
Chapter 6 - Office of Criminal Investigations

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Center for Biologics Evaluation and Research

Unapproved New Drug: Botulinum Toxin

In November 2004, the Centers for Disease Control and Prevention (CDC) notified FDA that four individuals had been hospitalized after receiving an unapproved Botulinum toxin Type A treatment manufactured by Toxin Research International (TRI), an Arizona firm. The Office of Criminal Investigations (OCI) initiated investigations throughout the United States to investigate the purchase and usage of this unapproved and potentially harmful product.

Dr. Mark Van Wormer, an Albuquerque physician, was identified as having purchased 20 vials of 500 units of unapproved Botulinum toxin Type A, which was labeled "For research purposes only, not for human use."

The investigation revealed that after Dr. Van Wormer learned of the TRI investigation, he instructed his office manager to purchase an Allergan® Botox® rubber stamp. He then had her go through his patient files to stamp them and write in an Allergan® Botox® lot number. Dr. Van Wormer also pressured the office manager and another employee to lie to OCI agents.

On June 14, 2006, Dr. Van Wormer was indicted for tampering with documents and misbranding a drug while held for sale.

On August 8, 2006, Dr. Van Wormer was subsequently indicted for a scheme to defraud of honest services.

On July 5, 2007, Dr. Mark Van Wormer pled guilty to misbranding a drug while held for sale. Dr. Van Wormer admitted to injecting patients at his Albuquerque GreatSkin® clinic with the non-FDA approved Botulinum toxin Type A, while leading them to believe they were receiving the approved Allergan® Botox®. Dr. Van Wormer's plea agreement called for restitution to be paid to all of the patients who received the unapproved toxin.

On December 13, 2007, Dr. Van Wormer was sentenced to one year and a day incarceration, was fined \$3,000 and was ordered to pay a \$100 special assessment and victim restitution in the amount of \$65,265.

Center for Devices and Radiological Health

Stolen Laser Devices

This case was initiated in May 2003, after a Military Police investigator at the Fort Hood Army Installation notified OCI that infrared laser aiming devices and other military hardware equipment were being stolen from the base and being sold on eBay and other Internet auction Websites. Infrared Laser Aimers are classified as FDA Class I Devices and are regulated by the FDA.

OCI located various Internet postings by an individual named Terry Hensley who was selling laser aiming devices. As a result, an OCI agent made undercover contact with Hensley and obtained incriminating statements from him regarding the source of the stolen items. OCI successfully made an undercover purchase of the device from Hensley; traced the serial number; and determined that this laser device and two other devices had in fact been delivered to the Fort Hood Army Installation by the device manufacturer, but had not been forwarded to the armory for the unit deploying to Iraq.

OCI initiated a joint investigation with the Army Criminal Investigations Division and the Federal Bureau of Investigation (FBI) and it was subsequently determined that the scheme was being perpetuated by enlisted soldiers who stole the items and then sold them to a civilian named Brian Spriggs. Investigation further determined that Spriggs, members of his immediate family, and several other associates would purchase the stolen items and distribute them to Hensley and other individuals.

On February 10, 2004, Brian Spriggs, Brenda Laurenti, Betty Murfin, and Walter Robinson, all purchasers of the stolen laser devices, were indicted in the Western District of Texas for conspiracy and receiving stolen public money, property or records.

On May 9, 2004, Spriggs pled guilty to theft of public money, property, or records. He was sentenced to 15 months incarceration and ordered to pay \$46,357 in restitution to the U.S. Army.

On March 12, 2004, Murfin pled guilty to conspiracy to receive stolen money, property, or records. On February 16, 2005, she was sentenced to 36 months of supervised release and ordered to pay \$25,000 in restitution to the U.S. Army.

On August 18, 2004, Robinson pled guilty to theft of public money, property, or records. On October 15, 2004, he was sentenced to 36 months probation and ordered to pay \$10,000 in restitution to the U.S. Army.

On November 19, 2004, Laurenti pled guilty to conspiracy to receive stolen money, property, or records. Laurenti, who was already in state custody on an unrelated charge, was sentenced on February 17, 2005, to 24 months incarceration and ordered to pay \$11,000 in restitution to the U.S. Army.

Several other enlisted army personnel involved in the thefts were subject to military court martial as a result of the investigation.

Although Hensley and Joseph Sizemore illegally sold laser devices to OCI, they were not indicted in this scheme. Instead, OCI initiated a joint investigation with the FBI, the Defense Criminal Investigative Service (DCIS) in the Northern District of Texas, Fort Worth, and the Fort Worth Police Department. This investigation revealed that Hensley was also selling methamphetamines while running an organized prostitution ring in addition to selling of military property over the Internet.

In October 2005, a search of Hensley's residence found various firearms, narcotics and military hardware which were seized. A search was also conducted at Sizemore's residence in Amarillo, Texas. Sizemore was an individual of interest to investigators because he was employed as a federal agent with the Department of Energy, Nuclear Materials Courier Division at the Pantex Nuclear Facility. During the search of Sizemore's residence, various documents and unregistered weapons were seized. Sizemore admitted to using Department of Defense letterhead to fraudulently obtain infrared laser aimers and other military hardware which he then sold to Hensley for personal gain.

On September 19, 2006, Sizemore pled guilty to wire fraud and possession of unregistered firearms. He was sentenced to 30 months incarceration and ordered to pay restitution. He was also terminated from his position with the Department of Energy.

On September 26, 2007, Hensley pled guilty to false statements and theft of government property. On February 11, 2008, he was sentenced to 21 months incarceration to run consecutive with his 7 year sentence on State drug charges.

Illegal Sales of Unapproved Devices

This was a joint investigation involving OCI, U.S. Postal Inspection Service, the U.S. Attorney's Office for the Central District of California, the Office of Consumer Litigation, and the Department of Justice.

The investigation involved FDA regulated medical devices classified as dental hand piece sterilizers, manufactured by John Bowen. Hand pieces need to be sterilized between patients so that one patient's blood, saliva, and tissue are not transferred to the next patient while undergoing dental work. Though never approved as required by FDA, Bowen manufactured these sterilizers from 1994 through February 2006.

On February 16, 2006, in U.S. District Court for the Central District of California, Bowen was indicted and arrested for continuing to manufacture, sell, and repair unapproved medical devices. On the same date, Bowen was ordered by the U.S. District Court to not be involved, or cause others on his behalf to be involved, in any sale, transfer, or exchange of any kind of any item or service to any person or entity involved in any way the dental profession.

Based on his arrest, Bowen engaged the services and conspired with Autumn Toth, to continue the same activities for which he had been charged and arrested.

On September 9, 2007, Toth and Bowen were indicted for conspiracy, contempt, mail fraud, and adulteration of a medical device with intent to defraud and mislead, failure to register an establishment, and aiding and abetting. Toth and Bowen were arrested on September 24, 2007.

On November 5, 2007, Bowen was sentenced to four months incarceration, eight months home detention, and 36 months of supervised release.

On May 12, 2008, Toth pled guilty and was sentenced to one year of supervised release and a \$500 fine.

Center for Drug Evaluation and Research

Failure of Clinical Investigators' Oversight

In July 2003, OCI initiated an investigation based upon a referral from the Baltimore District Office (BLT-DO) findings relating to suspect activity occurring

in a clinical study. The study was being conducted by a clinical investigative firm identified as International Clinical Research Associates (ICRA), Richmond, Virginia.

Beginning in 1999 and continuing until May 2003, Dr. John Gilliam (principal investigator) and Roy Hartsook, Ph.D. (clinical coordinator) failed to prepare and maintain adequate records for a number of patient visits which affected at least seven clinical trial studies. Specifically, Drs. Gilliam and Hartsook routinely created source documents which reflected that they were present for and conducted evaluations of patients when, in fact, they were traveling overseas or otherwise not in the office.

In May 2003, an FDA Consumer Safety Officer (CSO) conducted an inspection of a study being conducted by ICRA. The CSO had received information prior to the inspection that Dr. Hartsook was allegedly falsifying medical data. During the inspection and while being questioned regarding his general practice for creating source documents, Dr. Hartsook knowingly made false statements.

Prior to the completion of the investigation, Dr. Gilliam passed away.

On February 26, 2008, in U.S. District Court for the Eastern District of Virginia, Dr. Hartsook pled guilty and was convicted of making a false statement to a representative of the FDA.

On March 26, 2008, in U.S. District Court for the Eastern District of Virginia, Dr. Hartsook was sentenced to serve two years supervised release, undergo mandatory psychiatric care, and ordered to forfeit \$250,000.

Misbranded Products

This case was initiated after OCI was informed that a person had an allergic reaction after ingesting penicillin that was labeled in Spanish and was purchased from a Monett, Missouri, grocery store. This became a joint OCI and U.S. Immigration and Customs Enforcement (ICE) investigation.

A search was conducted at Calamex Produce, a store in Monett, Missouri. Jose Ines Ibarra and Nicolasa Salas-Serrano were subsequently interviewed and admitted to illegally selling the misbranded drugs from their store. During the search, additional illegal medications were discovered.

In November 2005, Ibarra and Salas-Serrano were indicted in the Western

District of Missouri for misbranding drugs while held for sale after shipment; receipt of misbranded drugs in interstate commerce; and goods smuggling. Ibarra was subsequently also indicted for the possession of alien registration procured by fraud.

Ibarra and Salas-Serrano were found guilty after a trial by a jury of misbranding drugs and receipt of misbranded drugs. On November 1, 2007, Ibarra and Salas-Serrano were sentenced to three years supervised release, each fined \$2,500, and ordered to pay a special assessment of \$700.

Pesticides used as Treatment for Cancer

This case was opened based on allegations that Dr. T. R. Shantha was using dinitrophenol (DNP), a commercial-grade weed killer, and other unapproved drugs in the treatment of cancer patients in his Stockbridge, Georgia, medical clinic. OCI's investigation identified the use of several unapproved drugs and inappropriate billing of insurance providers for unapproved drugs and treatments.

On January 24, 2008, Dr. Shantha and Dan Bartoli, an assistant, were sentenced in the Northern District of Georgia after both defendants pled guilty to health care fraud.

Bartoli was sentenced to ten months confinement. Dr. Shantha was sentenced to 400 days home confinement and to forfeit \$189,000.

Conspiracy, Trafficking in Counterfeit Goods, and Aiding & Abetting

In 2006, the U.S. Postal Inspection Service developed information that prescription drugs such as Viagra®, Cialis®, and Levitra® were being shipped by Ryan Wheele of Akron, Ohio, to addresses throughout the U.S. Wheele, who is not a licensed wholesaler, used an alias and a fictitious return address when he shipped the drugs to his customers. It was determined through the investigation that Wheele received the drugs in parcels from India, Pakistan, and the United Kingdom.

During this investigation, Akron Police, the U.S. Postal Inspectors, and OCI agents conducted a search at Wheele's residence in Akron. The search of the residence disclosed over 53,000 tablets that appeared to be counterfeit Viagra®, Cialis® and Levitra®. When questioned, Wheele admitted that he received

regular shipments of what appeared to be counterfeit versions of the drugs from a person who he met via the Internet and resides at an unknown location overseas. Wheele only knows this person by his first name, Chen.

Customers would order drugs through an Internet Website maintained by Chen, and Wheele would fulfill those orders and send to customers throughout the U.S. Wheele used pharmacy vials to package the orders and a label maker to create labels for the drugs. The drugs were seized and examined by FDA's Forensic Chemistry Center (FCC) which determined that the drugs were indeed counterfeit.

On September 26, 2007, in the Northern District of Ohio, Wheele pled guilty to conspiracy, trafficking in counterfeit goods, and aiding and abetting.

On December 21, 2007, Wheele was sentenced to 30 days incarceration to be followed by three years of supervised release.

Adulterated and Misbranded Drug and Food Products

On March 19, 2007, a tractor-trailer was inspected at the Cortez port of entry at the Colorado/New Mexico border. During the inspection, a Colorado Department of Revenue inspector discovered the following drugs and food products in the passenger compartment: 90 boxes of Pentrexyl Ampicilina 500 mg (28 dosage units per package); 37 boxes of Amoxil 500 mg (75 ml bottles); and 38 packages of Chimex brand bologna (10 pound packages). Pentrexyl Ampicilina (Ampicillin) and Amoxil (Amoxicillin) are antibiotics, manufactured in Mexico. According to the U.S. Department of Agriculture, Chimex bologna manufactured in Mexico has been found to foster hog cholera, also known as classical swine fever (CSF), and is a prohibited item under the Federal Meat Inspection Act. The product was not refrigerated when discovered and may have spoiled prior to consumption.

The passenger of the truck, Rodrigo Pasillas-Cossio, a resident of El Paso, Texas, told the Colorado State Patrol Investigator that the drugs belonged to him and he bought all of the drugs from an unidentified person in El Paso. He stated he purchased the Pentrexyl Ampicilina for \$8 per bottle and the Amoxil for \$6 per bottle and was going to attempt to resell the drugs and bologna to small convenience stores catering to Mexican immigrants in Colorado and Utah.

The Colorado State Patrol Investigator contacted OCI and requested assistance with this investigation. Subsequently, OCI presented the case for prosecution in

the District of Colorado. Pasillas-Cossio was charged with adulterated and misbranded food and drug charges.

On January 8, 2008, Passillas-Cossio pled guilty on those charges and was sentenced to pay a fine of \$1,000.

Center for Food Safety and Applied Nutrition

Failure to Provide Prior Notice of Shipment

This case began on March 22, 2006, when OCI was notified that the Canadian Food Inspection Agency rejected 784 cans of pacific salmon roe at Peace Bridge, Buffalo, New York, by North Fish Ltd., Ontario, Canada, due to potential pathogen growth. Examination of the cans revealed that some cans were empty, some contained salmon roe, and some contained tuna.

Further investigation by the U.S. Fish and Wildlife Service, the U.S. Customs and Border Protection, and OCI revealed that the co-owner and Vice President of North Fish Ltd., Tatiana Popenko, deliberately entered the cans of tuna and empty cans into the U.S. in an effort to make the shipment appear to contain the entire 784 cans of rejected salmon roe in order to avoid penalties by the Canadian authorities. By doing so, she failed to provide prior notice of the importation of the tuna to the FDA.

On May 29, 2007, Popenko appeared in the Western District of New York in Buffalo and pled guilty to failing to submit prior notice of the importation of a food.

On September 5, 2007, Popenko was sentenced to pay a fine of \$2,500.

Concealment of FDA Violations During an Inspection of Dietary Supplement Manufacturer

OCI initiated a joint investigation with the FBI, U.S. Postal Inspection Service, and the Internal Revenue Service's Criminal Investigation Division. OCI opened its investigation after FDA Cincinnati District Office (CIN-DO) inspected Berkeley Premium Nutraceuticals (Berkeley) of Cincinnati, Ohio. Berkeley sold various dietary supplements, including Enzyte, by advertising on the Internet, television and in the print media. CIN-DO identified significant misbranding of

Berkeley's products, which resulted in an FDA issued Warning Letter. The investigation determined that Berkeley concealed FDA violations during an official inspection.

Based on the joint investigation, seven Berkeley employees including President Steven Warshak were arrested and pled guilty to mail and wire fraud involving Berkeley's unauthorized charges to customer credit cards and other financial crimes.

On September 20, 2006, Warshak and the remaining six defendants, which included the companies Berkeley and TCI Media, were charged in a 112 count indictment in the Southern District of Ohio. One defendant died prior to trial.

On February 22, 2008, Berkeley employees, including Berkeley President Steven Warshak, were convicted in U.S. District Court for conspiracy to commit mail and wire fraud, bank fraud, mail fraud, false statements to a bank, access device fraud, money laundering, conspiracy to misbrand, misbranding, conspiracy to obstruct FDA proceedings, and conspiracy to obstruct a Federal Trade Commission (FTC) proceeding. The companies TCI Media and Berkeley were also convicted.

On August 27, 2008, Warshak was sentenced to 25 years of incarceration, to be followed by a five year period of supervised release, a fine of \$93,000, and a criminal forfeiture of over \$503 million.

TCI Media was fined \$160,000 and placed on probation for five years. TCI Media has shared responsibility for the criminal forfeiture of over \$503 million. Berkeley was fined \$15 million to be paid in monthly increments of \$250,000, placed on probation for five years, and has shared responsibility along with TCI Media and Warshak for the criminal forfeiture of over \$503 million.

Harriet Warshak was sentenced to serve two years incarceration and three years of supervised release and shares the responsibility of the criminal forfeiture of over \$503 million.

On August 28, 2008, James Teegarden was sentenced to one year of incarceration, fined \$5,000, and three years of supervised release. He is to provide 300 hours of community service.

William Bertemes was sentenced to 30 days incarceration, ordered to pay a fine of \$10,000, and three years of supervised release. Bertemes is to provide 300 hours of community service.

Shellie Kinmon was sentenced to one year of incarceration, three years of supervised release, and 300 hours of community service

Michael Wagner was sentenced to one year and one day of incarceration, three years of supervised release, and 300 hours of community service.

Sue Cossman was sentenced to one year of incarceration, three years of supervised release, and 300 hours of community service. She is to share the responsibility of criminal forfeiture with Greg Cossman of \$1 million.

Greg Cossman was sentenced to one year of incarceration, three years of supervised release, and 300 hours of community service. No fine or restitution was imposed. Cossman is to share the payment of the \$1 million criminal forfeiture with Susan Cossman. He was ordered to report to prison in 30 days.

Samuel Grote was sentenced to 30 days incarceration, fined \$1,000 and two years of supervised release.

Steve Pugh was sentenced to one year and one day in jail, three years of supervised release, and 300 hours of community service.

On August 29, 2008, Paul Kellogg was sentenced to one year and one day of incarceration and three years of supervised release. Kellogg shares responsibility for the forfeiture of over \$503 million.

Center for Veterinary Medicine

Tissue Residue Violations

This case was initiated based upon a complaint to OCI that the Cottonwood Cattle Company was selling medicated cattle to slaughter houses. Tissue samples from cattle sold by the Cottonwood Cattle Company tested positive for excessive levels of various medications which were unsafe for human consumption.

Through the course of the investigation, the Cottonwood Cattle Company was identified as being owned and operated by Randy Stewart, who had previously been issued several Warning Letters by the FDA for selling medicated cattle for human consumption.

After receiving the Warning Letters, subsequent analysis of tissue samples from Stewart's cattle continued to show excessive levels of drug residues of

gentamicin, sulfadimethoxine, oxytetracycline, penicillin, tilmicosin, and sulfamethazine.

In addition, the U.S. Department of Agriculture (USDA) issued Stewart nine tissue residue violation letters, the majority of which he refused to accept.

In April 5, 2007, Stewart was charged in the Western District of Wisconsin with four misdemeanor counts of introduction into interstate commerce articles of adulterated food.

On August 27, 2007, Stewart pled guilty to the above violations. He was sentenced on November 8, 2007, to serve one year probation and 96 hours of community service and ordered to pay a fine of \$2,500.

Counterfeit Animal Drugs

In 2004, OCI initiated an investigation after receiving information that Animal Pharmaceuticals, Inc. (AP), an animal drug distributor located in Yakima, Washington, was selling counterfeit veterinary drugs originating from Mexico. OCI was informed that the counterfeit drugs being sold by AP were Nuflor®, Excenel®, Baytril®, and Naxcel™. All of these drugs are injectable antibiotics that are used primarily in beef and dairy cattle.

The investigation revealed that Joseph Frank Flores, owner of Valley Vet Supply (VVS), located in California, was complicit with AP in the smuggling of counterfeit drugs from Mexico.

During a search at both AP and VVS, large quantities of the counterfeit drugs Nuflor®, Excenel®, Baytril®, and Naxcel™ were seized. Also discovered were records identifying large amounts of counterfeit drugs acquired from a Mexican firm.

On July 18, 2006, Joseph Flores, Bruce Noyes, and an AP affiliated company were indicted for conspiracy to distribute counterfeit drugs, mail fraud, and trafficking in counterfeit drugs.

Once the indictments went public, OCI was contacted by former AP customers who had purchased counterfeit antibiotics. It was revealed that most of the former customers of AP were owners and operators of large cattle feedlots in Eastern Washington. It was estimated that these victims lost approximately \$20 million in cattle that died as the result of their livestock being treated with the

counterfeit antibiotics lacking active ingredients.

On November 20, 2007, Noyes and AP pled guilty in U.S. District Court in Yakima, Washington, to conspiracy to misbrand a drug. Noyes was sentenced to five years of supervised release. In addition, AP was ordered to pay \$330,000 in restitution to its former customers and pay a fine of \$270,000. Flores was sentenced to three months of home confinement and five years of supervised release and ordered to pay a \$2,000 fine.

Enforcement Statistics

FDA Office of Criminal Investigations
Fiscal Years 2004 – 2008 (Reported on
11/18/2008)

