
Office of Criminal Investigations

In Fiscal Year 2005, the efforts of FDA's Office of Criminal Investigations (OCI) resulted in 535 arrests, 275 convictions, and \$29,127,442. in asset forfeitures and \$179,792,041. in fines and restitution.

Center for Biologics Evaluation and Research

Bioresearch Monitoring

Civil Complaint Filed Against University of Pennsylvania

Investigation at Institute of Human Gene Therapy Found Toxicities Experienced by Patients Were Not Reported Accurately to FDA or IRB

This investigation was predicated upon an allegation that physicians James M. Wilson, Steven Raper and Mark Batshaw withheld information and provided false information to FDA and the University of Pennsylvania's Investigational Review

Board (IRB) regarding the gene therapy trial. Wilson ran the University of Pennsylvania's prestigious Institute of Human Gene Therapy (IHGT) and sponsored the trial as a Sponsor/Investigator.

In 1997, the physicians began enrolling patients in a Phase I gene therapy trial using an adenoviral vector to insert a gene expressing Ornithine Transcarbamylase (OTC) into the livers of patients deficient in this enzyme, which is needed to metabolize protein consumed in the diet. Few neonates deficient in OTC survive beyond a week after birth, but some do on a regimen of high dose drugs and a very restricted diet. The disease is particularly deadly in male infants.

The trial progressed through June 1998, when the tenth patient experienced significant liver toxicities from the vector transfusion. Unbeknownst to FDA, the physicians then amended the study protocol to remove the stopping rules which required that the trial be halted if patients experienced such toxicities.

The next patient experienced the same toxicities. From then on, most of the patients experienced what should have been study-stopping toxicities, but the protocols no longer required the trial to be halted and FDA was provided with data in cohort summaries that understated the toxicities. The clinical investigators, meanwhile, came to expect the toxicities as "normal."

An 18-year old male from Arizona, was a patient in the trial. Even though he would have been ineligible for the trial because of his high ammonia levels, he was enrolled in the trial in September 1999. Because the dose of the vector was based on the patient's weight, and because he weighed more than any previous patient or primate who preceded him in the trial, the patient received the largest dose of OTC vector. He died within days later.

FDA's Center for Biologics Evaluation and Research (CBER) immediately launched inspections of the IHGT, the University of Pennsylvania's Institutional Review Board (IRB) and the animal studies used in support of the study. The inspectors found gross violations of good clinical practices, good laboratory practices, record keeping requirements and good manufacturing practices with respect to the vector itself.

CBER also found the protocol amendments that had not been provided to FDA and the toxicities experienced by later patients that were not reported accurately to either FDA or the IRB. CBER referred the matter to FDA's Office of Criminal Investigations (OCI).

The investigation pieced together the chain of non-communications and miscommunications that effectively kept the University's IRB, FDA and the National Institutes of Health (NIH) all unaware that the patients were being exposed to greater and greater risk. Three documents were never sent to FDA because the Quality Assurance Director failed to submit them and two annual reports hand-carried to the local IRB contained understated toxicities.

The father of the deceased, who initially stood by IHGT and the physicians after his son died, filed suit against the University of Pennsylvania and the three physicians. The complaint was immediately settled. In the settlement, the University of Pennsylvania and CNMC each agreed to pay grant restitution and fines. Both institutions agreed to increase research subject protection and spend millions of dollars increasing the size of their IRBs, revamping their review procedures, initiating and mandating training for clinical investigators and upgrading their adverse event reporting.

Wilson, Batshaw and Raper each agreed not to conduct clinical research on human subjects until they completed additional training in patient protection, and then only in a restricted fashion for periods of between three and five years. Under the restrictions, the physicians cannot participate in more than one clinical study at a time and must do so under the supervision of a medical monitor and the oversight of a Contract Review Organization. Both the medical monitors and the Clinical Review Organization must make semi-annual reports to both FDA and NIH concerning the physicians' activities. Finally, federal grant funding cannot be used to pay for any costs associated with complying with the settlement.

Restitution Ordered for Victims of Unapproved Clinical Trial

**FDA Investigation Found
"Egg Powder" Sold to Treat
Foot Fungus and Arthritis**

The investigation of Ovimmune, Inc. was based on information from FDA's Cincinnati District Office that the firm and its two corporate officers were conducting unapproved trials with a dried egg powder that they claimed had curative powers.

In 1992, Marilyn Coleman, who held a Ph.D. in poultry science but claimed to have two Ph.D.s and a medical degree, and Mitchell V. Kaminski, M.D., a plastic surgeon practicing outside Chicago, Illinois, formed the corporation Ovimmune, Inc., to manufacture antibodies to treat diseases in humans and other animals. They claimed to make the antibodies by inoculating chickens and drying the chickens' eggs, which allegedly contained the antibodies.

In 1999, Coleman and Kaminski convinced an owner of a health food store in Washington State to fund the venture with \$85,000. In 2000, Coleman purchased 10,000 chickens, arranged for an experimental vaccine to be created and inoculated the chickens in three stages. Over 1,000 chickens died, but the remaining hens began producing eggs. Within months, Ovimmune, Inc., had thousands of pounds of dried egg powder, far more than the health food store could sell as a cure for yeast infections. Ovimmune, Inc., soon canceled their contract with the owner of the health food store and began seeking other outlets for the powder.

In March 2001, Coleman approached a rural school system in central Ohio and asked if the school would permit her to experiment on the students. She claimed that the egg powder now cured Attention Deficit Disorder, autism, and other disorders. The school contacted FDA.

FDA instructed Coleman and Kaminski to conduct no further clinical trials until they had the appropriate Investigational New Drug Application on file with FDA. The following morning, Coleman held a meeting at a local church, soliciting local citizens to submit experiential data in exchange for dozens of free eggs. FDA's Cincinnati District Office was notified of this solicitation and contacted FDA's OCI.

A search warrant was executed at Coleman's residence which chronicled the filthy conditions under which the eggs were stored and broken, including the existence of a dead cat found in a freezer three feet away from the un-refrigerated eggs.

FDA analyzed the egg powders and found none of the antibodies Ovimmune, Inc. claimed the eggs contained, but did find several different pathogens and molds. Ovimmune, Inc. made nearly \$240,000 selling their "egg antibodies" to human

patients, and to farmers trying to control diseases in farm animals, all without the United States Department of Agriculture (USDA) or FDA approvals.

On April 29, 2005, Coleman and Kaminski were sentenced to 5 years probation, including 6 months incarceration in a federal halfway house and another 6 months under electronically monitored home confinement; fined \$6,000; and ordered to pay restitution in the amount of \$33,000 to their patients. Coleman and Kaminski were previously convicted by a jury of multiple Federal Food, Drug, and Cosmetic Act (Act) charges.

On June 30, 2005, Ovimmune, Inc., was sentenced to 5 years probation and ordered to pay \$33,604 in restitution to the patients who purchased the powder.

Center for Devices and Radiological Health

Injections of Liquid Adulterated Devices

Defendant Posed as Physician - Injected Liquid Silicone Into Patients
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From June 2001 through March 2002, Carlos Orrego-Martinez traveled once a month from the Dominican Republic to Puerto Rico to treat clients at the Salon de Belleza, which was operated by Evelyn Valentin. The treatments consisted of injections of liquid silicone (an adulterated device), injections of a product identified as “Karchy Swed” (another adulterated device) and various unapproved drugs. Orrego-Martinez posed as a physician, and his treatment was advertised on Puerto Rico TV stations and various magazines by his co-conspirator, Sergio Lopez. Orrego injected these products into famous artists, judges, attorneys, physicians, and others.

On August 22, 2002, Valentin was convicted of violating 18 U.S.C. § 4 - Misprision of Felony.

On September 11, 2002, Lopez was convicted of violating 18 U.S.C. § 1343 - Wire Fraud.

On September 23, 2002, after a trial, a hung jury was declared and Orrego-Martinez was acquitted by the presiding judge. The judge explained that there was not enough evidence submitted in trial to sustain the charge that Orrego-Martinez had knowledge

about the wire transfers charged in the indictment. Subsequent to this decision, Orrego-Martinez was charged pursuant to a new indictment.

On January 17, 2003, Valentin was sentenced to 1 month probation.

On March 5, 2004, Lopez was sentenced to time served and to 3 years supervised release.

On June 27, 2005, Orrego-Martinez was sentenced to 58 months incarceration and 3 years probation. He was previously convicted in a second trial of violating 18 U.S.C. § 371 – Conspiracy; 21 U.S.C. § 331(a) - Introduction into Interstate Commerce of Adulterated Devices; and 21 U.S.C. § 331(d) - Introduction into Interstate Commerce of an Unapproved New Drug.

Injection of Silicone Oil Leads to 20-Year Prison Sentence

This case was initiated based on information received from the El Paso Police Department indicating that Irma Agripino was injecting women with a substance in their lips, breasts and buttocks. The investigation revealed that many of the women had suffered injuries as a result of these injections. Analysis performed by FDA determined that the substance injected was mineral oil. Agripino was arrested and later indicted on 16 counts in violation of Texas Occupational Code 165.152 - Practicing Medicine without a License and 11 counts of Texas Penal Code 22.02 – Aggravated Assault.

On January 27, 2005, Agripino was convicted on all counts. She was sentenced to 20 years incarceration in state prison on all the aggravated assault counts and 10 years for all counts of practicing medicine without a license. The judge ordered the sentences to run concurrently. In addition, Agripino was fined \$10,000 on all of the 27 counts.

This case was worked as a joint investigation with the El Paso Police Department.

Stolen Blood Glucose Test Strips Sold on eBay

Defendant Found Stealing Blood Glucose Strips and Reselling Them on eBay

This investigation was initiated based on information received from Roche Diagnostics Corp. (RDC), Indianapolis, Indiana. RDC learned that between March 2002 and October 2003, Shirley Mendoza, who previously worked for Roche Molecular Systems (RMS),

Berkeley, California (a division of RDC), stole numerous shipments of Comfort Curve brand blood glucose test strips, manufactured in Indianapolis, by RDC for use as physician samples.

While employed with RMS, Shirley Mendoza used false pretenses and representations to order the blood glucose test strips from RDC, which were shipped to RMS for distribution to physicians. Once the test strips were received by Shirley Mendoza she sold them on eBay. Shirley Mendoza was not authorized by RDC to order, sell or ship glucose test strips.

An internal audit revealed that approximately \$10,000 worth of Federal Express billings were incurred by RMS for shipments of merchandise sent to a Massachusetts company. FDA learned that, for a subsequent one-year period, the company's owner paid approximately \$2.5 million for merchandise by using cashiers checks and business checks made payable, at the direction of Shirley Mendoza, to "Jose Mendoza and/or RD Corporation."

On April 20, 2004, Shirley and Jose Mendoza were arrested and during a search of their residence, several high-value items were seized. Shirley Mendoza admitted to stealing RDC's Comfort Curve brand glucose test strips, which she and her husband sold for personal profit.

On June 30, 2004, Jose Mendoza was convicted of violating 18 U.S.C. § 1341 – Mail Fraud. On September 3, 2004, Jose Mendoza was sentenced to 31 months incarceration; 2 years supervised probation, and ordered to make restitution to RDC in the amount of \$1,250,000.

On September 24, 2004, Shirley Mendoza, was convicted of violating 18 U.S.C. § 1341 – Mail Fraud and 18 U.S.C. §§ 1957 and 2 - Engaging in Monetary Transactions in Property Derived from Specified Unlawful Activity. On January 15, 2005, Shirley Mendoza was sentenced to 35 months incarceration and ordered to make restitution to RDC in the amount of \$1,250,000. This was a joint investigation with the Federal Bureau of Investigation (FBI).

Ozone Generator Promoted for Treatment of AIDS and Cancer

This case originated based on information supplied by the Internal Revenue Service's (IRS). IRS reported the business, Water Oz, was selling misbranded and adulterated mineral waters, in addition to ozone generators. OCI was previously aware of this firm because of a report from FDA's Seattle District Office, indicating that one of their inspectors was prohibited from inspecting the Water Oz facility in 1999.

Information on the Water Oz website and literature received with the products indicated these water products were intended to treat specific diseases, including AIDS and cancer. In addition, an ozone generator and ozone body suit were purchased from Water Oz, which were intended to treat diseases such as skin cancer and gangrene. Subsequent analysis by FDA indicated these products were misbranded, because claims made on the Water Oz labels were inaccurate.

In July 2002, David Hinkson, owner of Water Oz, was indicted for multiple tax-related charges and multiple counts of introducing adulterated and misbranded drugs and devices into interstate commerce.

In April of 2003, Hinkson was arrested again after the FBI uncovered evidence that Hinkson had attempted to hire associates to murder the IRS case agent, the Assistant U.S. Attorney (AUSA), and the U.S. District Court judge assigned to this case. In addition, Hinkson allegedly solicited the murder of the children of the AUSA and IRS agent. Based on these new allegations, Hinkson's bail was revoked, and he was remanded to custody.

In April 2004, Hinkson was convicted of violating 21 U.S.C. §§ 331(a) and 333(a)(1) - Introduction into Interstate Commerce of a Misbranded Drug and Medical Device. On May 4, 2004, after a seven day jury trial, Hinkson was convicted on all tax-related counts.

On January 28, 2005, after a two week jury trial, Hinkson was convicted of 3 counts of solicitation of murder of federal officials. A joint sentencing hearing was scheduled for both cases.

On June 3, 2005, Hinkson was sentenced to a total of 10 years incarceration on the IRS and FDA counts, 10 years each on the 3 counts of solicitation, and an additional 3 years, because the solicitation crimes were committed while Hinkson was on pre-trial release. This 43-year sentence was ordered to be served consecutively.

The judge concluded that Hinkson showed a "complete lack of remorse," continued to blame others for his crimes, and was "not amenable to any form of rehabilitation." In addition, the judge also indicated that he would recommend to the Bureau of Prisons that Hinkson be considered a high-risk inmate because of his continued hatred of federal officials and his financial ability to carry out his threats and flee the country if he escaped.

Ozone Generator Promoted as Cure for Autism

Physician Loses Medical License as a Result of Fraudulent Activity

This case involved the use of an ozone generator as a cure for autism in children by Dr. Stephen B. Edelson, M.D. d.b.a. The Edelson Center for Environmental & Preventive Medicine, Inc., (“Edelson Center”) Atlanta, Georgia. As early as December 2000, Dr. Edelson utilized an unapproved imported ozone generator medical device to provide fraudulent treatments. The parents of an autistic minor male paid between \$40,000 and \$50,000 to The Edelson Center, for treatment, which included the ozone therapy.

On September 1, 2004, a search warrant was executed at the Edelson Center. Two ozone generator machines were recovered along with numerous documents pertaining to the purchase and use of the ozone generator.

On July 18 2005, Dr. Edelson’s medical license was revoked by the Georgia Medical Board.

This was a joint investigation with FDA’s Atlanta District Office, the Georgia Medical Board and the Georgia Drugs and Narcotics Agency.

Falsification of Data in Violation of the Mammography Quality Standards Act

Defendant Fabricated Credentials and Falsified Inspection Data, Often “Guessing” Results if He Was Unsure

This case was initiated in October 2002, when FDA’s Baltimore District Office advised that Perry M. Beale, Stafford, Virginia, had been recently administratively sanctioned by the Nuclear Regulatory Commission (NRC) for fabricating the results for radioactive xenon gas clearance testing rates at various hospitals.

Beale, working as a radiation physicist, falsified calibration data regarding mammography machines, in violation of the Mammography Quality Standards Act (MQSA) and fabricated his academic and professional credentials to be qualified and licensed as a radiation physicist.

FDA learned that Beale had previously worked as an intern for a genuine radiation physicist. Upon the death of the physicist in the mid-1980’s, Beale purchased all of

his testing equipment, and falsely assumed the role as the radiation physicist for the deceased physicist's customer base.

In addition, Beale altered his undergraduate transcript to reflect advanced science courses never taken as well as higher course grades. It was determined that Beale had counterfeited his radiation physicist certificate from the American Board of Radiology, and completely fabricated his claim of earning a Master of Science degree from the University of Virginia. Beale represented himself as a radiation physicist at over 50 medical facilities in the Maryland, Virginia, Pennsylvania, West Virginia, District of Columbia, and North Carolina areas for approximately 15 years.

Using his false credentials, he was contracted by facilities that ranged from single-practice physician offices to major institutions such as a well-known University Medical Center and the Central Intelligence Agency's (CIA) Office of Medical Services.

Beale's responsibilities as a radiation physicist entailed full quality assurance and safety testing of a myriad of radiological medical devices and accessories, ranging from basic x-ray machines to mammography and fluoroscopy machines. He was also responsible for vital tasks such as determining lead wall thickness in radiology suites and the accountability of highly controlled sealed sources of radiation used to calibrate medical devices.

Beale not only fabricated his credentials, but also falsified his inspection data, often times "guessing" the results if he was unsure and on at least "twenty five to fifty times" admitted generating an inspection report without even visiting the facility and physically looking at the machines. Beale had certified radiological medical devices as fully operable and safe when, in fact, they had been taken out of service years earlier.

Additionally, he verified, at numerous facilities, that their sealed sources of radiation were present and accounted for, when in fact they had been properly disposed of years earlier. At one facility, for a ten-year period, Beale falsely certified that a highly radioactive sealed source was present and accounted for when it had already been disposed of years prior.

On May 12, 2005, Beale was convicted of violating 38 counts of 18 U.S.C. § 1341 - Mail Fraud. Beale was sentenced to serve 54 months incarceration, ordered to pay restitution in the amount of \$375,000 to the facilities he defrauded, and ordered to pay a special assessment of \$3,800. Upon his release from prison, Beale was ordered to be placed on supervised probation for a period of 36 months.

This joint investigation was conducted by FDA's OCI and Baltimore District Office, and NRC.

Center for Drug Evaluation and Research

Biomedical Research

Research Assistant/Study Monitor Convicted of Criminally Negligent Homicide

False Documentation Allowed Patient Who Did Not Meet Study Criteria Into Clinical Investigation

This was a joint investigation with the Veterans Affairs Office of Inspector General. This investigation revealed that Dr. Paul Kornak, who was employed by the

Department of Veterans Affairs as a Research Assistant/Study Director, falsified documentation regarding patients and study subjects and repeatedly enrolled persons as study subjects who did not qualify under a specific study protocol. This was a scheme to defraud the sponsors of the clinical trials and studies to obtain money and property from them.

Dr. Kornak, with criminal negligence, caused the death of one patient by falsely documenting the results of blood chemistry analysis. The false documentation allowed the patient to meet the inclusion and exclusion criteria for participation in the study when the actual results did not meet the criteria and showed impaired kidney and liver function. The patient was administered chemotherapeutic drugs in connection with the study and died two months later.

Kornak was convicted of 18 U.S.C. § 1001 - False statements; 18 U.S.C. § 1341 – Mail fraud; and New York State Penal Law § 125.10 - Criminally negligent homicide.

On November 21, 2005, Kornak was sentenced to 71 months incarceration, to be followed by supervised release for 3 years, and ordered to make restitution in the total amount of \$638,755.05.

Conspiracy

Theft of Pharmaceutical Drugs

Hospitals Lose Over \$2 Million in Stolen Cancer Drugs

This case was initiated based on information that Fred Solmor directed the hi-jack and robbery of a Cardinal Distribution truck, which was transporting \$344,000 of various prescription medications. The Houston Police Department's (HPD) Robbery Squad, was contacted and confirmed that a Cardinal Distribution truck had been hi-jacked, the driver bound, and all of the truck's contents stolen.

Investigation led to the arrests of MD Anderson pharmacy technicians Debra Griggs, Jeffery Huddleston, Jeremy Gutierrez and Chris Felan, all related to the thefts of cancer drugs from MD Anderson Hospital and Methodist Hospital. Internal audits revealed MD Anderson lost over \$2,000,000 and Methodist Hospital lost over \$300,000 in cancer drugs to the thefts.

The defendants in this case were sentenced to various terms of incarceration and probation.

This case was worked jointly between FDA's OCI and HPD's Robbery Squad.

Conspiracy to Distribute Misbranded Drugs

OCI Investigation Disclosed DNP - a Highly Toxic Drug Sold Over the Internet Resulting in a Death

This investigation was initiated in October 2002, and involved the encapsulation and Internet sale of 2, 4 Dinitrophenol (DNP) a highly toxic industrial chemical that resulted in a death. The Internet web site had encouraged the use of DNP as a weight loss drug. The father of the deceased wrote a letter to U.S. Postal Service (USPS) advising that his daughter died after ingesting the DNP. The deceased purchased the DNP over the Internet and the DNP was mailed to her using the U.S. mail system.

This investigation linked two independent ongoing USPS investigations regarding suspicious mailings to the shipment of DNP. This investigation provided sufficient evidence to obtain arrest warrants for Matthew Cahill and Jason Sacks and search warrants for their respective residences. During the execution of the search warrants, additional evidence, such as DNP, computer records, adulterated foreign drugs and the criminal proceeds were recovered.

On May 21, 2003, Cahill and Sacks were convicted on 11 counts of violating 18 U.S.C. § 371 and 21 U.S.C. §§ 331(a) and 333(a)(2) - Conspiracy to Introduce Adulterated and Misbranded Drugs into Interstate Commerce, specifically DNP.

On March 11, 2005, Cahill and Sacks were sentenced to 24 months incarceration for each of the 11 counts, to be served concurrently. They were also sentenced to 3 years of supervised parole after their release and forfeiture of \$40,635.

Controlled Substances

Unlawful Distribution/Dispensing of Controlled Substances

**DEA Officer Surrendered License
after Entering into Plea Agreement
with U.S. Attorney**

On October 26, 2001, Pedro Colon-Cardona surrendered his Drug Enforcement Administration (DEA) license after entering into a plea agreement with the U.S. Attorney's

Office in another OCI investigation. Colon-Cardona was sentenced to a term of one year probation.

On March 25, 2003, after receiving information that Colon-Cardona was still purchasing and selling controlled prescription drugs at his pharmacy, Farmacia Colon, DEA and FDA's OCI executed a search warrant at Farmacia Colon. The search warrant produced large amounts of evidence and led to Colon-Cardona's new indictment.

On October 7, 2004, Colon-Cardona was arrested for violations of 21 U.S.C. §§ 841(a)(1) - Unlawful distribution/dispensing of controlled substances, 21 U.S.C. § 846 - Conspiracy to unlawfully distribute/dispense controlled substances, and 21 U.S.C. § 853 - Asset forfeiture provisions. Colon-Cardona was released on bail.

On August 26, 2005, Colon-Cardona was arrested at Salinas, Puerto Rico, for violation of 18 U.S.C. § 1512(b) (1) - Tampering with a Witness.

On September 9, 2005, Colon-Cardona was convicted of 21 U.S.C. § 841(a)(1) - Unlawful distribution/dispensing of controlled substances.

On December 12, 2005, Colon-Cardona was sentenced in U.S. District Court, San Juan District, to a term of 30 months of incarceration and to 3 years of supervised release.

Trafficking in Controlled Substances

Defendant Received 6-7 Year Prison Sentence
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On June 11, 2003, information was received about Charles Ghera, who claimed abandoned luggage at a Boston, Massachusetts hotel. The bag contained hypodermic needles and several large clear plastic bags containing a white powdery substance (later determined to be 8 pounds of Ketamine).

Ketamine is a tranquilizer most commonly used on animals. Ketamine comes in a clear liquid and a white or off-white powder form. The liquid form can be injected, consumed in drinks, or added to smokable materials. The powder form can be used for injection when dissolved. Ketamine, along with the other "club drugs," has become popular among teens and young adults at dance clubs and "raves."

Use of Ketamine can cause delirium, amnesia, depression, and long-term memory and cognitive difficulties.

A subsequent search of Ghera's hotel room resulted in the seizure of numerous prescription tablets, syringes, gamma butyrolactone (GBL), and Ecstasy.

GBL-related products have been associated with reports of numerous adverse health effects, including at least one death. In some cases, the consumers became unconscious or comatose and several required intubation for assisted breathing. Other reported effects included seizures, vomiting, slow breathing, and slow heart rate. FDA has issued a numerous warnings to consumers regarding the use of GBL.

In addition to the above information obtained by OCI, numerous ledgers were found outlining Ghera's criminal activity, including descriptions of the sale of pharmaceuticals and other prescription drugs. Also recovered was Ghera's laptop computer. A tally of the figures indicated over \$1 million in sales. Also found were several prescription receipts for various drugs with the prescribing doctor's identifying information blacked out.

On September 22, 2004, Ghera was convicted on state charges of Possession to Distribute a Class A Drug (Ketamine and Ecstasy); Trafficking a Controlled Substance (Cocaine); and Possession to Distribute a Class B Drug (Oxycodone). Ghera was sentenced to between 6 and 7 years incarceration.

Conspiracy to Distribute Controlled Substances

**Controlled Substances and Rx
Drugs Offered for Sale Over
the Internet**

This case focused on vinci-online.com, a web site that offered various prescription drugs and controlled substances for sale. The investigation identified the Owner/President as Christian

Frederic Finze, with associated companies Vinci-American Ltd., Las Vegas, Nevada, and CFF Pharma Consult GmbH, Bergkirchen, Germany.

The investigation identified purchases of Valium and the injectable steroid Deca-Durabolin without valid prescriptions. The aforementioned prescription drug products were also misbranded, as the pharmaceutical package inserts, directions for use, and labeling were in the German language.

On May 2, 2002, a federal search warrant was executed at the Finze residence in Nevada. Among evidence seized, were thousands of documents, e-mail messages for prescription drugs/controlled substance orders, purchase invoices, financial instruments, computers and small quantities of misbranded prescription drugs, to include, Rohypnol, commonly referred to as the "date rape drug." Also discovered at the residence was a one-way air ticket for Finze to return to Germany that week.

On December 18, 2002, a 20-count Superseding Indictment was returned by the Federal grand jury charging Finze with violating 18 U.S.C. § 371 - Conspiracy to Defraud the U.S., 18 U.S.C. § 1001 - False Writings, 21 U.S.C. § 846 - Conspiracy to Distribute Controlled Substances, 21 U.S.C. § 963 - Conspiracy to Import Controlled Substances, 21 U.S.C. § 841 - Distribution of Controlled Substances, 18 U.S.C. § 1957 - Engaging in Monetary Transaction In Property Derived from a Specified Unlawful Activity, 18 U.S.C. § 2 - Aiding and Abetting, 18 U.S.C. § 982(a)(1) and(b)(1) - Forfeiture; and 21 U.S.C. § 853(a) and (p) - Forfeiture.

On October 28, 2004, Finze was convicted by a jury on all counts.

On May 6, 2005, Finze was sentenced to the following terms of imprisonment: Conspiracy – 60 months, False Writing to an agency of the U.S. and Aiding and Abetting – 60 months each count, Conspiracy to Distribute Controlled Substances – 120 months, Conspiracy to Import Controlled Substances – 120 months, Distribution of Controlled Substances and Aiding and Abetting – 36 months, Distribution of Controlled Substances and Aiding and Abetting – 60 months, Engaging in a Monetary Transaction in Property Derived from Specified Unlawful Activity and Aiding and Abetting – 120 months each count. All sentences to run concurrently.

Additionally, Finze was placed on Supervised Release for a period of 3 years at the conclusion of the term of incarceration, pending deportation proceedings. Finze was also ordered to pay a criminal fine in the amount of \$15,000.

Counterfeit Drugs

Defendants Found Selling Counterfeit Labels

Some Counterfeit Labels Printed by Defendant Were for Anti-Psychotic Drugs Used to Treat Schizophrenia

This investigation began when it came to the attention of OCI's Miami Field Office that Jose Lopez was printing labels for prescription medications and selling these labels to various individuals. FDA learned that Lopez was selling various medication labels for drugs such as Zyprexa and Risperdal, which are anti-psychotic drugs used to treat schizophrenia.

Once these trademarked labels were counterfeited, they were potentially placed on bottles of tablets, regardless of their contents. Lopez did not place pills or other substances in the bottles. His conduct was limited to selling the trademarked labels.

On October 17, 2005, Jose Lopez, owner of Printing 2000, Miami, Florida, was convicted of violating 18 U.S.C. § 2320(a) – Trafficking in Counterfeit Goods. Lopez was sentenced by the U.S. District Court to 30 months incarceration. He was also sentenced to a 2-year period of supervised release, was ordered to pay \$1,090 in restitution, and to forfeit to the U.S. all rights and title to a Canon Laser Color Copier, which was employed in the commission of the offense.

Human Growth Hormone (hGH)

Human growth hormone (hGH), made by the pituitary gland, promotes the normal development and maintenance of tissues and organs by triggering the release of insulin-like growth factors and inducing other beneficial physiological and metabolic effects. Synthetic hGH was made through genetic engineering and became widely available after 1985.

hGH replacement therapy is approved for a limited number of medical conditions, including treatment of children and adults with scientifically proven growth hormone deficiency whose bodies produce insufficient or ineffective levels of the hormone. In addition, hGH is approved to treat muscle wasting in people with AIDS. A physician must prescribe the growth hormone. The dose is individualized for each person and is taken by injection.

Illegal Sale of hGH

Defendant, a Federal Government Employee, Used Government Computer to Sell hGH

This case was initiated based on information that injectable hGH was being imported into the U.S. from China by Mark Niehold, Phoenix, Arizona. Niehold had attempted to import injectable hGH into the U.S. in the past. Representative samples were taken from the shipment of hGH, which tested positive for the presence of hGH.

On October 28, 2003, a shipment of injectable hGH intended for Niehold was intercepted by the Department of Homeland Security's (DHS) Bureau of Customs and Border Protection (CBP) in California. The shipment contained 60 vials of injectable hGH, and laboratory analysis revealed that it tested positive for the presence of hGH.

On December 17, 2003, a delivery of hGH was sent to Niehold at his residence. Niehold stated that he was an employee of the Federal government.

Niehold operated the website www.thelowestcosthgh.com, and advertised the sale of hGH and other prescription drugs. Investigators learned that individuals who purchased hGH from Niehold over the Internet confirmed that they purchased hGH from an individual named "Mark," whom they met at the Internet web site.

On March 1, 2004, an analysis of Niehold's government-issued laptop computer revealed that Niehold continued to distribute hGH over the Internet by using his government-issued computer after he was notified that it was illegal. E-mail correspondence recovered from Niehold's computer revealed that Niehold directed the importation of hGH from China to be labeled on CBP importation documents as "Ceramic Figures."

On April 14, 2004, a search warrant was conducted at Niehold's residence in Arizona. Two computers were seized in the search warrant for analysis. Also seized were miscellaneous documents implicating Niehold in the distribution of hGH. Analysis of Niehold's computers revealed additional evidence of the illegal distribution of hGH.

On December 23, 2004, Niehold was convicted of violating Arizona Revised Statute 13 § 3406 - Possession, Use, Administration, Acquisition, Sale, Manufacture or Transportation of Prescription Only Drugs.

On December 31, 2004, Niehold was sentenced to 3 months of supervised probation and a \$1,000 fine.

Illegal Sale of Serostim (hGH)

**Serostim Sold for Use in
Body Building - an Illegal Use**

In October 2002, FDA's OCI was contacted by the FBI, Honolulu, Hawaii, regarding the illegal sale of Serostim (hGH) in Honolulu, Hawaii, for use in bodybuilding. The investigation revealed that Eddie Gaviran (a Honolulu, Hawaii Firefighter) and Eddie Belluomini (a Honolulu, Hawaii Police Officer) were selling Serostim to body builders (an unapproved use) for \$400 to \$650 per box, substantially under wholesale prices (\$800 to \$1,400).

Some of Serostim (thought to be counterfeit) was forwarded to FDA for analysis. The packaging, labeling, and product were found to be consistent with authentic Serostim.

On February 26, 2004, Belluomini was convicted of violating 21 U.S.C. § 333(e) - Distribution/Possession of hGH.

On July 6, 2004, Gaviran was convicted of violating 21 U.S.C. § 333(e)(1) – Illegal Sale of hGH and sentenced to 6 months probation. Gaviran was removed from serving as a Honolulu, Hawaii firefighter.

On December 8, 2004, Belluomini was sentenced to 3 years probation, and ordered to serve 60 days of home detention with electronic monitoring. Belluomini was removed from his duties as a Honolulu, Hawaii police officer.

Customs Finds hGH at New York Mail Facility

**hGH Discovered During Routine
Inspection by Immigration and
Customs Enforcement**

On July 20, 2004, OCI was notified by FDA's New York District Office that a shipment containing 252 - 10 IU vials of hGH had been discovered. The package was found that day during a routine inspection by Immigration and Customs Enforcement (ICE) personnel at the New York mail facility. It had been shipped from China and was destined for Albert Milano in New Middletown, Ohio.

Milano was interviewed and admitted to importing hGH without a prescription for himself and three or four friends. Milano also showed U.S. Postal Inspectors where he had hidden an additional 113- 10 IU vials of hGH.

The investigation disclosed numerous e-mails between Milano and Chinese hGH suppliers in which Milano claimed to have been purchasing 3000 – 5000 IU hGH per month. Milano also discussed with his suppliers various methods to avoid detection of the hGH by ICE personnel as it entered the country.

Milano was convicted of 21 U.S.C. § 333(e) – Possession with intent to distribute Human Growth Hormone. On October 25, 2005, Milano was sentenced to 3 years probation, 100 hours community service in U.S. District Court for the Northern District of Ohio, Eastern Division.

This case was investigated by OCI, the U.S. Postal Inspection Service and New Middletown Police Department.

Kickbacks Offered for Prescriptions for Human Growth Hormone (hGH)

**U.S. Attorney General Announced
\$704 Million Settlement in Serono
Case**

This investigation was initiated in November 2000, based upon complaints alleging Serono Labs sold Serostim® (a human growth hormone) outside of its approved label

indication for the treatment of AIDS wasting, which is an unintentional loss of at least 10% of body weight. A complaint also alleged that clinical research data was falsified and submitted to FDA, that prescriptions for the drug were falsified by sales representatives upon direction of Serono management, and kickbacks were given to doctors, patients, and pharmacies.

Although the allegations of falsified clinical research data were not proven, the investigation did result in several allegations being corroborated, including Serono's off-label promotion of Serostim.

While Health and Human Service's Office of Inspector General (HHS/OIG) and FBI agents focused on the kickbacks and Medicare fraud allegations, OCI agents discovered that the off-labeling allegation referred to a complex scheme to broaden the indication from AIDS wasting through the use of bioelectrical impedance analysis (BIA) tests on patients in order to justify prescriptions of Serostim®. OCI also learned that Serono marketed Serostim® for lipodystrophy, which is unrelated to AIDS wasting, but may have similar signs and symptoms.

FDA cleared the BIA machine only for use in healthy individuals. The investigation revealed that RJL Systems, the manufacturer of the BIA machine used by Serono, had changed the algorithms in the BIA software but did not submit these changes to FDA and, therefore, was marketing a device that had not been approved.

FDA learned that Serono worked with Rudy Liedtke, the owner of RJL Systems, to create the "Somascan" software specifically for Serono. This software was used by Serono sales representatives in tests on AIDS patients to show loss of lean body mass and body cell mass. Serono persuaded doctors to use this as a criteria to determine AIDS wasting and persuaded third-party payers to use this measure as a justification for reimbursement.

On December 21, 2004, Adam Stupak, a former Serono Regional Director of Sales, was convicted of three counts of 42 U.S.C. § 1320A-7(b)(2)(A) - Offering to pay illegal remunerations; and 18 U.S.C. § 2 - Aiding and abetting, for his part in offering three doctors in the New York City area all-expenses paid trips to a medical conference in Cannes, France, in exchange for writing thirty Serostim® scripts.

On April 19, 2005, Rudy Liedtke, the owner of RJL Systems, was convicted of 18 U.S.C. § 371 - Conspiracy to commit an offense against the U.S.

In April, 2005, Serono executives Mary Stewart, former Vice President of Sales; John Bruens, former Vice President of Marketing; Melissa Vaughn, former Regional Sales Director; and Marc Sirockman, former Regional Sales Director, were indicted in the District of Massachusetts on charges relating to offering kickbacks to doctors in the form of a trip to a medical conference in Cannes, France, in exchange for writing additional prescriptions of Serostim®.

Vaughn was charged with one count of 18 U.S.C. § 371 - Conspiracy; and two counts of 42 U.S.C. § 1320a-7(b) - Offering to pay illegal remunerations for causing the offers to two doctors in Florida.

Sirockman was charged with one count of 18 U.S.C. § 371 – Conspiracy; and two counts of 42 U.S.C. § 1320a-7(b) - Offering to pay illegal remunerations, for offering the trip to a doctor in New Jersey and causing the offer to be made to another doctor in New Jersey.

On October 17, 2005, Serono was convicted of 18 U.S.C. § 371 - Conspiracy to introduce into interstate commerce, with intent to defraud or mislead, adulterated medical devices; and one count of 18 U.S.C. § 371 - Conspiracy to offer and pay illegal remuneration. Serono was ordered to pay a \$136,935,000 criminal fine and to repay \$567,065,000 to the government to settle civil liabilities in connection with fraud upon the Medicare and Medicaid systems.

On the day of Serono's conviction, Attorney General Alberto Gonzales and U.S. Attorney for the District of Massachusetts Michael Sullivan announced the investigation's findings, as well as the \$704 million settlement, at a press conference in Washington, DC.

Smuggling, Selling, and Distributing hGH

Extensive Investigation Resulted in Conviction of 6 Individuals

This investigation was initiated in October 2002, based on information received by the Department of Homeland Security's Immigration and Customs Enforcement (ICE), Blaine, Washington. During the course of its investigation, FDA learned that Darrellene Lowery and her associate, Lawrence Neri, were involved in purchasing and distributing hGH at the Bellingham Health and Fitness Gym, Bellingham, Washington, and David Thomas of Seattle, Washington, was illegally supplying hGH.

On June 27, 2003, Lowery was arrested in Ferndale, Washington. She admitted that she used steroids and hGH and that she had gone to Mexico on several occasions for the purpose of smuggling steroids into the U.S.

On July 7, 2003, Thomas was arrested in Seattle, Washington. During a search of his vehicle, hypodermic needles, steroid price list sheets, one vial of Cynomel, one vial of Deposterona, one vial of Norandren-200, and one bottle of Reforvit Simple were seized. The vials all bore Spanish labels and indicated they originated from Mexico.

FDA learned that Robert Sutton supplied drugs. Further inquiries revealed that Sutton and his associate Melanie Meo used a P.O. Box in Lynwood, Washington, to conduct their illegal drug business. Assistance was received from the Drug Enforcement Administration, Blaine, Washington, and U.S. Postal Service (USPS), Seattle, Washington. USPS learned that Sutton and Meo received many foreign and unusual packages at that mailing address.

On September 23, 2003, Thomas was convicted of violating 1 count of 21 U.S.C. § 331 (e)(1) and 18 U.S.C. § 371 - Conspiracy to Distribute hGH. Both Neri and Thomas were convicted of violating 1 count of 21 U.S.C. § 352 - Sale of a Misbranded Drug.

On December 18, 2003, Neri was sentenced to 15 days incarceration. Lowery was sentenced to time served and 3 years probation.

On December 29, 2003, Thomas was sentenced to 30 days incarceration.

On February 6, 2004, a package destined for Meo was opened pursuant to a federal search warrant. The package contained a large quantity of veterinary medicine and unapproved steroid drugs from Mexico. The street value of these drugs was estimated at approximately \$60,000 to \$80,000.

Sutton admitted that he was the largest anabolic steroid and hGH dealer on the West Coast. Sutton admitted to selling approximately 1,500 boxes of hGH, including counterfeit hGH, to individuals throughout the U.S. Sutton received the prescription medicines, veterinary medicines, hGH, and anabolic steroids from Mexico, India, China, Iran, Pakistan, and Europe.

On February 9, 2004, Meo was arrested after she arrived at her residence in Washington. Meo admitted that she assisted Sutton in delivering hGH and anabolic steroids.

FDA learned that Adolfo Torres (in Mexico) supplied drugs. On March 5, 2004, Torres was arrested subsequent to the issuance of an arrest warrant at George Bush International Airport in Houston, Texas, after he entered the U.S. (in transit) bound for Spain.

The defendants were convicted for their parts in the scheme and received various terms of incarceration and probation.

Prescription Drug Marketing Act

Owners of Pharmacy Found in Violation of Prescription Drug Marketing Act

Investigation Disclosed Large Scheme of Selling Physician Drug Samples

This case originated as a result of an investigation in a federal search warrant was executed at a pharmacy in Philadelphia, Pennsylvania. That investigation revealed that many of the physician drug samples seized had been provided by Bruce Goldberg.

On December 14, 2000, subpoenas for Goldberg were issued for exemplars of his handwriting, and business records for Marcus Foster Pharmacy and K & A Pharmacy, both owned by Goldberg.

Kenneth Walsh and William Szymanski were Searle Sales Representatives. Goldberg paid \$7,500 to Walsh and \$1,000 to Szymanski for drug samples.

On October 8, 2004, Szymanski was convicted of violating 21 U.S.C. §§ 331(k) and 352(a) - Introduction of Misbranded Drugs While Held for Sale, and was sentenced to 36 months probation, a \$2,500 fine, and ordered to pay \$6,000 in restitution.

On January 26, 2005, Walsh was convicted of violating 21 U.S.C. §§ 331(t), 333(b)(1)(B), and 353(c) - Illegal Distribution of Prescription Drug Samples. He was

sentenced to 4 years probation, 6 months home detention with an electronic monitoring device, \$19,500 in restitution, and a \$5,000 fine.

On May 11, 2005, Bruce Goldberg was sentenced to 3 years probation, and fined \$25,000. Goldberg was previously convicted of violating 21 U.S.C. §§ 331(t) and 333(b)(1)(B), and 353(c) - Sale of Drug Samples; and 18 U.S.C. §§ 371 and 1347 - Conspiracy to Commit Health Care Fraud.

Violation of Prescription Drug Marketing Act

**Drugs Were Purchased at Hospital
Discount Prices - Then Sold for Profit**

This case was initiated in June 2003, based on information received from the HHS/OIG that Robert F. Kwasniewski, was a part-time pharmacist employed at the Lake Area

Hospital in Webster, South Dakota. He purchased prescription drugs for his pharmacy, Cornwell Drugs, using the Lake Area Hospital's 503(c) exemption.

On July 8, 2003, an investigation conducted by the Sioux Valley Regional Health Services (SVRHS), Sioux Falls, South Dakota, determined numerous prescription drugs (Prevacid, Ipratropium) were ordered by Kwasniewski for use at the Lake Area Hospital and paid for with Lake Area Hospital's 503(c) exemption.

These drugs were then diverted to Cornwell Drugs by Kwasniewski. All of these prescription drugs/medications that were purchased used the hospital's 503(c) exemption. This exemption was to be used only by hospitals or health care entities for drug purchases. It allowed Kwasniewski to purchase drugs at a fraction of the Average Wholesale Price. Kwasniewski pocketed the difference making a huge profit for himself and Cornwell Drugs.

In June 2003, during the investigation, Kwasniewski admitted ordering drugs from SVRHS suppliers and setting them aside when they were delivered to the Lake Area Hospital pharmacy. Kwasniewski ordered the drugs from the hospital because the cost was much lower than non-503(c) suppliers. Kwasniewski paid cash for the drugs he ordered. Inventory records from the Cornwell Drugs suppliers indicated that Kwasniewski did not purchase any high-priced drugs from his suppliers. At no time did Kwasniewski pass on savings to his drug customers.

On July 23, 2003, HHS served administrative subpoenas upon a Minnesota firm and a South Dakota firm, requesting documents, print media, electronic files, and correspondence relating to the sales of pharmaceuticals from companies to Cornwell Drug and/or Kwasniewski. This request also included contracts, billing information,

invoices, and other documents from 1998 to the present.

On March 25, 2005, Kwasniewski was convicted of violating 21 U.S.C. §§ 331(t), 353(c)(3)(A) and 333(a)(1) - No person may sell, purchase, or trade, or offer to sell, purchase, or trade any drug which was purchased by a public or private hospital or other health care entity. Kwasniewski was ordered to pay a total of \$83,323 in restitution, \$57,074 to the manufacturer of the drugs, TAP Pharmaceuticals, and \$25,724 to HHS/OIG.

Convictions for Sale of Prescription Drug Samples

**Pharmaceutical Sales Representative
Caught Selling Physician Drug
Samples to Pharmacist**

This case involved a pharmaceutical sales representative selling physician drug samples to a pharmacist. It was a joint investigation that began in January 2001, and was conducted by OCI with the assistance of the FBI. The case was initiated from information received from the New Jersey Lumberton Township Police Department, New Jersey Medford Township Police Department, and the State of New Jersey, Department of Law and Public Safety, Division of Consumer Affairs, Enforcement Bureau.

Information provided by these law enforcement organizations revealed that Richard Small, a former pharmaceutical sales representative for Boehringer Ingelheim, was arrested for stealing physician drug samples from doctor's offices in Burlington County, New Jersey.

Small's problems began when his employment with Boehringer Ingelheim was terminated. Small began to experience financial problems and devised a scheme in which he would return to the doctor's offices he used to service and continue to purport himself as a Boehringer Ingelheim pharmaceutical sales representative. However, instead of dropping off physician drug samples he began stealing them. This illegal activity continued until a couple of area medical practices noticed what Small was doing and reported it to the local authorities, which led to his arrest by the Lumberton Township Police Department. Small subsequently confessed to stealing the samples and then selling them to New Jersey pharmacist, Daniel Shack.

Shack owned and operated Eastern Professional Pharmacy in Trenton, New Jersey. Shack confessed to his illegal conduct.

On August 25, 2004, Small was convicted of violations of 18 U.S.C. § 371 – Conspiracy to Defraud the U.S. Government, and 21 U.S.C. § 333(b)(1)(B) – Sale or Trade of Physician Drug Samples.

On May 19, 2005, Shack was convicted of violations of 18 U.S.C. § 371 -Conspiracy to Defraud the U.S. Government; and 21 U.S.C. § 333(b)(1)(B) – Sale or trade of physician drug samples.

On June 6, 2005, Small was sentenced in the District of New Jersey, Trenton, New Jersey, to 4 years probation and ordered to pay a fine of \$1,000.00.

On September 19, 2005, Shack was sentenced in the District of New Jersey, Trenton, New Jersey, to 3 years probation and was ordered to pay a fine of \$5,000.00. He was also ordered to perform 150 hours of community service.

Pediatrician Billed Patients for Prescription Drug Samples

This investigation involved allegations that Dr. Suvarna Shah, a pediatrician, Norwalk, Connecticut, was selling various prescription drug samples to her patients and then billing Medicaid and private insurance carriers for the samples. In addition, Dr. Shah was also billing Medicaid for free prescription drug vaccines she received from the Vaccine for Children's Program administered by the State of Connecticut, Department of Public Health. Dr. Shah also failed to report to the IRS cash payments she received as payment for her medical services.

In December 2002, search warrants were executed at Dr. Shah's office, Norwalk, Connecticut, and on three safe deposit boxes Dr. Shah maintained. Records, documents, and \$758,000 in cash were seized.

On May 20, 2004, Dr. Shah was convicted of violating 18 U.S.C. § 1347 – Health Care Fraud; and 26 U.S.C. § 7201 – Tax Evasion. On June 29, 2005, Dr. Shah was sentenced to 3 years probation, ordered to pay restitution in the amount of \$831,565.74, and fined \$10,000.

This was a joint investigation with the FBI's Health Care Fraud Task Force, New Haven, Connecticut, the IRS' Division of Criminal Investigations, New Haven, Connecticut, and HHS/OIG, Hartford, Connecticut.

Pharmacy Found Violating Prescription Drug Marketing Act

Physician Drug Samples Were Sold at Defendant's Pharmacy, Then Billed to Medicaid and Blue Cross/Blue Shield

This investigation focused on Mark Kaploe, Owner, Rosedale Pharmacy, Detroit, Michigan, who was selling

pharmaceutical drug samples he received. Kaploe then repackaged these samples and sold them at his pharmacy.

On October 18, 2001, search warrants were executed at Rosedale Pharmacy and Kaploe's residence. Numerous pharmaceutical drug samples and empty drug sample packaging were seized at both locations. During the searches, Kaploe was interviewed and admitted to obtaining sample pharmaceutical drugs and dispensing them from his pharmacy.

Kaploe's source admitted to providing drug samples to Kaploe, but stated that he thought Kaploe was giving the drug samples to indigent customers at his pharmacy. FDA learned that Kaploe removed the samples from the packaging, and subsequently took the drugs to his pharmacy where he dispensed them.

An audit was conducted by Blue Cross/Blue Shield of Michigan, and the State of Michigan Medicaid Program of claims filed by Rosedale Pharmacy for prescription drugs. The audit focused on the most commonly found drug samples and drug sample packaging found in FDA's investigation during the search warrants, which were billed to Blue Cross/Blue Shield and Medicaid. The audit identified a loss of \$64,000 to Blue Cross/Blue Shield and \$16,000 to the State of Michigan Medicaid Program.

On November 9, 2004, Kaploe was convicted of violating 18 U.S.C. § 1347 - Health Care Fraud.

On March 29, 2005, Kaploe was sentenced to 180 days home confinement, 3 years probation, ordered to make restitution in the amount of \$64,000 to Blue Cross/Blue Shield of Michigan and \$16,000 to the State of Michigan Medicaid Program. This was a joint investigation with the FBI.

Illegal Distribution of Prescription Drug Samples Resulted in Prison Sentence

FDA learned that Mark Rubin was offering to sell prescription drugs at 60% of the Average Wholesale Price. Rubin was the Owner/Operator of Summerdale Pharmacy located in Philadelphia, Pennsylvania. Rubin made several of these sales during March 2000.

On September 26, 2000, federal search warrants were executed at Rubin's residence and at the pharmacy.

On January 11, 2005, Rubin was convicted of violating 18 U.S.C. §§ 371 and 1347 - Conspiracy to Commit Health Care Fraud; and 21 U.S.C. §§ 331(t), 333(b)(1)(B), and 353(c) - Illegal Distribution of Prescription Drug Samples.

On May 13, 2005, Rubin was sentenced to 12 months and 1 day incarceration; 3 years supervised release, and ordered to pay a \$75,000 fine.

In addition, there were other multiple defendants associated with this investigation.

Andrew Poulshock, D.O., sold prescription drug samples to Rubin and was paid \$50,000. On October 12, 2004, Poulshock was convicted of violating 21 U.S.C. §§ 331(k) and 352(a) - Introduction of Misbranded Drugs While Held for Sale. On January 10, 2005, Poulshock was sentenced to 36 months probation, 5 months of home confinement with electronic monitoring, and a \$30,000 fine.

Philip Lipson, D.O., received and illegally sold prescription drug samples to Rubin. On January 13, 2005, Lipson was convicted of violating 21 U.S.C. §§ 331(t), 333(b)(1)(B), and 353(c) - Illegal Distribution of Prescription Drug Samples. On June 22, 2005, Lipson was sentenced to 6 months home detention, and a \$40,000 fine.

Richard Koff, M.D., sold prescription drug samples to Rubin. On January 27, 2005, Koff was convicted of violating 21 U.S.C. §§ 331(t), 333(b)(1)(B), and 353(c) - Illegal Distribution of Prescription Drug Samples. On May 5, 2005, Koff was sentenced to 4 years probation, 6 months home detention with electronic monitoring, and a \$20,000 fine.

Unapproved Drugs

Smuggling Pharmaceuticals into U.S. from Mexico

Smuggling of Unapproved Rx Drugs from Mexico Resulted in Death

This investigation began because of a pharmaceutical drug-related overdose death of a Snohomish County woman who purchased drugs from the defendants in this case. The defendants were engaged in a conspiracy to smuggle pharmaceuticals into the U.S. from Mexico and distribute them in the Snohomish County, Washington area. The pharmaceuticals involved included OxyContin, Percocet, Percodan, Vicodin, Lortab, and Soma.

The investigation determined that Troy Queen, Donna Chambers and Gary Chambers were making bi-weekly trips from Washington State to Tijuana, Mexico, to acquire

the drugs. The pharmaceuticals were obtained from Tijuana pharmacies and smuggled into the U.S. Travel records confirmed that the defendants made numerous trips on Alaska Airlines and Amtrak from Washington State to San Diego, California.

In July 2004, a search of the defendants' residence(s) uncovered a large quantity of assorted pharmaceutical drugs, along with cash and firearms. Queen was taken into custody immediately. Donna Chambers and Gary Chambers fled Washington State and were subsequently arrested two weeks later.

On June 30, 2005, Queen was convicted of violating 21 U.S.C. § 331(a) – Distribution of Misbranded Drugs. Queen was sentenced to one year probation. Donna Chambers was convicted of 21 U.S.C. § 841 – Distribution of a Controlled Substance. Donna Chambers was sentenced to 2 years probation.

Gary Chambers died of natural causes before his criminal case could be adjudicated.

This was a joint investigation with the Snohomish Regional Drug Task Force.

Physician Found Using Unapproved Drug in Treatment of Varicose Veins

**Court Ordered Defendant to Pay
\$150,000 Restitution under
False Claims Act**

This case originated based on information provided by HHS/OIG. HHS reported that Dr. Mark Isaacs was advertising the use of Sotradecol, an unapproved drug, in the treatment of varicose veins. Isaacs' advertisement appeared on his web site, Northern Vein Specialists of California.

The web site stated that sodium tetradecyl sulfate (STD) was not approved by FDA and Dr. Isaacs continued to import STD directly from England, because he felt "it is [was] the best solution for treating varicose veins."

A review of records revealed that Dr. Isaacs billed Medicare for 62 surgeries, for which Medicare refused to pay, since the drug was unapproved.

FDA's CDER advised there was no approved drug containing STD. A manufacturer, Elkins-Sinn, had the only current NDA in the U.S. for STD under the brand name Sotradecol. Elkins-Sinn stopped manufacturing Sotradecol in September 1991.

FDA's review of Dr. Isaacs' brochure explaining the sclerotherapy procedure found no mention of Sotradecol in the material. FDA learned that former patients believed the solution was a saline solution, and none of them recalled any discussion about FDA approval. FDA also learned that a videotape on the solution was only shown to

the patient at the initial consultation, which also included an ultrasound of the veins, a treatment plan, and discussion of cost and insurance.

In 2003, during the investigation, Dr. Isaacs stated that patients were given a 3-page evaluation, brochures, and documents explaining the sclerotherapy procedure and a written estimate of the cost. Regarding the use of Sotradecol, Dr. Isaacs stated patients were given a general explanation of what it was and that, since it was no longer manufactured in the U.S., the solution he used was imported from England. Dr. Isaacs stated Sotradecol was a Wyeth product that was no longer manufactured in the U.S. He imported a product called Fibrovein directly from England. Dr. Isaacs stated he was informed by his malpractice insurers that the use of this unapproved generic form of a drug was acceptable, and it could be used legally if the patient was informed of its use and provided consent to its use.

Dr. Isaacs voluntarily provided a copy of a videotape that was shown to patients during the initial consultation visit. The videotape stated the solution used by Dr. Isaacs in the treatment of varicose veins was Sotradecol and did not mention the use of Fibrovein.

On March 8, 2005, Dr. Isaacs was convicted of violating 1 count of 21 U.S.C. §§ 331(d) and 333(a)(1) – Introduction into Interstate Commerce of an Unapproved Drug. He was sentenced the same day to 1 year probation, and was ordered to pay \$5,000 in court fines and \$150,000 restitution under the False Claims Act.

"Mesotherapy" Treatment Results in Hospitalization of 16 People

Defendant Provided Treatment by Injection of Products into Human Body to Burn Fat and Reduce Body Volume

This investigation was initiated based on a complaint received in December 2004 from Puerto Rico. The complainant alleged that Felicita Ilarraza-Pantojas was engaged in providing a treatment called “Mesotherapy,” which consists of injecting products into the human body to burn fat and reduce body volume. As a result of the therapy, 16 people were hospitalized suffering severe health problems.

FDA’s search uncovered a large number of used and unused syringes, syringes containing a clear substance, unapproved drugs, and some prescription drugs.

On May 6, 2005, Ilarraza-Pantojas was convicted of violating 21 U.S.C. § 331(k) - Misbranding of Drugs.

On August 26, 2005, Ilarraza-Pantojas was sentenced to 4 months incarceration and 1 year of supervised release.

Illegal Sale of DNP Capsules

This investigation originated with a referral from FDA's Detroit District Office concerning the hospitalization of an individual from Michigan. The victim, in an attempt to lose weight quickly, purchased the unapproved substance known as DNP. Communicating with the e-mail address Flex-It@Ziplip.com, the victim purchased the DNP tablets from an individual subsequently identified as Joseph F. Pavlik. After digesting several of the tablets over a 3-day period, the victim was rushed to a hospital suffering from tachycardia, flushing, and profuse sweating.

Payment for the DNP was mailed to a P.O. Box in Strongsville, Ohio. Pavlik, of Strongsville, Ohio, received monthly deliveries of DNP. Pavlik admitted his personal use of, and the sale of DNP capsules, and was subsequently arrested.

This was a joint investigation with U.S. Postal Service.

Osteopath Found Administering Intravenous Laetrile Treatments to Cancer Patients

This investigation was initiated in May 2002, based on a consumer complaint to FDA's Cincinnati District Office regarding Dr. Jack Edwin Slingluff, Canton, Ohio, a licensed osteopath. The complaint alleged that Dr. Slingluff was administering intravenous Laetrile treatments for cash to a cancer patient now deceased.

In August 2002, while at Lake Cable Medical Center, his medical practice in Canton, Ohio, Dr. Slingluff confirmed that he administered Laetrile treatments to his patients but required them to obtain their own Laetrile. FDA reviewed a paper entitled "Laetrile Order Info" which contained the name Betty Miller, a telephone number, and a company name of Healthy Options, and later a Laetrile package with a return address listing a post office box located in West Palm Beach, Florida.

In October 2002, U.S. Postal Service records were reviewed and it was determined that the post office box listed on the package was registered to Marilyn Norton in Florida.

On January 30, 2003, three federal search warrants were served for Dr. Slingluff's medical practice, Norton's business address, and Norton's residence. During the

search at Norton's residence, she advised that she had been in business for approximately two years, that she was aware that Laetrile was used for the treatment of cancer and that she has been involved with Laetrile for approximately 30 years as her former husband, Steven Michaelis (deceased) also sold Laetrile. After the warrant, it was determined that Norton was the mother of Kenneth Michaelis who had been previously prosecuted. Kenneth Michaelis was convicted of two felony counts of distributing the unapproved new drugs Laetrile and Hydrazine Sulfate.

In March 2004, Dr. Slingluff was convicted of violating 21 U.S.C. §§ 331(d), 355(a) and 333(a)(1) - Interstate Distribution of an Unapproved New Drug.

In May 2004, Dr. Slingluff was sentenced to serve 1 year supervised probation.

In April 2005, Norton was convicted of violating 18 U.S.C. § 371 – Conspiracy; 21 U.S.C. §§ 331(p) and 333(a)(1) - Failure to Register a Drug Manufacturing Facility; and 21 U.S.C. §§ 331(a), 333(a)(1) and 352 – Introduction into Interstate Commerce of a Misbranded Drug. Norton was sentenced to serve 2 years supervised probation.

Illegal Sale of Nitrous Oxide

Defendant Found Selling Nitrous Oxide for Recreational Purposes
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The investigation involved an allegation that Chad Beauchamp was selling nitrous oxide for recreational use. Invoices subpoenaed from a welding supply firm showed that approximately 476 medical grade nitrous oxide cylinders were sold to Beauchamp, d/b/a B & B Headshop. Tests of the nitrous oxide indicated that the nitrous oxide was medical grade.

On June 20, 2002, a search warrant was executed and Beauchamp's nitrous oxide cylinders and related equipment were seized.

On May 25, 2005, in the Eastern District of Michigan, Beauchamp was convicted of one felony count of 18 U.S.C. § 1623 – False Declaration.

On September 22, 2005, in the Eastern District of Michigan, Beauchamp was sentenced to 5 years probation, the first 5 months of which are to be served in a "halfway house" so may continue his employment. Beauchamp was sentenced to serve the subsequent 5 months in home confinement.

Pharmaceutical Firm Found Altering Methods to Manufacture Cefaclor - Falsifying Records

The case against Biochimica OPOS (OPOS) was initiated in 1997, based on a referral from FDA's Center for Drug Evaluation and Research (CDER). FDA learned that OPOS, an Italian manufacturer of bulk active pharmaceutical ingredients, had falsified FDA submissions related to the locations and methods they used to manufacture Cefaclor and other drug products. CDER directed that an inspection be conducted on-site at OPOS' facility in Agrate Brianza, Italy, where evidence of falsified production records was discovered.

The investigation uncovered 3 specific crimes committed during OPOS' manufacture of Cefaclor. First, the company subcontracted out the manufacture of one intermediate ingredient to another company. Second, OPOS subcontracted out the manufacture of 2 additional intermediates to the other company, which it was not allowed to do under its own drug master file. Finally, OPOS substituted a required chemical in the processing of Cefaclor with a different, unapproved chemical. The investigation revealed Luigi Ratti controlled both OPOS and the other company and would make 5% of the profits realized by OPOS.

On October 19, 2001, Aventis Pharmaceuticals, Inc., a parent company, and OPOS, was convicted of violating 18 U.S.C. § 371 – Conspiracy and 21 U.S.C. § 331(a) - Distribution of Adulterated Drugs. The company was sentenced to pay a criminal fine of \$23,193,660 and to voluntarily forfeit \$10,000,000 to the U.S.

The investigation into the people who were behind the conspiracy continued. The investigation revealed that Ratti orchestrated the creation and maintenance of false records that were used to mislead FDA during its inspections of OPOS. The documents stated the drug was manufactured in accordance with the company's FDA submissions, but concealed the fact that elements of the manufacture had been subcontracted out to another Ratti-controlled corporation and a Romanian firm that were not authorized to conduct those steps. Those documents also concealed the fact that an unapproved chemical was used in the process of making Cefaclor.

On July 16, 2003, Ratti, former President and Chief Executive Officer of OPOS, was named in a sealed indictment. The indictment listed 12 charges, including shipment of adulterated drugs in interstate commerce, making false statements, wire fraud and conspiracy. A warrant was issued for his arrest, but Ratti remained an Italian citizen residing in Switzerland.

On March 30, 2004, Ratti attempted to enter the U.S. at the Miami International Airport, and was arrested and placed in the custody of the U.S. Marshals Service. On

April 1, 2004, Ratti was detained without bond and extradited to the District of Maryland.

Eventually, on May 2, 2005, Ratti was convicted of violating 21 U.S.C. §§ 331(d) and 333(a)(2) – Introduction or Delivery into Interstate Commerce an Unapproved Drug. Ratti was sentenced to 1 month and 2 days incarceration, 12 months of home detention, pay a criminal fine of \$16,481,000, and forfeit \$300,000 to the U.S. government.

Physician at Weight-Loss Center Distributed Phentermine

Physician Distributed Phentermine to Physicians in Other States Under Guise of Clinical Study Without Approved NDA

The investigation of Robert Keenan, M.D., was based on information received by FDA's CDER. In 2001, Keenan had obtained bulk phentermine hydrochloride from a supplier in Wyoming. He manufactured the phentermine into capsules and distributed those capsules to numerous physicians in interstate commerce.

The investigation revealed that Dr. Keenan operated weight-loss centers in Towson and Columbia, Maryland, where he prescribed and dispensed phentermine to his own patients. At the same time, Keenan distributed the medication to other physicians in other states under the guise of a clinical study, without an approved IND. Keenan obtained the bulk phentermine from a colleague in Minnesota, and manufactured 30mg and 37.5mg capsules at a local culture media manufacturing firm by using an encapsulation machine. Keenan refused all of FDA's attempts to inspect his encapsulation operation, claiming it constituted "physician compounding" and was thus exempt from FDA jurisdiction.

FDA determined that Keenan was conducting a manufacturing operation and distributing an unapproved new drug in interstate commerce.

In 2003, search warrants were executed for Keenan's weight-loss center in Towson, Maryland, the culture media manufacturing firm in Baltimore, Maryland, and a weight-loss center in Minnesota, where evidence of the illegal manufacture of phentermine capsules was found and seized.

In January 2004, the Baltimore City Police Department received information regarding an illegal MDMA (Ecstasy) manufacturing organization operating in the southeastern district of Baltimore, Maryland. The organization used at least two locations in the operation, one of which was a condominium owned by Keenan. Search warrants were conducted at these locations and the evidence seized included

large quantities of phentermine powder, precursor chemicals and paraphernalia used in the manufacture of MDMA, and over 1,000 dosage units of Valium. Four individuals, including Keenan, were arrested.

Shortly thereafter, a second search warrant executed for Keenan's weight-loss clinic in Towson, Maryland, revealed additional evidence of the illegal manufacture of phentermine and MDMA.

On April 25, 2005, Keenan was convicted by jury of violating 21 U.S.C. § 846 - Conspiracy to Manufacture MDMA (Ecstasy) and Attempting to Manufacture MDMA.

On June 30, 2005, Keenan was sentenced to 84 months incarceration, and 3 years supervised probation.

This was a joint investigation with the Drug Enforcement Administration and the Baltimore City Police Department.

Illegal Distribution of Dietary Supplement Containing Tiratricol

This investigation was initiated based on a referral from FDA's Cincinnati District Office. A Cincinnati-based fitness products firm named Pinsons Fitness Products was engaged in fraudulent activity involving the production and distribution of weight loss products containing the active ingredient Tiratricol. Pinsons Fitness Products was owned and operated by Phillip R. Henson out of his residence in Ohio.

On November 11, 1999, FDA issued a warning to consumers against the consumption of products containing the active ingredient Tiratricol. FDA noted that several products containing Tiratricol were being marketed as dietary supplements for weight-loss purposes. The warning identified two specific companies that were ordered to discontinue marketing products that contained Tiratricol, to include Syntrax Innovations and Pharmatech. Both companies complied with the request and discontinued manufacturing products containing Tiratricol.

On December 13, 2001, a search warrant was executed for Pinsons Fitness Products, Cincinnati, Ohio. During the execution of the warrant, products, documents, and computers were seized from the business and residence.

As a result of information obtained during the search warrant, it was determined that between June 6, 2000 and December 11, 2001, Henson sold approximately 57,240

pills containing Tiratricol to customers located throughout the world and collected approximately \$30,144 from those sales.

On January 29, 2002, FDA sent an informational letter to customers that had purchased products containing Tiratricol from Henson over the last 4 months. This letter was sent to warn consumers against the consumption of products containing Tiratricol and the hazards associated with such consumption.

On August 16, 2004, Henson was convicted of violating 21 U.S.C. § 331(a) - Introduction of a Misbranded Drug into Interstate Commerce.

On March 30, 2005, Henson was sentenced to 9 months home confinement with electronic monitoring, and 3 months supervised release.

Center for Food Safety and Applied Nutrition

Adulterated Food

Conviction and \$1 Million Fine for Extensive Rodent Infestation

In March 2005, the U.S. Attorney's Office, Chicago, Illinois, provided information to OCI regarding an investigation by USDA's Food Safety and Inspection Service (FSIS). The investigation involved Certified Grocers Midwest (CGM), a grocery cooperative, Hodgkins, Illinois.

Several inspections were conducted at CGM by USDA's FSIS and FDA. During these inspections, a large infestation of mice was discovered. In addition to the mice, birds and cats were also discovered roaming the warehouse.

On March 7, 2005, USDA's FSIS provided copies of numerous documents the Agency obtained and created during the investigation of CGM. In addition, several FDA District employees were interviewed regarding the details of FDA's inspection. A video was also provided, which showed several live and dead mice, numerous baby mice, and adulterated food.

On March 29, 2005, CGM and Theodore Clinnin, the former Vice President of Operations of CGM, were charged with 1 count of violating 21 U.S.C. § 458(a)(3) and § 461(a); 21 U.S.C. § 610(d) and § 676(a); and 18 U.S.C. § 2 - Storing Poultry and Meat Products under Unsanitary Conditions. In addition, CGM and Clinnin were also charged with 1 count of violating 21 U.S.C. §§ 331(b), 333(a)(1), 342(a)(4), and 18 U.S.C. § 2 - Adulteration.

On April 5, 2005, both CGM and Clinnin were convicted.

On June 14, 2005, CGM was sentenced to pay a \$1,000,000 fine and 5 years probation for the extensive rodent infestation and threat to public safety. Clinnin was fined \$1,000 and sentenced to 6 months unsupervised probation.

Poultry Products Found Contaminated with Ammonia

Tainted Food Delivered to Elementary School in Illinois
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This case began when the OCI Chicago Field Office was contacted by the U.S. Department of Agriculture, Office of Inspector General, (USDA-OIG), St. Louis, Missouri, in reference to an ongoing investigation they were conducting in conjunction with the Food Safety Inspection Service (FSIS). The investigation involved an ammonia leak at the Gateway Cold Storage, St. Louis, Missouri, which occurred on November 19, 2001. As a result of the ammonia leak, certain food products became contaminated with high levels of ammonia.

USDA-OIG and FSIS investigation determined that Lanter Refrigerated Distribution Company Inc. (LRD), Granite City, Illinois, improperly re-boxed/re-labeled the tainted food that which was ultimately delivered to the Laraway Elementary School in Joliet, Illinois, causing approximately 43 students and staff to become ill and/or hospitalized.

On February 24, 2005, Edward Wuebbels, Operations Manager of LRD, was convicted of one count of 18 U.S.C. § 371 - Conspiracy to Defraud the U.S.; 21 U.S.C. §§ 458(a)(2) - Transportation of poultry products in commerce not properly inspected and with the intent to defraud; and 18 U.S.C. § 1001 - False Statements.

On March 8, 2005, Stephen Lanter, President, LRD, was convicted on behalf of the corporation in U.S. District Court, Southern District of Illinois. The corporation was convicted of 21 U.S.C. § 458(a)(2) – Transportation of poultry products in commerce not properly inspected and with the intent to defraud.

LRD was also ordered to pay \$175,000 in community restitution, to be paid directly to the Laraway School District; \$275,400 in restitution, for the victims not yet compensated; a fine of \$102,000; and to serve one year probation.

On July 29, 2005, Wuebbels was sentenced to 1 year and 1 day incarceration, 3 years court supervision, 240 hours of community service, \$4,000 fine and \$200 special assessment.

Bribery

Importer of Food Products Bribed Federal Official

On June 8, 2004, information was received that a Consumer Safety Officer employed at FDA's Import Operations Group, Ontario, California, was offered a bribe by Ruddy Korompis, an importer of food products (edible bird nests/Asian delicacy) from Indonesia. Korompis offered the bribe in return for release of a shipment that was detained by FDA for adulteration.

On June 9, 2004, Korompis was arrested. On June 30, 2004, Korompis was indicted in the Central District of California for violation of 18 U.S.C. § 201(b)(1)(A) - Bribery of Public Officials.

On August 17, 2004, Korompis was convicted of the above violation.

On December 6, 2004, Korompis was sentenced to 6 months home detention, 2 years probation, and a \$2,000 fine.

Smuggling

Imported Produce Found Contaminated with *Salmonella Poona*

Smuggling of Contaminated Produce Resulted in \$2 Million Fine

Information was received from FDA's Center for Food Safety and Applied Nutrition (CFSAN) that adulterated food products were imported from Mexico via the Nogales, Arizona, Port of Entry during the months of April and May 2001.

The produce was distributed in seven states, and analysis revealed that they were contaminated with *Salmonella poona* bacteria. FDA information revealed that the produce was imported by Shipley Sales Service, Inc (Shipley), Nogales, Arizona. Lee Shipley was the export manager in Mexico. The produce imported by Shipley was then restricted by a Detention Without Physical Examination (DWPE) order.

Robert Shipley violated the DWPE, which also meant that U.S. Customs and Border Protection laws were violated. OCI requested the assistance of the Department of Homeland Security, Immigration and Customs Enforcement (ICE), to determine the extent of the violation. Subsequently, as a joint effort with OCI and ICE, 5 search warrants were executed simultaneously on the residence and business properties of Robert Shipley.

On November 12, 2002, based on the evidence recovered from the search warrants, Robert Shipley and his son, Lee Shipley, were indicted in a 67-count indictment. Charges included violations of 21 U.S.C. § 331 - Introduction of Adulterated Food; 18 U.S.C. § 371 - Conspiracy; 18 U.S.C. § 545 - Smuggling; and 18 U.S.C. § 982(a)(2)(B) - Criminal Forfeiture.

On January 10, 2005, Robert Shipley and Lee Shipley were each convicted of 1 count of 18 U.S.C. § 371 - Conspiracy; 19 U.S.C. § 1508 - Failure to Keep Records; and 18 U.S.C. § 545 - Smuggling. Both were sentenced to 4 years of federal probation and ordered to pay forfeiture in the amount of \$2,779,150.85.

Tampering

Needles Found in Sausages

On December 11, 2003, U.S. Department of Agriculture's Office of the Inspector General, Houston, Texas, requested assistance from OCI in the investigation of a food tampering case. The tampered food product was a packaged Hillshire Farms sausage that was reported to have had metal needles inserted into it. During the course of the investigation, Linda Allard confessed during a polygraph interview to placing the needles in the sausage.

On October 8, 2004, Allard was convicted by a jury of violating 1 count of 18 U.S.C. § 1365 - Tampering with Consumer Products.

On January 10, 2005, Allard was sentenced to 366 days incarceration, and 3 years probation.

**Gerber Baby Food Tampered with Boric Acid,
Splinters of Glass, and Hydraulic Fluid**

**Individual Who Tampered with
Foods Demanded 9,000 ATM Cards**

This case was initiated based on an extortion letter received at a Ralph's grocery store, Compton, California. The initial investigation identified the recipient of the extortion letter as the Ralphs/Kroger General Administrative Offices, Compton, California. The extortion letter arrived at the facility's mail room in a cardboard box that contained 4 consumer products identified as horseradish, Gerber carrot baby food, powdered baby food, and Gerber baby juice drink, alleged to have been tampered with boric acid, splinters of thin walled glass, and hydraulic fluid.

The letter advised that the tampered goods were not in the marketplace at the time, but could be introduced in an "all out assault" on all types of food and all manufacturers. The extortion letter indicated a subsequent mailing would identify demands and was signed, "Fun Boy Three." The parcel bore a Venice, California U.S. Postal Service, Priority Mail, serial number/receipt and postmark.

On the same day, Kroger Corporate Offices, Cincinnati, Ohio, received a copy of the same extortion letter signed, "Fun Boy Three." The postage affixed to the letter did not bear any type of postmark and/or cancellation process.

On March 1, 2004, a follow-up extortion letter was received at the Ralphs/Kroger General Administrative Offices, Compton, California, that demanded \$180,000 and a \$100,000 "penalty" if Ralphs/Kroger failed to proceed with payment as dictated. The extortionist demanded that Ralphs/Kroger issue 9,000 ATM cards, disguised in any format, for simultaneous distribution on March 26, 2004, to 3 specified Ralph's stores locations in the San Diego, Los Angeles, and San Francisco, California areas. Prior to the distribution, Ralphs/Kroger was to place an advertisement in the Los Angeles Recycler newspaper for a musical instrument, and within the advertisement, the Personal Identification Number (PIN) for the ATM card would be located, disguised as the "model" number. This PIN would then enable the extortionist to access the money anywhere in the world.

Subsequent forensic analysis of the food items by FDA confirmed the presence of the contaminants as threatened by "Fun Boy Three."

On May 5, 2004, a federal search warrant was executed at the residence of David Ian Dickinson, in California. Subsequent to the search warrant, Dickinson confessed to the tampering of food products and the extortion of Ralphs/Kroger Companies and was placed under arrest.

On November 30, 2004, Dickinson was convicted of violating 18 U.S.C. § 1951 - Interference with Commerce by Threats or Violence (Hobbs Act); and 18 U.S.C. § 1365 - Consumer Product Tampering.

On April 1, 2005, Dickinson a.k.a. "Fun Boy Three" was sentenced to 60 months incarceration on each count to run concurrently. Additionally, Dickinson was placed on supervised release for a period of 24 months.

Center for Veterinary Medicine

Illegal Sale of Veterinary Drugs

This investigation related to various misbranded and unapproved foreign injectable veterinary drugs that were being sold and distributed by Gilbert Leblanc in the Delaware, Ohio area.

On February 4, 2003, record checks conducted on Leblanc indicated that Leblanc was wanted on an outstanding warrant in South Carolina. Checks with Kershaw County, South Carolina, Parole and Probation, revealed that Leblanc attempted to run over a South Carolina police officer with a stolen vehicle in order to evade capture. Approval was received from South Carolina for the extradition of Leblanc if captured during the course of this investigation.

On February 10, 2003, Leblanc was located at the Delaware County Fairgrounds, Delaware, Ohio. He sold the prescription injectable drug Legend, and was subsequently arrested.

On September 20, 2004, Leblanc was convicted of violating 21 U.S.C. 331(k) – Introduction of a Misbranded Drug into Interstate Commerce while Held for Sale. On February 1, 2005, Leblanc was sentenced to serve 3 months confinement to the Alvis House and placed on probation for a term of 3 years.

The Lacey Act

Smuggling of Illegal Caviar

Firm Received Sentence of \$1 Million Criminal Fine for Violating Lacey Act

This case involved the smuggling of illegal caviar and the sale of adulterated and misbranded product throughout the U.S. Marky's Caviar, also doing business as

Optimus, Inc., purchased sturgeon caviar smuggled into the U.S. by couriers inside suitcases without a Customs and Border Protection declaration or U.S. Fish and Wildlife Service (USFWS) inspection. The investigation determined that the sturgeon caviar and other fish roe sold were adulterated and mislabeled. The caviar was adulterated by mixing Beluga caviar with less valuable caviar. The caviar was mislabeled by claiming it to be Russian caviar when it was Chinese.

On April 15, 2005, Optimus, Inc., doing business as Marky's Caviar, was sentenced to pay a \$1 million criminal fine into the Lacey Act Reward Fund, to adhere to a stringent wildlife compliance plan, and 5 years probation. The sentence was imposed on Optimus, Inc., for knowingly purchasing sturgeon caviar with false wildlife invoices, knowingly purchasing smuggled caviar, and failing to exercise due care in purchasing smuggled caviar.

This was a joint investigation with USFWS and Department of Homeland Security, Immigration and Customs Enforcement.

White Tail Deer Tranquilized – Then Killed

In February 2004, the Indiana Department of Natural Resources, Law Enforcement Division, contacted OCI and requested investigative assistance. Earlier, the Indiana Department of Natural Resources and U.S. Fish and Wildlife Service (USFWS) had executed three search warrants at locations owned by Russell G. Bellar, including Bellar's Place, Inc., a hunting preserve operated by Bellar and Hinds Thomas Jones, in Peru, Indiana. These warrants sought evidence of state (Indiana Code 44-22 et al) and federal (Lacey Act) game law violations.

It was determined that white-tail deer harvested at Bellar's Place, Inc., were tranquilized and then killed by hunters a short time later. This caused concern about adulterated deer meat entering the human food chain.

A subsequent investigation determined that the defendants had tranquilized the white-tail deer by injecting them with a mixture of the prescription new animal drugs

Telazol (Tiletamine Hydrochloride and Zolezapam Hydrochloride) and Sedazine (Xylazine Hydrochloride). They did so to facilitate loading the deer into trailers for transport to the hunting area. Then the defendants injected the deer with the prescription new animal drug Tolazine (Tolazoline Hydrochloride) to reverse the tranquilizing effects of the Telazol and Sedazine. This would restore the deer's ambulatory functions to provide a more realistic hunt.

Samples of meat taken from white-tail deer harvested at Bellar's Place, Inc., were forwarded to FDA. These examinations found the presence of Tiletamine Hydrochloride, Zolezapam, Hydrochloride, Xylazine Hydrochloride, and Tolazoline Hydrochloride.

None of these animal drugs are approved by FDA for use in food-producing animals. All are required to be dispensed by, or on the lawful written or oral order of, a licensed veterinarian in the course of his or her professional practice where a legitimate Veterinary Client Patient Relationship exists.

On July 14, 2004, a federal grand jury indicted defendants Bellar and Jones, charging each with 38 violations of federal laws including conspiracy to violate the Act.

On December 31, 2004, Jones was convicted of violating 1 count of 18 U.S.C. § 371 - Conspiracy to Violate the Lacey Act.

On January 11, 2005, after 8 days of trial, Bellar was convicted of violating 18 U.S.C. § 371 - Conspiracy to Violate the Act and the Lacey Act; and 16 U.S.C. § 372(a)(2)(A) - Lacey Act.

On April 26, 2005, Jones was sentenced to serve a 1 year term of probation and to pay a \$3,000 fine.

On May 6, 2005, Bellar was sentenced to serve 366 days incarceration to be followed by 2 years of supervised release. He was ordered to pay the government \$450,000 as a substitute for forfeiture of assets, to provide \$120,000 restitution to USFWS for reimbursement of investigative costs, and to pay a \$5,000 fine.

White Tail Deer Sedated - Illegally Transported to Texas

In March, 2005, the U.S. Fish and Wildlife Service (USFWS) contacted OCI's Chicago Field Office and requested investigative assistance. USFWS agents investigated Paul D. Papczynski, Indiana, and others, for violating federal game laws under 16 U.S.C. § 3371 (Lacey Act). The hunters poached white-tail deer from northern Indiana state parks, by placing bait on state park property to attract the deer.

They hunted at night over this bait using tranquilizer guns which fired darts loaded with prescription new animal drugs.

They used two-way radios to communicate and scanners to monitor Indiana Department of Natural Resources law enforcement radio frequencies. While one person hunted, another drove the roads continuously until the hunter radioed the driver that he tranquilized a deer. The driver then responded to a pre-arranged location, loaded tranquilized deer into the truck and relocated them to property owned by Papczynski.

Investigators learned that Papczynski and others shaved the necks of these deer to give the appearance that they received the TB tests required by Indiana law. Tuberculosis (TB) is a contagious disease to both animals and humans. It is caused by 3 specific types of bacteria that are part of the Mycobacterium group. Bovine TB, caused by *Mycobacterium bovis*, can be transmitted from animals to humans. No other TB organism has as great a host range as bovine TB, which can infect all warm-blooded vertebrates.

White-tail deer illegally taken by Papczynski and others had been introduced into interstate commerce by being sold to Texas. This was done at a time when Texas banned the importation of white-tail deer to prevent the spread of disease.

Papczynski admitted that he used "Sedazine" (Xylazine Hydrochloride) to "dart deer." He also admitted that he did not employ the services of a veterinarian, and that he did not receive the Xylazine Hydrochloride as the result of a prescription written by, or on the lawful order of, a licensed veterinarian.

On August 30, 2005, Papczynski was convicted in the U.S. District Court, Northern District of Indiana, to 16 U.S.C. § 3372(d) - Control of Illegally Taken Fish and Wildlife.

On December 1, 2005, Papczynski was sentenced in the Northern District of Indiana, South Bend to 4 months home detention, a \$4,000 fine, and to serve 3 years probation.

Health Care Fraud

OCI and FBI Uncovered Health Care Fraud

Medicare Paid over \$5 Million for Alleged Infusion Treatments of Neupogen® and Procrit®

This case was initiated based on a request for assistance from the FBI. Bolanos Institute and Lefebvre Institute allegedly billed Medicare for services and equipment

that patients never received.

Bolanos Institute was located in Miami Beach, Florida, and was in business from December 2001 until it closed in July 2003. Lefebvre Institute was also located in Miami Beach, Florida, and was in business from April 2002 until it closed in July 2003.

Both Bolanos and Lefebvre Institutes submitted claims to the Medicare program, seeking reimbursements for the cost of infusion treatments of Neupogen® and Procrit® that were supposedly provided to patients. Bolanos Institute was paid approximately \$3,700,000 and Lefebvre Institute was paid approximately \$1,600,000 in Medicare reimbursements based upon claims for the alleged treatments.

Leonardo Javier Bolanos owned and operated Bolanos Institute. He was also the registered agent for Lefebvre Institute and had signature authority on the business bank account.

Robert Peter Sauve assisted in the operation of Bolanos Institute. Further, he owned and operated Lefebvre Institute.

Alejandra Vanessa Carnaru was the Office Manager and Director at Bolanos Institute and handled the billing for the Bolanos and Lefebvre Institutes.

Joseph Shane Elliott was employed as the Office Manager at Lefebvre Institute and performed clerical duties. Further, he worked intermittently at Bolanos Institute.

Jorge Humberto Forcada, Clark Carlton Mitchell, and Jose Joaquin Vega are Medical Doctors licensed to practice medicine in the State of Florida. Forcada was the Medical Director at Bolanos and Lefebvre Institutes. Bolanos Institute billed Medicare under Forcada's provider numbers. Mitchell was employed by Lefebvre Institute and treated patients. Further, Mitchell was also the Medical Director at Bolanos Institute. Vega was employed at Bolanos Institute and treated patients. He was also the Medical Director at Lefebvre Institute.

Rebecca Nereyda Nunez and Orlando Amigo worked as Medical Assistants at Bolanos Institute. Nunez also worked at Lefebvre Institute.

On November 10, 2004, Nunez was convicted of violating 18 U.S.C. § 1347 – Health Care Fraud.

On November 12, 2004, Amigo was convicted of violating 18 U.S.C. § 1347 – Health Care Fraud.

On November 18 2004, Elliott and Carnaru were convicted of violating 18 U.S.C. § 1347 – Health Care Fraud. Carnaru was also convicted of violating 18 U.S.C. § 1956 - Money Laundering.

On February 4, 2005, Vega was convicted of violating 18 U.S.C. § 1347 – Health Care Fraud.

On February 28, 2005, Carnaru was sentenced to 47 months incarceration, and 3 years supervised release. Carnaru was also ordered to pay \$4,957,203 in restitution. Nunez was sentenced to 24 months incarceration, and 3 years supervised release. Nunez was also ordered to pay \$1,570,832 in restitution. Elliott was sentenced to 21 months incarceration, and 3 years supervised release. Elliott was ordered to pay \$1,476,077 in restitution.

On March 14, 2005, Amigo was sentenced to 6 months incarceration and 3 years supervised released. Amigo was ordered to pay \$400,000 in restitution.

On April 27, 2005, Mitchell and Forcada were convicted by jury for violating 18 U.S.C. §§ 371 and 1347 - Conspiracy and Health Care Fraud.

On May 31, 2005, Vega was sentenced to 51 months incarceration, and 3 years supervised release. Vega was ordered to pay \$2,951,524 in restitution.

On July 29, 2005, Mitchell was sentenced to 33 months incarceration, and ordered to pay \$803,838 in restitution. Forcada was sentenced to 39 months incarceration, 3 years supervised release, and ordered to pay \$3,743,853 in restitution.

As of mid-March 2006, Bolanos and Sauve remained fugitives from justice.