

APPROVED: *Daniel L. Henson*  
Daniel L. Henson, Special Agent in Charge

DATE: *8/5/05*



Dr. William R. Work

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On May 4, 2005, SA Ottaviano interviewed DR. WILLIAM R. WORK at his office, 1660 E. Herndon Avenue, Suite 101, Fresno, California. DR. WORK was asked the questions contained on the "Doctor Interview" questionnaire produced by the Miami Field Office. The pertinent information from the interview is as follows:

DR. WILLIAM R. WORK maintains a Family Practice and Pain Management office in Fresno, California. He is a board certified Family Practitioner who does not conduct research.

DR. WORK stated that he attended a conference in Nashville, Tennessee, in June of 2003, and was told by a colleague about TRI. In December 2003, DR. WORK attended another conference in Las Vegas, Nevada, where TRI was a vendor. DR. WORK met and discussed the Botulinum Neurotoxin Type A with CHAD LIVDAHL at the conference. DR. WORK did not attend any conferences put on by TRI, POWDERZ, or COSMETIC PHARMACY, nor did he attend any workshops or demonstrations.

DR. WORK admitted to purchasing Botulinum Neurotoxin Type A from TRI. He claimed he made the purchase on the Internet and paid with a credit card. He discussed his order with CHAD LIVDAHL, by telephone. He made the purchase to use on patients for cosmetic purposes such as wrinkles. DR. WORK claimed he bought the TRI product because it was cheaper than Allergan. The product was received from TRI, air-shipped, packed in ice, in glass vials.

DR. WORK admitted that he saw the "Research Use Only" and "Not for Human Use" labeling on the vial. He said that he asked TRI about the statements and was told that they were there to by-pass the patent that Allergan had on their Botox® product. He was told it was like Allergan's Botox®.

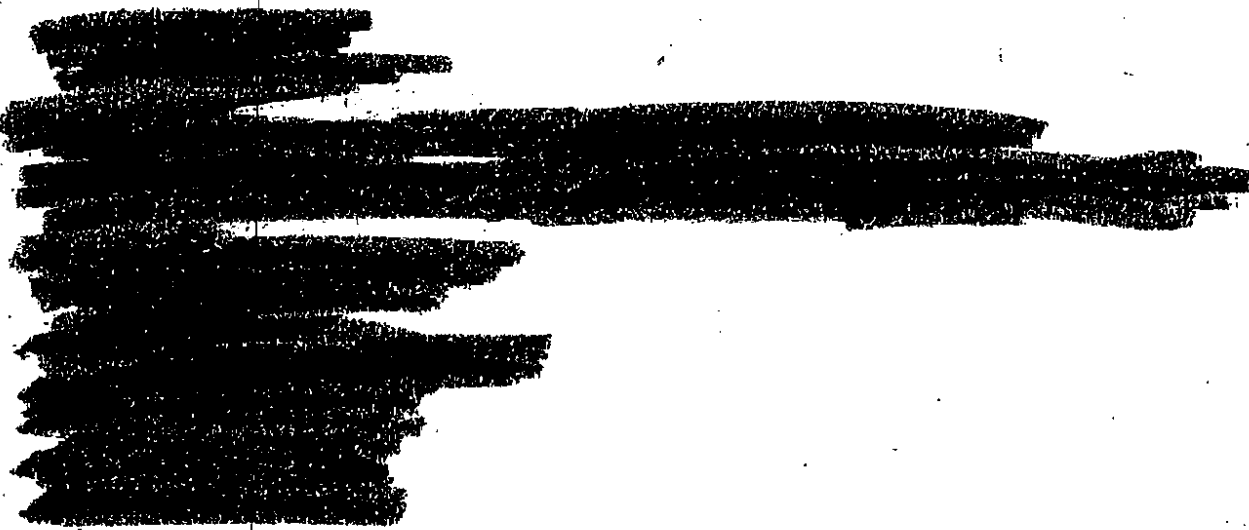

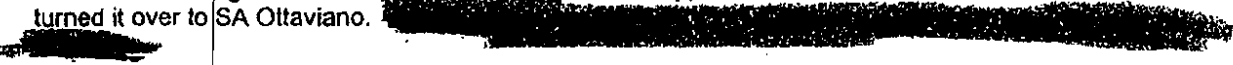
DR. WORK stated that he injected approximately 15 - 20 patients with the TRI product. DR. WORK also stated that he sometimes told his patients that the product was Botox®. But, he claimed he used the term Botox® as a generic term for Botulinum Neurotoxin Type A that his patients would understand. DR. WORK said he did receive written consent from his patients for the treatments. DR. WORK sold the TRI product in 20 unit doses and charged \$11.00 per dose, or \$220.00. He also said that there were ten doses per syringe.

DR. WORK reported good results with the TRI Botulinum Neurotoxin Type A. He said that he had some repeat patients for the injections. DR. WORK admitted that he knew the TRI product was not for use in humans, but said he was told by TRI that it was the same as Allergan's product and that the patent issue made them put the "Research Use Only" and "Not for Human Use" on the vial's label. He was aware that Allergan's Botox® and Elan's Myoblock® were the only approved Botulinum Neurotoxin Type A available, but said he thought it was the equivalent of Allergan's Botox® and it was cheaper.

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DR. WORK said he was never a paid participant or presenter at any seminars for TRI and never was paid to test their product.

DR. WORK said he had no records or documents pertaining to TRI or POWDERZ. He did say that he had one remaining vial of the TRI Botulinum Neurotoxin Type A. DR. WORK retrieved the vial and turned it over to SA Ottaviano.



EX 5

Panagotacos



Mr. Nessum provided the following information regarding his client, DR. PANAGOTACOS:

DR. PANAGOTACOS began her own practice in Westlake, California, in April 2001 and has never had any patient complaints, nor has she ever been involved in any criminal or civil actions.

In January 2004, DR. PANAGOTACOS' office received several unsolicited faxes from TOXIN RESEARCH INTERNATIONAL (TRI) in regards to their Botulinum Toxin A. DR. PANAGOTACOS instructed her head nurse, unknown name, to contact TRI and get the details of their product. DR. PANAGOTACOS told Mr. Nessum that she remembered that there was some caution in using the Botulinum on her patients, because the vial of TRI's Botulinum was labeled for experimental use only and not to be used on humans, but she was told by a female at TRI that it was labeled like that for legal reasons only. The female at TRI told the nurse that the Botulinum Toxin A was labeled that way because of trademark issues, but that it was safe to use on humans.

Mr. Nessum said that TRI instructed DR. PANAGOTACOS to change the patient consent forms from Botox to Botulinum. DR. PANAGOTACOS purchased two (2) vials of Botulinum Toxin A, which she used on herself and a couple of her employees. When she did not observe any side effects on herself or her co-workers, she began injecting her patients.

In May 2004, DR. PANAGOTACOS contacted TRI, and the person that answered the telephone said that their Botulinum Type A was safe to use on humans. Mr. Nessum said that DR. PANAGOTACOS ordered approximately twenty-three (23) vials of Botulinum Toxin A from TRI in 2004.

In December 2004, DR. PANAGOTACOS learned about the individuals in Florida who contracted Botulism from TRI's product, and in January 2005, she received a recall letter from TRI. In February 2005, DR. PANAGOTACOS returned two (2) vials of Botulinum to TRI.

Mr. Nessum said that DR. PANAGOTACOS did not believe she was doing anything illegal. DR. PANAGOTACOS believed that TRI's product was a generic version of Allergan's Botox.

Mr. Nessum stated that someone from Allergan contacted DR. PANAGOTACOS and informed her that it was a problem ordering non-approved Botulinum product, but Mr. Nessum could not recall when the telephone call was made.

Mr. Nessum did not know if DR. PANAGOTACOS told her patients that the Botulinum she was injecting them with was different than Allergan's Botox.