Office of Criminal Investigations

In Fiscal Year 2004, the efforts of FDA's Office of Criminal Investigations (OCI) resulted in 356 arrests and 188 convictions.

Center for Biologics Evaluation and Research

Doctor Found Diluting Vaccines

This investigation was initiated to review the activities of Dr. Wallace Gonsalves and pharmacy owner Anthony Albanese. Gonsalves was a Cranston, Rhode Island, based doctor who provided patients with diluted/adulterated vaccines and provided the Immigration and Naturalization Service with false documents relative to health/blood screenings of immigrant patients. Additionally, Gonsalves sold large quantities of drug samples to Albanese who subsequently distributed the samples through Cameron's Pharmacy, a business Albanese owns and operates.

On March 17, 2004, after a 3 week jury trial, Gonsalves was convicted by a jury on 31 felony counts including Title 18 U.S.C. 1365 - Tampering with a Consumer Product; Title 21 U.S.C. 331(k) - Adulteration of a Drug; Title 18 U.S.C. 1001 - False Statements; Title 26 U.S.C. 7201 and 2 - Making False Statements to the IRS; and Title 26 U.S.C. 7206 - Tax Evasion.

On September 14, 2004, Gonsalves was sentenced to 10 years incarceration for diluting vaccines administered to immigrant patients, and 5 years incarceration for each of the remaining 30 counts all of which are to be served concurrent to the imposed 10 year sentence. Gonsalves was ordered to pay $465,000 in restitution to patients to whom he administered diluted vaccines, and serve 5 years supervised release.

Also on September 14, 2004, Gonsalves was convicted of Title 18 U.S.C. 371 and Title 21 U.S.C. 331(t) - Conspiracy to Sell Drug Samples and Unlawful Sale of Drug Samples; and Title 18 U.S.C. 1347 - Health Care Fraud. Gonsalves was sentenced to 37 months incarceration to be served concurrently with the 10 year sentence. In addition, Gonsalves was ordered to repay $431,411 to health insurers that reimbursed Cameron's Pharmacy for the prescriptions that were filled with the free samples. Gonsalves was also fined $45,000.

On November 5, 2004, Albanese was sentenced to 37 months incarceration, forfeited $431,410 to the U.S. government and fined $45,000. Albanese was previously convicted of Title 18 U.S.C. 371 - Conspiracy; Title 21 U.S.C. 331(t) - Unlawful Sale of Drug Samples; Title 18 U.S.C. 1347 - Health Care Fraud; and Title 18 U.S.C. 1956 - Money Laundering.

The conviction was based on a scheme which diverted drug samples received by Gonsalves through Cameron's Pharmacy located at 2206 Broad Street, Cranston, Rhode Island. Between July 2000 and August 2002, Gonsalves sold Albanese samples of a variety of drugs, including Avandia, Prilosec, Vioxx, Lipitor, Celebrex and Paxil. Cameron's Pharmacy, in turn, sold 209,797 of the sample pills in prescriptions and then illegally received $431,410.62 from health insurers by filing fraudulent reimbursement claims.

This was a joint investigation with the Department of Health and Human Services' Office of the Inspector General, the Department of Homeland Security, the Internal Revenue Service, the Rhode Island Department of Public Health, and the Rhode Island Medicaid Fraud Control Unit.

Center for Devices and Radiological Health

Oxygen Chambers Used to Treat Autism

This case was initiated based on a referral from OCI's Kansas City Field Office. Information was developed relating to the manufacture and sale of unapproved devices without a 510(k) application by Ken Nix, President, Inland Divers, Inc., Broken Arrow, Oklahoma. During the investigation of Nix, information was developed that Gary Zack, owner of Michigan Neurologic and Wound Services, Saint Clair Shores, Michigan, purchased three hyperbaric oxygen chambers for his company. Zack was using the chambers to treat autistic and other brain damaged children. The chambers are not approved for these conditions.

In addition, a confidential informant alleged that Zack was forging his brother's name, Dr. Joseph Zajchowski, on prescriptions and administering treatment to the children without his brother's presence at the facility.

On April 3, 2003, Dr. Joseph Zajchowski was interviewed and denied having any knowledge of his brother signing his name to prescriptions. Dr. Zajchowski claimed that Zack does not operate the chambers when he is not at the facility.

On April 4, 2003, Zack admitted that he forged his brother's signature on prescriptions and correspondence. Zack also admitted that he administered treatment for conditions not approved by FDA, and with chambers that do not have 510(k) pre-market approval. Zack presented invoices from Inland Divers, Inc. which confirmed that he purchased the chambers from Nix.

On July 13, 2004, Zack was convicted of a felony count for violating Title 21 U.S.C. 331(k) and 333(a)(2) - Misbranding a Drug While Held for Sale by repeatedly dispensing the prescription drug without a valid prescription (21 U.S.C. 353(b)(1)).

On September 28, 2004, Zack was sentenced to 3 years probation.

Injection of Industrial Grade Silicon Results in Five-Year Prison Term

This case involved the administration of silicon injections for cosmetic purposes by an unlicensed person. FDA's OCI received information that a man posing as a physician was traveling to Dallas, Texas, from Miami, Florida, to inject the lips of Dallas area women with New Fill and Silicex, an industrial grade silicon.

The suspect, Luis Sanchez, was arrested after an undercover sting operation and indicted on 5 felony counts for violations of the Texas Occupation Code for Practicing Medicine without a License and causing psychological or physical harm.

On January 14, 2004, Sanchez was convicted of all 5 felony counts. Sanchez was subsequently sentenced to 5 years incarceration at the Texas Department of Corrections.

This case was a joint investigation with the Texas Rangers and Dallas Police Department. The case was prosecuted by the Dallas County District Attorney's Office.

Misbranded Monopolar Electrodes Seized
Defendants Receives Prison Sentences

This investigation was initiated upon a referral from the U.S. Attorney's Office, Chicago, Illinois, involving U.S. Endo, Inc., owned by Jonel Manciu. The referral involved the manufacturing and selling of unapproved medical devices. The unapproved medical devices that U.S. Endo, Inc. had been manufacturing and selling were monopolar electrodes. The monopolar electrodes were purchased by Vital Concepts, Inc., with the knowledge that they were misbranded. According to the referral and information developed, U.S. Endo, Inc., is a defendant in an ongoing civil suit brought by New Eder, Inc., a manufacturer and distributor of FDA-cleared monopolar electrodes.

Federal search warrants were executed at U.S. Endo, Inc., manufacturing facility and business office and Vital Concepts, Inc., manufacturing, warehouse, and distribution facility and business office. During these searches, monopolar electrodes, raw materials used in the manufacturing of monopolar electrodes, business records, and other items associated with the manufacturing and sale of monopolar electrodes were seized.

On January 27, 2003, Vital Concepts, Inc. was convicted of violating Title 21 U.S.C. 331(a) and 333(a)(2) - Introduction into Interstate Commerce with Intent to Defraud and Mislead Misbranded Medical Devices. On January 28, 2003, Vital Concepts, Inc., was sentenced to 30 months probation and fined $150,000. Prior to sentencing, Vital Concepts, Inc. had paid restitution of $148,600 to the victims.

On September 18, 2003, Manciu was convicted of violating Title 21 U.S.C. 331(a) and 333(a)(2) - Introduction into Interstate Commerce with Intent to Defraud and Mislead Misbranded Medical Devices. On May 10, 2004, Manciu was sentenced to 3 years probation, and fined $5,000.

On October 10, 2003, U.S. Endo, Inc. was convicted of violating Title 21 U.S.C. 331(a) and 333(a)(2) - Introduction into Interstate Commerce with Intent to Defraud and Mislead Misbranded Medical Devices. On May 10, 2004, U.S. Endo, Inc., represented by its owner Manciu was fined $ 75,000.

Center for Drug Evaluation and Research

Warner-Lambert Fined for Off-Label Promotion of Neurontin

This investigation was initiated subsequent to the filing of a qui tam by a former employee of Parke Davis, a division of Warner Lambert. Warner Lambert was subsequently sold to the Pfizer Corporation (Pfizer). The investigation revealed that the drug Neurontin, which was approved by FDA for adjunctive therapy in the treatment of partial seizures, was being promoted for off label uses by Warner Lambert sales representatives and medical liaisons through the use of consultant's meetings, advisory boards and teleconferences. Neurontin is approved for uses to include bipolar disorder, Amyotrophic Lateral Sclerosis, restless leg syndrome, and anxiety disorders.

Hundreds of boxes of documents were obtained from Warner Lambert relating to their sales and strategic marketing practices of Neurontin. The records indicated that doctors were paid to attend "so-called" consultant's meetings and teleconferences at various sites in the U.S. during which presentations about off label uses of Neurontin were made.

Interviews conducted and records obtained also indicated that Warner Lambert paid physicians to allow a sales representative to accompany the physician while they examined patients, with the sales representatives offering advice regarding the patient's treatment, which was biased towards the use of Neurontin.

On June 7, 2004, Pfizer was convicted of 1 felony count of violating Title 21 U.S.C. 331(a) - Distribution of a Misbranded Drug; and 1 felony count of Title 21 U.S.C. 331(d) - Distribution of an Unapproved New Drug. A $430 million global financial settlement was accepted which included a criminal fine of $240 million and a $190 million civil fine. Pfizer also entered into a Corporate Integrity Agreement.

This was a joint investigation with the Department of Health and Human Services' (DHHS) Office of the Inspector General (OIG), the U.S. Department of Veterans Affairs' (VA) OIG and the Federal Bureau of Investigations (FBI).

Prison Time for Jason Vale, Owner of Christian Brothers, and Promoter of Laetrile

This investigation was initiated based on information provided by FDA's New York District Office. The New York District Office had an open investigation against Christian Brothers Contracting Inc., and the owner and president, Jason Vale. Vale promoted the sale of laetrile, amygdalin, Vitamin B-17 and other products containing the previously listed components with the claim that they prevented, treated and cured cancer. The products were promoted and sold by telephone orders and by use of the Internet on several websites including www.apricotsfromgod.com.

On April 4, 2000, an injunction was ordered which prohibited Vale and his corporation from holding, packing, processing, labeling or distributing laetrile, amygdalin and Vitamin B-17 products or any products containing the listed items.

In a scheme developed and implemented by Vale, multiple websites were created on the Internet to advertise the enjoined laetrile products. Vale incorporated a separate company named Praise Distributing to sell the enjoined products. Vale traveled to Phoenix, Arizona, and opened a mailbox in the name of Praise Distributing. Any mail received, however, would be forwarded to Vale's residence in Queens, New York. Vale obtained multiple telephone lines which all terminated at his residence. Particular telephone numbers were designated as Christian Brothers Contracting Inc., and the remaining were designated as Praise Distributing.

When a customer called the Christian Brothers Contracting Inc., numbers and attempted to order laetrile products they would be given another number to contact a separate company named Praise Distributing to make the purchases. In reality, the caller contacted the same operators in Vale's home. Any package containing the enjoined products was labeled with the Phoenix, Arizona, return address and enclosed with invoices bearing the Praise Distributing title in an illusion to deceive the customers that they had purchased products from an Arizona company. Vale also created other fictitious company names to hide his

involvements. These company names included Cyto, Cyto-International, Health Clearing House, Herbal AID Corporation and ABC Shipping.

During this investigation, 5 separate undercover purchases of laetrile products were conducted.

On October 16, 2000, a search warrant was executed at Vale's residence. Documentary evidence was discovered which showed that Christian Brothers Contracting Inc., and Praise Distributing were the same entity. Laetrile and related products were found at this location in violation of the Injunction. These products were seized. Additional evidence was found that Vale continued to sell laetrile products in violation of the Injunction and they were seized.

On July 21, 2003, Vale was convicted by a jury of 3 counts of violating Title 18 U.S.C. 401(3) - Criminal Contempt in Violation of Title 21 U.S.C. 331(a), (d) and (k).

On June 18, 2004, Vale was sentenced to 63 months incarceration on each charge to be served concurrently followed by 3 years supervised release.

This was a joint investigation with the U.S. Postal Inspection Service (USPIS).

Investigation Finds John D. Copanos Continuing His Illegal Activities

This case was initiated based upon information received from FDA's Baltimore District Office that former pharmaceutical company owner John D. Copanos, was continuing to manage operations at Consolidated Pharmaceutical Group (CPG). In 1996, FDA permanently debarred Copanos from managing the company as a result of a prior felony conviction for violation of the Act. The company functioned as a Baltimore based manufacturer of various human and veterinary antibiotic drug products. In 1997, James H. Coleman, President of CPG, provided affidavits and other documents, to both FDA and the court, which gave assurances that Copanos was no longer associated with the firm.

On May 19, 1999, federal search warrants were executed at the CPG manufacturing facility as well as the residence of Copanos. The investigation disclosed that Copanos continued to substantially participate in and direct drug manufacturing operations at the firm.

On March 27, 2001, Coleman was convicted of violating Title 18 U.S.C. 1001 - False Statements. On January 27, 2004, Coleman was sentenced to 2 years probation, 4 months home detention and a $2,000 fine.

In October 2001, Copanos and his son, John S. Copanos, were indicted by a federal grand jury for violations of Title 18 U.S.C. 371 - Conspiracy; and Title 18 U.S.C. 1001 - False Statements.

On September 9, 2003, John D. Copanos was convicted of violating Title 18 U.S.C. 371 - Conspiracy. Charges against John S. Copanos were dropped.

On December 1, 2003, John D. Copanos was sentenced 2 years probation, 6 months home detention, and a $250,000 fine.

Pharmacist Ordered to Pay $2 Million in Restitution

This case was initiated based on information received from the Georgia Drugs and Narcotics Agency (GDNA). According to GDNA, Alvin C. McDowell, a licensed pharmacist, had purchased large quantities of prescription drugs from November 2001 through January 2002 although he closed his pharmacy in Fayetteville, Georgia, in October 2001.

On May 28, 2004, McDowell was sentenced to 3 years and 5 months incarceration and ordered to pay restitution in the amount of $2 million and ordered to pay tax liabilities of $228,000. McDowell was previously convicted of charges relating to Health Care Fraud, Misbranding of Drugs, Controlled Substance Violations, and filing Fraudulent Tax Returns.

Defendant Confesses to Manufacturing Drugs for AIDS and Arthritis in Her Kitchen for Over 20 Years

This case was initiated in October 1998 based on an allegation that Karl Hans Sturchow, a licensed physician, was dispensing unapproved drugs. Sturchow dispensed the drugs “Chondriana/ATP” and “Liefmann Formula” from his clinic in Lakeside, California to patients suffering from AIDS and arthritis.

Ursula Liefmann, who resides in San Diego, California, was identified as the source of the Liefmann Formula. FDA’s Forensic Chemistry Center (FCC) conducted an analysis of the Liefmann Formula and determined that 2 of the 4 formulas contained controlled substances. Based on this analysis and documentation, FDA’s Center for Drug Evaluation and Research (CDER) determined that the Liefmann Formula posed a Class I Health Hazard in that there was a reasonable possibility that the use of the Liefmann Formula would cause serious adverse health consequences or death.

In coordination with USPIS Inspectors, OCI determined that Liefmann used a false return address when mailing the Liefmann Formula to customers located throughout the U.S. A federal search warrant was executed at the premises occupied by Liefmann. Liefmann

subsequently confessed that she had manufactured the unapproved drug in her kitchen for over twenty years and had failed to pay income tax on the revenues from the sale of the Liefmann Formula. Liefmann admitted to using accounts in the Cayman Islands to conceal the proceeds from the sales, and using various techniques to conceal her activities from FDA.

Subsequent to execution of the search warrant, Liefmann attempted to surreptitiously sell the residence in San Diego, California. The U.S. Attorney's Office in San Diego, California, successfully seized the property 1 day before the closure of escrow.

On October 7, 1999, Liefmann was convicted of violating Title 18 U.S.C. 371 - Conspiracy; and Title 26 U.S.C. 7201- Attempt to Evade or Defeat Tax. Liefmann, an illegal alien, was deported. The Medical Board of California revoked Sturchow's license.

Search Warrant Discloses Fraudulently Procured Pharmaceuticals

This case was initiated based on information received from the Phoenix, Arizona, Police Department (PPD), Drug Enforcement Bureau (DEB). According to PPD, Mark Forster used the identity, billing information, and Drug Enforcement Administration (DEA) number of David Hurtado, M.D., to acquire pharmaceuticals from General Injectables and Vaccines, Inc. (GIV), and Henry Schein, Inc. Forster then sold the fraudulently procured pharmaceuticals to unknown parties.

In November 2002, Dr. Hurtado, at St. Luke's Medical Center, 525 N. 18th St., Suite 402, Phoenix, Arizona, contacted PPD because one of his employees observed a delivery notice for prescription drugs taped to the door of Suite #305, located in the same medical center as his office. According to Dr. Hurtado and St. Luke's Medical Center, Suite #305 is vacant. Dr. Hurtado contacted the pharmaceutical company, GIV, which advised him an additional order for pharmaceuticals was ordered and scheduled to be delivered to Suite #305, under the name of Richard Aguilar. Dr. Hurtado contacted PPD in reference to someone ordering pharmaceuticals using his identity and DEA number without his authorization. PPD contacted GIV and set up a controlled delivery.

In November 2002, surveillance was conducted at St. Luke's Medical Center, Suite #305. An individual, later identified as Forster, also known as Richard Aguilar, was loitering in the vicinity of Suite #305. Forster was observed removing a note from the door of Suite #305 and departing the medical center.

PPD and OCI executed a search warrant at Forster's residence. Pursuant to the search warrant, financial documents, a notebook computer, and personal-use misbranded prescription drugs were discovered and seized as evidence.

During the course of this investigation, PPD and OCI established that Forster, utilizing Dr. Hurtado's identity, had ordered approximately $100,000 worth of pharmaceuticals and sold them to prescription drug wholesalers.

On July 13, 2004, Forster was convicted of violating Arizona State felony statues, specifically, Title 13 U.S.C. 2310 - Attempted Fraudulent Schemes and Artifices; and Title 13 U.S.C. 2008 - Taking the Identity of Another.

On August 27, 2004, Forster was sentenced 36 months incarceration and ordered to pay restitution to all victims in an amount not to exceed $200,000.

RxBazaar, Inc. Fails to Provide Required Pedigree for Brand Prescription Drugs

This investigation was initiated based on information and evidence obtained from OCI's New York Field Office. Information developed and provided indicated that FPP Distribution, Inc. of Cincinnati, Ohio, sold prescription drugs with counterfeit labels and inserts. The sales were made to 2 pharmacies in the New York City area.

RxBazaar, Inc. is a publicly traded corporation located in Forest Park, Ohio. RxBazaar, Inc. is a wholesale distributor of prescription drugs and other products online. Superior Pharmaceutical is a trade name through which RxBazaar, Inc. acts as a distributor of brand prescription drugs and other products. FPP Distribution, Inc. is a corporation that since February 2001 has been a wholly-owned subsidiary of RxBazaar, Inc. All 3 companies are located in Cincinnati, Ohio. From about 2000 to the present, FPP Distribution, Inc. has acted as the fulfillment center for RxBazaar, Inc. and Superior Pharmaceutical. FPP Distribution, Inc. receives and distributes brand prescription drugs and other products to retail pharmacies and other wholesale distributors.

RxBazaar, Inc. and FPP Distribution, Inc. are licensed by the State of Ohio to act as wholesale distributors of brand prescription drugs. RxBazaar, Inc. and FPP Distribution, Inc. are not drug manufacturers or authorized distributors of record for brand name prescription drugs.

While investigating information regarding counterfeit drugs that were sent to pharmacies in New York, OCI was subsequently notified about several unrelated incidents involving the sale and distribution of counterfeit or otherwise misbranded or adulterated units of Zyprexa by RxBazaar, Inc. Pharmacy customers of RxBazaar, Inc. and FPP Distribution, Inc. had reported numerous incidents in which the strength of Zyprexa tablets in the bottles differed from the label, indicating illegal repackaging had occurred.

As part of the investigation of the Zyprexa complaints, OCI requested pedigree information to determine where FPP Distribution, Inc. had purchased the drugs. During the investigation it was determined during conversations with officials of the companies, Robert Cusick and Vanett Marshall, that the companies had not been providing the statutorily required pedigrees when they distributed brand prescription drugs to all retail pharmacies and to some wholesale distributors.

OCI's investigation uncovered that from April 2000 to July 2004, RxBazaar, Inc. and Superior Pharmaceutical obtained pedigrees for some sellers of brand prescription drugs, but in many cases did not obtain the pedigrees. RxBazaar, Inc.'s website stated that sellers were required to provide an identifying statement, that is, a pedigree, but RxBazaar, Inc. did not enforce the requirement. Neither RxBazaar, Inc. nor Superior Pharmaceutical provided the required pedigree for brand prescription drugs distributed by them to retail pharmacies and other wholesale distributors. FPP Distribution, Inc. which distributed drugs for both companies, did not provide the required pedigree for brand prescription drugs distributed by them to retail pharmacies and other wholesale distributors.

The companies asserted that as a result of misleading reports in the trade press about FDA's decision to postpone the regulations relating to the pedigree, the companies believed the pedigree requirement was not in effect. The U.S. Attorney's Office disagreed and advised the companies that ignorance of the law or a mistake of law is not a defense to a strict liability crime. The U.S. Attorney's Office advised the companies that the statute requires the pedigree to be provided even though FDA regulations have not become effective.

On August 27, 2004, wholesale drug distributors RxBazaar, Inc. and FPP Distribution, Inc., were convicted for failing to comply with Title 21 U.S.C. 353(e)(1)(A) and Title 21 U.S.C. 331(t) - Failure to Provide a Statement (Pedigree) Identifying Each Prior Sale, Purchase, or Trade of the Drug. RxBazaar, Inc. and FPP Distribution, Inc. issued a statement advising 3 separate trade publications that the above-mentioned companies were convicted for the above-mentioned offense.

RxBazaar, Inc. and FPP Distribution, Inc. were each sentenced to serve a 5 year period of probation and fined approximately $100,000.

Defendant Found Conducting
Clinical Drug Studies Without a Medical License

OCI began this criminal investigation after receiving information that Mary Sawaya was conducting clinical drug studies without a medical license. The subsequent investigation developed conclusive evidence that Sawaya had falsified at least 2 medical licenses and provided them to study sponsors. The sponsors then provided the false licenses to FDA as part of their Investigational New Drug (IND) submissions.

On January 22, 2004, Sawaya was convicted of violating Title 18 U.S.C. 1001 - False Statements. Sawaya was sentenced to 24 months probation. Sawaya also forfeited an office building (assessed at $141,402) and was disqualified from participating in any clinical drug study.

The Florida Department of Health, Criminal Investigations Unit also participated in this investigation.

Wholesale Distribution of a Prescription Drug without a Wholesale License

This case was initiated in October 2000, based on information received from the FBI regarding the purchase of a large quantity of prescription drugs from a Miami pharmacy. The pharmacy, Nova Pharmacy, was operated and owned by Alex Fernandez.

Orders were placed through Walter Lopez who in turn ordered the drugs from Fernandez. Orders were placed for 5,000 Viagra tablets, 3,000 Vicodin tablets and 2,000 Xanax tablets. The price was negotiated at $58,300. During the negotiations, Fernandez did not mention or request any type of permit, license or paperwork concerning the transaction. An undercover purchase was conducted for some of the drugs after which Fernandez was arrested.
On April 3, 2003, Lopez and Fernandez, were indicted for violations of Title 18 U.S.C. 371 - Conspiracy; Title 21 U.S.C. 841(a)(1) and 846 - Possession with Intent to Distribute and Conspiracy to Distribute a Controlled Substance; and Title 21 U.S.C. 331(t), 353(e)(2)(A) and 333(b)(1)(D) - Wholesale Distribution of a Prescription Drug without a Wholesale License.

On June 26, 2003, Lopez was convicted of the charges in the indictment.

On July 8, 2003, Alex Fernandez was convicted by a jury on all counts in the indictment.

On September 11, 2003, Lopez was sentenced to 6 months incarceration and 3 years probation. Lopez, who had been in custody since his arrest, remained incarcerated.

On September 18, 2003, Fernandez was sentenced to18 months incarceration and 3 years probation.

Medical Doctor Found Under-Dosing Cancer Patients

This investigation involves a medical doctor, Victor Souiad, who under-dosed or failed to administer Lupron injections to prostate cancer patients. It was also determined that Souiad fraudulently billed Medicare and other insurance providers for Lupron injections not administered and unlawfully sold large quantities of Lupron to Florida wholesalers.

On September 22, 2003, Souiad was convicted of 32 felony counts of Title 18 U.S.C. 1347 - Health Care Fraud; and 27 counts of Title 21 U.S.C. 353(b)(1)(A) and 353(e)(2)(A) - Unlicensed Wholesale of Prescription Drugs. Souiad permanently surrendered all medical licenses.

On December 19, 2003, Souiad was sentenced to 51 months incarceration, ordered to pay $123,000 in restitution and $5,900 in special assessments. He was also sentenced to 3 years supervised release to be served subsequent to his incarceration.

The FBI also participated in this investigation.

Convictions for Distribution of Repackaged Counterfeit Labeled Prescription Drugs

This case involved the sale of counterfeit labeled prescription drugs. VRI Distribution (VRI), was a licensed drug wholesaler involved in the sale of counterfeit labeled prescription drugs. VRI was identified as a result of a related investigation involving another unlicensed wholesale drug company, Prodepharm. Prodepharm was operating out of Puerto Rico in 1995-1996 under the direction of Eimad Asmar with the assistance of Eddy Herrera. Both Asmar and Herrera were convicted of federal charges in that case. Herrera is currently serving time while Asmar died in Mexico while in fugitive status.

Parallel to the investigation of Prodepharm and VRI, investigations in Kansas City, Kansas, Austin, Texas, and eventually Atlanta, Georgia, resulted in the identification of several locations where counterfeit labeled Epivir and Zerit were appearing. These investigations had revealed that the suspect product was purchased from Stanford Trading, a Texas wholesaler, or directly from VRI in New York. The Austin investigation revealed that Stanford Trading had purchased the questioned product from VRI.

Forensic examinations conducted by the U.S. Secret Service, FDA's FCC, and the respective pharmaceutical manufacturers determined that the questioned product bore counterfeit labeling. These findings lead to the seizure of large quantities of Epivir and Zerit together with additional products which were suspected to also contain counterfeit labeling.

As Prodepharm was failing and under investigation, it was established that Asmar, using the assumed name Frank Smith, recruited an associate, Victor Marin of New York and Nicholas Guarino, a licensed Pharmacist, to serve as the President and Supervising Pharmacist for VRI. In 1996, New York State issued a drug wholesale license to VRI.

Guarino was subsequently located, interviewed and eventually agreed to cooperate in the investigation. It was learned that Asmar agreed to pay Guarino thousands of dollars monthly for allowing VRI to use his name as the supervising pharmacist. Guarino received cash payments delivered to him by Marin and others in amounts far short from what he was promised. Guarino revealed that he rarely was present at VRI and would only be contacted by Asmar when his signature was needed on VRI documents. Guarino said that he broke off his relationship with VRI approximately eight months after signing on since Asmar wasn't paying him for his services as agreed upon at their initial meeting.

VRI armed with a wholesale license and preferred pricing utilized the services of a Texas businessman, Robert Kay, to establish its business relationship with Stanford Trading, the Texas based wholesaler. VRI also initiated business directly with wholesalers in Alabama and Florida. Over a period of approximately 1 to 2 years VRI conducted sales with these wholesalers totaling in excess of $15,000,000. The buyers would forward payment by wire or check to a bank account owned by VRI or to a check cashing establishment, "Citi Check Cashing" located in Jersey City, New Jersey. In most instances, within 1 or 2 days of the sale, either Victor Marin or David Aburomi, representing VRI would appear at Citi Check Cashing. At this time they would either convert bank checks from VRI's various bank accounts to cash or withdraw funds which were wired directly to Citi Check Cashing by the victim wholesalers. The cash withdrawn by Marin or Aburomi would often be in amounts exceeding $500,000.

The source of VRI's product was either as a result of product diversion or offshore purchases. The product was then repackaged, labeled and then placed into interstate commerce by VRI.

Aburomi and Marin were both convicted of violating Title 18 U.S.C. 1343 - Wire Fraud; Title 18 U.S.C. 1956 - Money Laundering; and Title 18 U.S.C. 371 - Conspiracy. Guarino was convicted of violating Title 18 U.S.C. 1347 - Health Care Fraud; Title 18 U.S.C. 1343 - Wire Fraud; and Title 18 U.S.C. 842 - Transportation of Explosives.

On May 2, 2003, Marin was sentenced to 5 years incarceration and ordered to make restitution in the amount of $13,000,000.

On February 7, 2003, Aburomi was sentenced to 5 years incarceration and ordered to make restitution in the amount of $13,000,000.

On September 3, 2003, Guarino was sentenced to 26 months incarceration and ordered to make restitution in the amount of $300,000.

Wholesale Distribution of Pharmaceuticals Without a License

This investigation involved the wholesale distribution of pharmaceuticals without a license by Carol Sims and Tyrone Hill, as well as the possession of stolen U.S Government property (pharmaceutical products stolen from a U.S. Department of VA hospital pharmacy).

On September 18, 2003, Sims was convicted of violating Title 18 U.S.C. 641- Embezzlement and Theft of Public Money, Property or Records; and Title 21 U.S.C. 353(e)(2)(A) - Unlicensed Wholesale and Distribution of Pharmaceuticals.

On December 18, 2003, Sims was sentenced to 2 years probation, 4 months home detention and restitution of $70,341.

On August 28, 2003, Hill was convicted of violating Title 18 U.S.C. 641 - Embezzlement and Theft of Public Money, Property or Records; and Title 21 U.S.C. 353(e)(2)(A) - Unlicensed Wholesale and Distribution of Pharmaceuticals.

December 18, 2003, Hill was sentenced to 5 years probation, 6 months home detention and restitution of $40,074.

Registered Nurse Found Substituting Prescriptions

This case involves a registered nurse identified as James Kutzer, who was employed at the Ireland Army Community Hospital Emergency Room, Fort Knox, Kentucky.

Kutzer was identified as having substituted prescriptions of Percocet tablets, a Schedule II controlled substance, with Methocarbomal tablets, a generic muscle relaxant, for at least 2 patients. It was also determined that Kutzer was the subject of 3 separate investigations in 1998, conducted by the U.S. Army's Criminal Investigations Division (CID) for theft and possession of pharmaceuticals from the Ireland Army Hospital.

On January 27, 2004, Kutzer was convicted of violating 1 count of Title 18 U.S.C. 641 - Theft. Kutzer was sentenced to 3 years probation; 6 months monitored house arrest; and permanent loss of his nursing license.

This was a joint investigation between OCI and the U.S. Army's CID.

Pharmacy Technician Caught Stealing Prescription Drugs

This case was initiated on August 7, 2002, as a referral from the U.S. Department of VA's OIG. The VA Medical Center Pharmacy in Cleveland, Ohio, reported the loss of approximately 6,800 Viagra pills from the VA pharmacy.

In a joint operation with the U.S. Department of VA's OIG, video surveillance was conducted in the VA Pharmacy in an attempt to determine who was stealing the Viagra. No information regarding the theft of the Viagra was developed. However, Timothy Cole, a pharmacy technician, was observed stealing Zoloft from the VA pharmacy. Cole was subsequently arrested by VA Police and admitted that he had been stealing a number of pharmaceuticals. In addition, recorded conversations with John Raymond Steward, a pharmacy technician, were obtained in which Steward admitted to stealing and selling Viagra from the VA pharmacy.

On July 22, 2003, Cole was convicted of violating Title 18 U.S.C. 641- Theft of Government Property. On October 10, 2003, Cole was sentenced to 1 year probation and fined $2,000.

On September 25, 2003, Steward was convicted of violating Title 18 U.S.C. 669 - Theft from a Health Care Benefit Program. On December 17, 2003, Steward was sentenced to 2 years probation.

This case was investigated by OCI and the U.S. Department of VA's OIG.

Manufacture of Unapproved New Drug Gamma Hydroxybutyrate

This case involved the manufacture of an unapproved new drug gamma hydroxybutyrate (GHB), prior to GHB being listed as a controlled substance. Joseph and Andrew Mauro, along with Michelle Dryer and Brett Cohen manufactured large amounts of GHB, and controlled a large distribution network in the Houston area, including several clubs owned by the Mauro brothers. Evidence also revealed the same group was involved in the distribution of methamphetamine, via the same distribution network.

One female's death was attributed to GHB given directly by Joseph Mauro to the victim during a party at one of the Mauro owned clubs. Evidence also showed both Mauro brothers would on many occasions give GHB to women in their clubs, and in some cases the women were unwilling to receive the drug.

On November 22, 2002, Dryer, Cohen, and both Mauro brothers were convicted of violating Title 18 U.S.C. 371- Conspiracy.

On May 29, 2003, Dryer was sentenced to 8 months incarceration.

On August 14, 2003, Cohen was sentenced to 15 years incarceration.

On August 21, 2003, Joseph Mauro was sentenced to 20 years incarceration.

On May 6, 2004, Andrew Mauro was sentenced to 11 years incarceration.

This was a joint investigation with the Internal Revenue Service's (IRS) CID and the DEA.

Breakthrough "Treatment" for AIDS

This case pertains to the distribution of an unapproved new drug, securities fraud and wire fraud. M. Keith Ives, President of Ives Health Company, Claremore, Oklahoma, promoted "T-Factor," a purported dietary supplement as a breakthrough treatment for immune system diseases including AIDS. The claims of effectiveness were based on clinical studies which the company knew to be false.

On March 15, 2003, Ives was convicted of violating Title 18 U.S.C. 371 - Conspiracy to Defraud the FDA and to Distribute an Unapproved New Drug; Title 15 U.S.C. 78 - Securities Fraud; Title 18 U.S.C. 2 - Aiding and Abetting; and Title 18 U.S.C. 1343 - Wire Fraud.

On March 11, 2004, Ives was sentenced to 51 months incarceration, 3 years of supervised release, and restitution to investors in Ives Health Company in the amount of $1,252,907.

On March 11, 2004, corporate defendant Ives Health Company, Inc., was sentenced to a 1 year term of probation.

This was a joint investigation with the FBI and the U.S. Securities and Exchange Commission (SEC).

Large Scale Diverse of Pharmaceuticals

OCI was contacted by the DEA's Tactical Diversion Squad and requested to provide assistance in the investigation of Norman L. Smith. According to the DEA, Smith was engaged in a large scale diversion scheme in which he purchased various pharmaceutical drugs from several individuals and sold the pharmaceuticals to at least 26 established customers. Additionally, Smith procured at least one fraudulent insurance card that was used for the payment of medical visits and the purchase of prescription drugs. A DEA confidential

informant advised that Smith sold approximately $2,000 worth of pills a day. Smith also co-mingled his drug proceeds with proceeds he derived from the operation of a locksmith franchise he owned named "Lockdoc."

Between April 2001 and December 2001, 10 undercover purchases were conducted resulting in a total of 1,118 oxycodone tablets and 238 hydrocodone tablets being purchased from Smith.

On December 11, 2001, Smith and three other individuals (David Terciera, Steven Neto and Loretta Costa) were arrested and charged with violating Title 21 U.S.C. 841(a)(1) - Distribution of a Controlled Substance.

On January 10, 2002, Smith, Costa, Terciera and Neto were indicted and charged with violating Title 18 U.S.C. 371 - Conspiracy; Title 21 U.S.C. 331(t) - Unlicensed Wholesale Distribution of a Prescription Drug; Title 21 U.S.C. 846 - Conspiracy to Distribute a Controlled Substance; and Title 21 U.S.C. 841(a)(1) - Distribution of a Controlled Substance.

On April 3, 2003, Terciera and Neto were convicted of violating Title 21 U.S.C. 331(t) - Unlicensed Wholesale Distribution of a Prescription Drug; and Title 21 U.S.C. 846 - Conspiracy to Distribute a Controlled Substance. Terciera was sentenced to time served and 3 years of supervised release. Neto was sentenced to 18 months incarceration followed by 3 years of supervised release.

On July 30, 2003, Smith was convicted of all charges in the indictment. Smith was sentenced to 10 years incarceration to be followed by 6 years of supervised release.

On September 16, 2003, Costa was convicted of violating Title 21 U.S.C. 846 - Conspiracy to Distribute a Controlled Substance; and Title 21 U.S.C. 841(a)(1) - Distribution of a Controlled Substance. Costa was sentenced to 33 months incarceration to be followed by 3 years of supervised release.

Defendant Caught Selling Stolen Viagra

This case was initiated based on a request for assistance from the FBI regarding an investigation of Ruperto R. Samiento, owner/operator of Fragancias Millenium (a perfume store) located in West New York, New Jersey. Samiento was selling stolen Viagra out of his store.

During August 2002, DeCaro Trucking located in Newark, New Jersey was hired to transport 54 pallets of Viagra, 100 mg from Hartford, Connecticut loading dock to Pfizer in Parsippany, New Jersey.

On August 14, 2002, a pallet of the above referenced Viagra was stolen before it reached its destination. This pallet contained 4,224 bottles of 100 pills each, and had an approximate wholesale value of more than $3.2 million (approximately $760 per bottle).

On September 16, 2002, a consent search of Fragancias Millenium resulted in the seizure of numerous products to include the following: 20 bottles of Viagra, 100 mg; 8 full blister cards of Viagra, a physician sample (50 mg); and 2 empty blister cards of Viagra, a physician sample (50 mg).

On September 16, 2002, Samiento was interviewed and admitted that he obtained numerous items which were from stolen shipments. The stolen items were brought to him by truck drivers on a regular basis. Samiento knew the above referenced Viagra was stolen. Samiento had purchased the Viagra from an unidentified Hispanic male. Samiento refused to identify this individual. Samiento purchased 24 bottles of Viagra from this individual for $4.00 per tablet or $400 per bottle. Samiento was reselling the Viagra for $5.50 per tablet or $550 per bottle.

The approximate wholesale price of 24 bottles (2,400 tablets) of Viagra 100 mg is $18,240.

On October 1, 2003, Samiento was convicted of violating Title 18 U.S.C. 659 and 2 - Receipt of Stolen Property and Aiding and Abetting.

On February 26, 2004, Samiento was sentenced to 24 months probation. Samiento was also ordered to pay $18,240 in restitution to Pfizer.

Unlicensed Pharmacist Found Mailing Prescription Drugs

This case was initiated on information received from USPIS, Rocky Mountain Division, Phoenix, Arizona. USPIS provided information that postal employees, during their normal course of duties, discovered a damaged box containing various misbranded pharmaceuticals some of which were labeled, in part, “Butalbital.” According to USPIS, the shipment of prescription drugs was mailed from Farmacia Carimas, Levittown Toa Baja, Puerto Rico, to Lourdes Gonzalez in Tempe, Arizona.

On May 20, 2003, Gonzalez was interviewed by USPIS. Gonzalez stated that she was an employee of Farmacia Carimas, and as an employee, she had the authority to possess the prescription drugs. Gonzalez also related that in the past, she received boxes through the mail, broke down the boxes into smaller shipments, and mailed them to brokers in Nogales, Arizona, and Calexico, California. The brokers delivered the prescription drugs to customers across the border in Mexico.

On May 20, 2003, the State of Arizona, Board of Pharmacy and Board of Medical Examiners was contacted, to determine if Gonzalez was a licensed pharmacist, a prescription drug wholesaler, or physician. The records inquiry yielded negative results.

On May 21, 2003, Gonzalez was re-interviewed by OCI. Gonzalez was advised that she did not have a license to distribute/wholesale prescription drugs, is not a physician with dispensing authority, and is not a licensed pharmacist in Arizona or any other State or Territory in the U.S. Gonzalez granted consent to open the two boxes that were mailed to her from Farmacia Carimas. The boxes contained a total of 500 bottles, labeled in part "Butalbital, Acetaminophen, and Caffeine Tablets, USP, 50mg/325mg/40mg tablets," each bottle containing 100 tablets, with an approximate retail cost of $100,000.

According to FDA's FCC laboratory analysis, the samples submitted for examination tested positive for Butalbital, Acetaminophen, and Caffeine Tablets, USP, 50mg/325mg/40mg, in the specified amounts.

Record checks revealed Farmacia Carimas is owned by Abdullah A. Yassin. Farmacia Carimas is a legitimate licensed pharmacy in Puerto Rico.

On July 1, 2004, Gonzalez was convicted of a felony by the State of Arizona, Superior Court, to Arizona Revised Statute Title 13 U.S.C. 3407 - Possession, Use, Administration, Acquisition, Sale, Manufacture, or Transportation of Dangerous Drugs.

On August 5, 2004, Gonzalez was sentenced to 36 months of supervised probation, 360 hours of community service, and ordered to pay a fine of $27,000.

Medical Grade Nitrous Oxide Sold For Recreational Use

The case was initiated upon a request for assistance from the Lincoln Park Michigan Police Department. The case was based on an allegation that John Michael Konyha, a.k.a. "Nitrous John," d/b/a John's Performance, sold medical grade nitrous oxide for recreational use. Lincoln Park Michigan Police Department officials advised that a successful "buy" of nitrous oxide for recreational use was made and a search warrant subsequently was executed on Konyha's residence. Approximately 50 tanks were seized from the residence along with balloons, customer names, and other associated paraphernalia. Many of the tanks were labeled as nitrous oxide, "Rx only." Some of the tanks were labeled with AGA as the manufacturer. In addition, some of the "necks" of the tanks were stamped with Wyandotte Welding Company. Konyha, when interviewed, stated that he had been selling nitrous oxide for the past 20 years. Konyha stated he did not have a permit or license to sell the nitrous oxide. He had been purchasing the nitrous oxide from Wyandotte Welding Company, who delivered the tanks to Konyha's residence approximately once a week. Konyha stated he did not claim the nitrous oxide business on his tax returns. Subsequent to the interview of

Konyha, information was developed that Nathan Hill assisted Konyha with the nitrous oxide recreational sales.

An AGA official confirmed that medical grade nitrous oxide was sold to Wyandotte Welding Company for approximately 2 years. Samples of seized cylinders were tested by AGA officials to verify they contained medical grade nitrous oxide. In general, the results of the tested samples revealed that nitrous oxide was present in the cylinders, with purity levels ranging from 98.48% to 99.98%.

Wyandotte Welding Company confirmed that it sold nitrous oxide to Konyha for approximately 10 years and indicated that the company only sold nitrous oxide with sulfur and/or commercial-grade nitrous oxide. After further review, Wyandotte Welding Company confirmed that it originally sold nitrous oxide with sulfur to Konyha, but later changed to the medical grade nitrous oxide.

Records revealed that approximately 3,164 cylinders containing nitrous oxide were sold to Konyha from approximately 1997 to 2002. The records revealed that the majority of nitrous oxide sold to Konyha was medical grade nitrous oxide.

Tax return information was subpoenaed from Konyha’s accountant. The information revealed that Konyha did not claim the nitrous oxide business on his tax returns.

Purchasers of nitrous oxide from Konyha were interviewed. Some purchasers confirmed they purchased nitrous oxide for recreational purposes, and some purchasers advised they purchased nitrous oxide for racing purposes.

On December 2, 2003, Konyha and Hill were indicted for violating Title 18 U.S.C. 371 - Conspiracy; and Title 21 U.S.C. 331(k) and 333(a)(2) - Misbranding of a Drug after Shipment into Interstate Commerce.

On February 12, 2004, Hill was interviewed. Hill stated he noticed some of the nitrous oxide labels were changed by Wyandotte Welding Company, and Konyha advised Hill the labels were changed since the nitrous oxide was "downgraded" from medical grade to automotive grade (due to the label change). Hill stated he believed many of the nitrous oxide purchasers were not racers due to the large amount of nitrous oxide they purchased, the times they purchased nitrous oxide, and due to the non-racer vehicles they drove and the "hip-hop" style of dress they wore. Hill stated Konyha should have known the purchasers were not racers due to the same reasons. Hill stated Konyha requested many of the purchasers to complete index cards indicating they were racers. Hill believed Konyha required this to prevent liability for Konyha.

On March 9, 2004, Hill and Konyha were both convicted of violating Title 21 U.S.C. 331(k) and 333(a)(1) - Causing Drugs to be Misbranded after Shipment into Interstate Commerce.

On November 9, 2004, Konyha was sentenced to 45 days of incarceration; 1 year supervised release, and fined $48,000. Hill was sentenced to 2 years probation.

Importation of Counterfeit Viagra

This case was initiated as part of an undercover operation named "Operation Charlatans," which targeted the import of counterfeit goods into the U.S. for sale to the public.

During this operation, a confidential informant introduced Louis Urbina, a Belize citizen, to undercover agents. Urbina indicated he could get any prescription drug counterfeited and packaged in counterfeit U.S. labeling. Urbina sold counterfeit Viagra and Lipitor, via mail to the undercover agents.

In May 2004, Urbina flew to the U.S. and met with an undercover agent in Beaumont, Texas. He delivered counterfeit Lipitor and completed a deal to sell counterfeit Lupron. Urbina bragged during the deal that it did not matter that the Lupron would not work, as the cancer patients were going to die anyway. Urbina was arrested and held without bond. During an interview, Urbina admitted the counterfeit drugs were manufactured in India but would not provide any additional details.

On May 21, 2004, Urbina was convicted of violating Title 21 U.S.C. 331(a) - Introduction into Interstate Commerce of a Misbranded Drug.

On September 24, 2004, Urbina was sentenced to 10 months incarceration and 1 year probation.

This case was worked jointly with Customs.

Diversion of Large Scale Pharmaceuticals

This investigation was initiated upon receipt of a request from the FBI in conjunction with the Nebraska Health Care Fraud Task Force, regarding an investigation of Kohll's Pharmacy. Marvin S. Kohll, Registered Pharmacist, and his three pharmacist sons (David, Louis and Justin), were involved in diverting large quantities of pharmaceutical drugs from a closed-door pharmacy to their 7 retail locations.

On February 16, 2000, the Nebraska Health Care Fraud Task Force members from OCI, FBI and the Nebraska State Health and Human Services, participated in the execution of 9 simultaneous federal search warrants at the 7 Kohll's retail pharmacies, the Unicare closed-door pharmacy, and Kohll's corporate office.

During August 2000, documents pertaining to a closed-door account set up entirely for diversion to Kohll's retail pharmacies were received from McKesson Wholesalers. Over $7,000,000 in pharmaceuticals was purchased and approximately $500,000 in charge backs resulted from this account in just a 3 year period.

On August 25, 2004, Louis Kohll was convicted of violating Title 18 U.S.C. 1341 and 2 - Mail Fraud.

On November 15, 2004, Louis Kohll was sentenced to probation for a period of 12 months, of which the first 3 months consisted of home confinement. Kohll was also ordered to pay a fine of $250,000, and restitution in the amount of $500,000.

Physician Involved in Health Care Fraud

This investigation is predicated upon a referral from DHHS' OIG. DHHS' OIG was investigating allegations that Vimlesh Ahmad, M.D., was up-coding bills for the office visits of Medicaid patients. In addition, Dr. Ahmad was distributing pharmaceutical drugs without a physical exam, patient history, or an appropriate treatment plan, thus violating Title 21 U.S.C. 331(k) and 21 U.S.C. 353(b)(1)(B) - Misbranding of Drugs While Held for Sale.

The Washington State Department of Social and Health Services reported that Dr. Ahmad was providing patients with high levels of pharmaceutical drugs, such as carisoprodol and cyclobenzaprine (muscle relaxants), and controlled substances, such as Oxycontin, Endocet, and Roxicet.

DHHS' OIG reviewed the Medicaid billing history for Dr. Ahmad and learned that Dr. Ahmad almost always used the Current Procedural Terminology (CPT) code 99215, which is the highest CPT code for an office visit, for all of her patient visits. CPT code 99215 is the billing code used for patients with moderate to high severity problems, typically requiring 40 minutes of individual time with the physician. It involves a comprehensive history and examination, and a high complexity of decision making.

Numerous surveillances of Dr. Ahmad's clinic were conducted. Patients were observed entering and leaving the clinic and vehicle licenses were noted and the registered owners of the vehicles identified. Several people were followed to local pharmacies and observed obtaining prescriptions. Many of the people were identified and their prescriptions noted. A few times the subjects exited the pharmacy, and were observed exchanging drugs with other unidentified subjects. On one occasion, a pharmaceutical drug representative was observed arriving at Dr. Ahmad's office with a medium-sized box. The drug representative left several minutes later without the box. It is believed that drug samples were left with Dr. Ahmad. Several minutes later an individual entered Dr. Ahmad's clinic and left several minutes later with what appeared to be the same box. The individual was observed sitting in a car outside

the office removing what was believed to be samples from individual boxes, repackaging the samples, and writing on the new packages. The individual was then followed to a local U.S. Post Office, where the packages were mailed.

On January 15, 2004, federal search warrants were served at Dr. Ahmad's clinic and residence. Patient records and financial records were seized at both locations. Dr. Ahmad's receptionist was interviewed by agents and agreed to cooperate with the investigation. The receptionist had worked for Dr. Ahmad for approximately 2 years. She admitted to calling local area pharmacies and requesting prescriptions for drug seekers using Dr. Ahmad's DEA number. She stated that she would call in 2 prescriptions in the name of a drug seeker, the drug seeker would normally pay her $100, and the receptionist would get the second prescription. She would then sell the drugs from the second prescription on the street for a profit.

In April 2004, a former employee of Dr. Ahmad's was interviewed. The former employee recalled that she had typed chart notes for an Everett, Washington man, who died of acute opiate poisoning in 2001. The man was a patient of Dr. Ahmad's who had allegedly told Dr. Ahmad that he thought he was over-medicated and was trying to reduce his narcotic medications. Allegedly, Dr. Ahmad told him that he needed to stay on the high dosages to satisfy Washington State Labor and Industries, who was paying for the man's treatment as the result of a work-related injury. The man later died, and Dr. Ahmad falsified chart notes that were submitted to the life insurance company.

On October 5, 2004, Dr. Ahmad was convicted of 1 count of Title 18 U.S.C. 1347 - Health Care Fraud. Dr. Ahmad was sentenced to 12 months and 1 day incarceration, and fined $100,000. She also agreed to give up her Washington State medical license, her DEA license, and she agreed not to practice medicine in the U.S.

This was a joint investigation with DHHS' OIG and the FBI.

Smuggling Combination of Viagra and Ecstasy

In February 2004, information was received by OCI's Seattle, Washington Domicile Office that Luc Claes, and his associates were involved in smuggling unapproved and misbranded drugs through the Blaine, Washington Port of Entry into the U.S. Claes and his associates were introducing a new unapproved drug into the U.S. from Canada known as "Double White Chocolate." This drug was deemed a "new culture drug" that contained a combination of both Viagra and Ecstasy.

On March 2, 2004, surveillance was conducted in Bellingham, Washington. During the surveillance, Claes along with another individual were observed in a rented Canadian vehicle bearing BC Plate AHM-805. Indices checks revealed that the vehicle had recently crossed

the border from Canada into the U.S. During a consensual search of the vehicle Claes was observed attempting to discard a bulky package by hiding it under a nearby vehicle. The package was seized and found to contain approximately 800 unlabeled white capsules divided into small plastic bags. The capsules contained a white powder with blue flakes. Claes was arrested and admitted that he smuggled the misbranded, unapproved drugs into the U.S. from Canada. Claes also stated that he knew the capsules he smuggled that day were some type of "party drug." The second individual was released and not charged. The capsules tested positive for methylenedioxymethamphetamine, otherwise known as MDMA, or Ecstasy. Additional tests were conducted to attempt to verify if Viagra was also present in the capsules. The results were negative.

On October 8, 2004, Claes was sentenced to 18 months incarceration. Claes was previously convicted of violating Title 21 U.S.C. 841(a)(1) - Possession with Intent to Distribute; Title 18 U.S.C. 371 - Conspiracy; and Title 21 U.S.C. 952 (a)(2) - Importation of a Controlled Substance. Claes was also processed for deportation back to Canada.

This was a joint investigation with the U.S. Immigration and Customs Enforcement (ICE).

Smuggling, Distributing and Selling Prescription Drugs

This case was initiated based on information received from the ICE. Throughout 2002, ICE inspectors at the Blaine, Washington, Ports of Entry made numerous seizures of misbranded amyl nitrate, a prescription drug. The ICE and OCI's Seattle, Washington Domicile Office, identified Locker Room Marketing, Ltd., as the Canadian company that was smuggling, distributing and selling prescription drugs within the U.S. The original complaint had identified Rod Quiros and his associates as the smugglers in this organization. Amyl nitrate was identified as a misbranded and adulterated vassal dilator. According to ICE regulations, amyl nitrate was an inadmissible product.

On December 18, 2002, 2 shipments of amyl nitrate were seized at the Pacific Highway Port of Entry in Blaine, Washington. Both shipments were on the same commercial truck carrying unrelated merchandise.

The first seizure consisted of 2,214 vials contained in 10 boxes with the seller listed as Locker Room Marketing. The buyer/consignee was listed as JSA CORP, 1360 West 1st Street, Pomona, California. The shipper was listed as AMCORP, 105-1005 Columbia Street, New Westminster, British Columbia. The ICE's Office in Vancouver, Canada assisted in identifying the Columbia Street address in Canada. The address was identified as a mail drop facility.

The second seizure consisted of 1,440 vials of amyl nitrate invoiced as "cleaning supplies-liquid form-10ml." The buyer was listed as John Lewis/Don Weston, #175-2997 Druid Hills

Road, Atlanta, Georgia. The shipper was listed as A-1 Janitorial Supplies Ltd., Suite 296-3495 Cambie Street, Vancouver, British Columbia. The ICE's Office in Vancouver, Canada assisted in identifying the Cambie Street address in Canada as a mail drop facility.

The ICE and OCI discovered that Locker Room Marketing, Ltd. was repeatedly attempting to smuggle amyl nitrate into the U.S. from Canada by disguising it as room deodorizer, cleaning supplies, and boot cleaner. Moreover, the seized vials were all marked with various names, such as Leather Cleaner, Jungle Juice, Rush, Taiwan Blue, Man Scent, and Z Best Cleaner. Some bottles were marked as flammable and toxic and not to be sold to minors.

On February 21, 2003, 2,996 vials of amyl nitrate were seized at the Port of Entry in Blaine, Washington. The shipper of the smuggled amyl nitrite was identified as Locker Room Marketing, Ltd. The shipper listed 2 consignees: JS Marketing at 219 East 26th Street, New York, New York, buyer of 1,298 vials invoiced as room odorizer; and Whirlwind, c/o Weston, in Decatur, Georgia, buyer of 1,698 vials, also described as room odorizer.

On October 14, 2003, OCI was contacted by the ICE's Attaché in Vancouver, Canada. The Attaché informed them that ICE in Atlanta, GA, was working a similar case involving misbranded isobutyl nitrite.

On October 14, 2003, the ICE in Atlanta, Georgia, contacted OCI and informed them that they had conducted several search warrants on a business identified as Whirlwind Distributing in Decatur, Georgia. The ICE advised that they believed that Whirlwind Distributing, Weston, and Roberto AMA were all associated to Locker Room Marketing, Ltd. in Vancouver, Canada. The ICE investigator Blaine and OCI's Seattle Office corroborated the information.

On October 17, 2003, OCI received a telephone call from an investigator with the Consumer Product Safety Commission stating that he also had conducted an investigation of Locker Room Marketing, Ltd.. The investigator stated that he spoke to AMA and wrote him a letter in late 2002 telling him to cease and desist in producing and distributing amyl nitrate product in the U.S. The investigator stated that AMA agreed and said he and his company would stop importing amyl nitrate products into the U.S. The investigator stated that AMA and his associates continued to distribute amyl nitrate in the U.S.

On January 16, 2004, an in-depth record check was conducted on Locker Room Marketing, Ltd. The checks revealed that, since 1998, Locker Room Marketing, Ltd. and its associates had attempted to smuggle approximately 1,528 kilograms (3,361 pounds) of unapproved amyl nitrate into the U.S. from Canada.

On June 15, 2004, a Civil Penalty was issued against Locker Room Marketing, Ltd. and AMA for $104,409.00 for violation of Title 18 U.S.C. 1595 - Undervalue of Merchandise.

On August 25, 2004, Weston was convicted of 1 felony count of Title 18 U.S.C. 545 - Smuggling Isobutyl Nitrite into the U.S. from Canada.

On November 19, 2004, Weston was sentenced to 180 days home confinement with electronic monitoring, 2 years probation, and a $3,000 fine. Weston also forfeited approximately $98,000 seized from his business bank account to the U.S. government.

Unapproved New Drugs Sold as Treatment for Cancer

This investigation was initiated based on information regarding the illegal activities of a food processing plant called Lumen Food Corporation, located in Lake Charles, Louisiana. Lumen Food Corporation advertised products via an Internet website www.altcancer.com under the name of Alpha Omega Labs, located in Nassau, Bahamas. These products were advertised as containing medicinal qualities for the treatment of cancer and many other diseases.

From 1999 to 2003, Gregory Caton, President of Lumen Food Corporation, and his employees utilized Alpha Omega Labs to take direct orders for these unapproved new drugs. The chemical substances were not approved for sale by FDA. As a result of the scheme, Caton received approximately $950,000. In order to legally market a drug in interstate commerce, the drug's manufacturer is required to comply with all applicable provisions of the Act in order to ensure that the products sold are safe for humans and effective for their intended uses.

On at least two occasions known to FDA, the items shipped by Caton's firm and used by consumers resulted in bodily injury and harm. The products were Cansema Tonic III and H_3O. Cansema Tonic III was advertised for use in the cure, mitigation, treatment or prevention of cancer. H_3O was advertised for use in the cure, mitigation, treatment, or prevention of athlete's foot, cuts and burns, eczema, fingernail fungus, chronic gas, gastroenteritis, gingivitis and periodontal disease, halitosis, herpes sores, ophthalmia, psoriasis, sore throat, strep throat and wounds. Caton did not have an IND application on file with FDA.

On September 17, 2003, a federal search warrant was executed at Caton's residence, Lumen Food Corporation, and an industrial site owned by Caton. All of these locations were in Lake Charles, Louisiana.

During the search of Caton's residence, a cache of weapons were found consisting of 3 semi-automatic rifles, 1 bolt action rifle, 2 shotguns, a semi-automatic pistol, 10/252 rounds of amunition, 3 body armor vests, 1 leg armor and 2 bullet resistant helmets. The weapons, armor and ammunition were found concealed in a hidden compartment that was inside a closet. Caton was arrested on possession of firearms by a convicted felon.

Numerous misbranded and unapproved new drugs were seized during the search at Lumen Food Corporation, as well as items deemed as hazardous materials by chemical engineers. Also seized were 16/55 gallon drums of a liquid corrosive material at the industrial site owned by Caton. This liquid was subsequently identified as sulfuric acid and was mislabeled as non-corrosive. All of the hazardous materials seized were subsequently destroyed by a hazardous materials disposal company.

On May 26, 2004, Caton was convicted of violating Title 18 U.S.C. 1341 - Mail Fraud; and Title 21 U.S.C. 331(d), 355(a) and 333(a)(2) - Introduction into Interstate Commerce of Unapproved New Drugs. Caton also forfeited 2 buildings and his residence in Lake Charles, Louisiana.

On August 24, 2004, Caton was sentenced to 33 months incarceration to be followed by 3 years supervised release.

This was a joint investigation with the Lake Charles and Westlake Police Departments.

Unlawful Sale of Pharmaceuticals

This investigation was initiated based on a request for assistance from the Louisiana State Board of Wholesale Drug Distributors (LSBWDD) regarding allegations they received concerning the unlawful sale of pharmaceuticals within the state by a firm identified as G & L Clinical. LSBWDD informed OCI's New Orleans Resident Office, that G & L Clinical was not licensed by the State of Louisiana as a wholesale drug distributor. Louis Lenfant, a pharmacist, was identified as the owner of G & L Clinical as well as another firm called Mediquip, an infusion pharmacy. From May 18, 1998 to September 17, 2001, G & L Clinical engaged in the unlawful wholesale distribution of pharmaceuticals totaling $722,506 in sales to a medical clinic in New Orleans.

During the course of the investigation, the Louisiana Board of Pharmacy (LBP) advised that Lenfant was terminated on October 30, 2002, by Memorial Medical Center for stealing from the pharmacy's inventory. LBP subsequently provided copies of the results of the audit conducted by Memorial Medical Center and additional information related to the pharmacy board's investigation. The audit revealed significant shortages in the drugs Aredia, Taxol and Epogen. These drugs were also documented to be wholesaled by G & L Clinical.

On June 9, 2004, Lenfant was convicted of violating Title 21 U.S.C. 331(t), 353(e)(2)(A) and 333(b)(1)(D) - Unlicensed Wholesale Drug Distribution.

On September 29, 2004, Lenfant was sentenced to 15 months incarceration, $500,000 restitution to Memorial Medical Center, and 3 years of supervised release.

This was a joint investigation with DHHS' OIG, the Louisiana Attorney General's Office, and the Orleans Parish Sheriff's Office.

Counterfeit Labeling

An investigation was conducted based upon information provided by the DEA in Mobile, Alabama. According to the DEA, Gary Smith, owner of Omega Pharmaceuticals, received and distributed prescription drugs that were repackaged with counterfeit labeling bearing registered trade names of prescription drugs.

On February 24, 2004, a federal search warrant was executed at Omega Pharmaceuticals in Daphne, Alabama. The items seized included images of computer hard drives, business documents, and various prescription drugs suspected to be in counterfeit packaging. These drugs consisted of multiple bottles of 11 registered trademarked prescription drugs used in the treatment of HIV/AIDS, gastric ulcers, acid reflux disease and psychotic mental disorders. Forensic analysis confirmed that the drugs were in fact counterfeit in that they were repackaged, relabeled and/or contained different strengths or mixed strength dosages differing from their labeled contents. In addition, the drugs bore extended expiration dates. Most of the drugs were defective as to packaging, labeling and inserts. Some of the seized prescription drugs showed signs that they were not stored in a temperature controlled environment.

On June 9, 2004, Omega Pharmaceuticals, represented by Smith, was convicted of violating Title 21 U.S.C. 331(i)(3) - Selling and Holding for Sale a Counterfeit Drug.

On October 6, 2004, Omega Pharmaceuticals was sentenced to 5 years probation, and fined $24,000.

This was a joint investigation with the FBI and the Daphne Police Department.

Nurse Found Tampering with Patient's Medication

This investigation centered on the criminal activities of a registered nurse at the Winter Haven Regional Hospital, Winter Haven, Florida. The investigation revealed that during the year 2001, Robert David Shedd, R.N. had tampered with 73 vials of Meperidine HCL and 25 vials of Morphine Sulfate by removing a portion of the medications and replacing the medication with water. Shedd used the stolen medication to satisfy his addictions.

During the course of this investigation conducted by the Winter Haven Police Department and OCI's Miami Field Office, Shedd was identified as having uncontrolled access to the

controlled medications container in the Winter Haven Regional Medical Center, Progressive Care Unit, Winter Haven, Florida. Several vials of Meperidine HCL had been found to be sub-potent and upon inspection appeared to have been punctured through the top.

During the course of this investigation 129 samples of Morphine, Meperidine HCL or Lorazepam were collected and submitted to FDA's FCC, Cincinnati, Ohio, for analysis. FCC conducted individual examinations of the samples and determined that 98 vials had been punctured through their rubber top/stoppers.

On October 17, 2004, Shedd was sentenced to 2 years house arrest and 10 years probation. Shedd was also ordered to permanently surrender his nursing license and to undergo periodic urinalysis and psychological treatment. Shedd had previously been convicted of state felony charges of Tampering with a Consumer Product and Criminal Possession of Morphine and Meperidine.

Nurse Found Substituting Morphine and Nitroglycerine with Stadol

This case was initiated based on information regarding the tampering of prescription drugs by the subject Nancy Dean. Dean was a nurse at Eastern Medical Center, Bangor, Maine, and Cummings Healthcare Facility, Howland, Maine. Dean was found to have been substituting vials of Stadol for vials of Morphine and Nitroglycerine tablets for Morphine tablets.

In May 2000, Dean was interviewed by the Maine Attorney General's Healthcare Crimes Unit and admitted to taking the Morphine liquid and replacing it with Stadol and to substituting the Morphine pills with Nitroglycerine tablets. Dean was subsequently charged with misdemeanor drug diversion by the Maine Attorney General's Office. Dean failed to appear at her arraignment and fled the state of Maine. Dean was later identified as living in Texas.

In June 2003, information was received from Susan Manning, the sister of Dean, that Dean and her boyfriend Michael Bracy had been living with Dean's parents in Texas. During the month of June 2003, Dean and Bracy moved to the Bangor, Maine area.

After Dean returned to Maine, the Attorney General's Office opened an investigation against Dean. On October 1, 2003, Dean was arrested and charged with violating Title 18 U.S.C. 1365(a) - Tampering with a Consumer Product; and Title 21 U.S.C. 331(k) - Misbranding of Drugs after Introduction into Interstate Commerce.

In February 2004, it was learned through Manning that Dean left Maine, thereby violating the conditions of release set by the court. An investigation by OCI identified that Dean was residing in Glenmont, New York. This information was relayed to the U.S. Marshals Service.

Later in the month, Dean was arrested in Pensacola, Florida, and transported back to Maine by the Marshals Service. Dean was remanded until her sentencing.

On March 16, 2004, Dean was convicted of violating Title 18 U.S.C. 1365(a) - Tampering with a Consumer Product.

On October 26, 2004, Dean was sentenced to 71 months incarceration and 3 years of supervised release.

This was a joint investigation with the Maine Healthcare Crimes Unit.

Distribution of Unapproved Drug

On July 29, 2002, information was received that Medi-Hut Inc., a medical and drug wholesaler, headquartered in Lakewood, New Jersey, and publicly traded on the NASDAQ, may have been involved in stock manipulation and the distribution of an unapproved drug called Syntest. Syntho Pharmaceuticals, Farmingdale, New York, the manufacturer of Syntest, and Medi-Hut, Inc. teamed up to market Syntest, a new generic hormonal replacement therapy similar to the drug Estratest made by Solvay Pharmaceuticals. FDA's CDER confirmed that Syntest had not been approved by FDA.

On August 19, 2003, Joseph A. Sanpietro, President and Chief Executive Officer, Medi-Hut, Inc., Laurence M. Simon, Chief Financial Officer, Medi-Hut, Inc., and Lawrence P. Marasco, Vice President of Sales and Marketing, Medi-Hut, Inc., were convicted of violating Title 18 U.S.C. 371 - Conspiracy to Commit Securities Fraud and Wire Fraud; and Title18 U.S.C. 1001 - False Statements to the SEC. Vincent J. Sanpietro, Chief Operations Officer and Director, Medi-Hut, Inc., was convicted of violating Title 18 U.S.C. 1505 - Obstruction of Proceedings.

On November 16, 2004, Joseph A. Sanpietro was sentenced to 46 months incarceration and a $50,000 fine; Simon was sentenced to 46 months incarceration and a $5,000 fine; and Marasco was sentenced to 42 months incarceration and a $70,000 fine. Vincent Sanpietro was sentenced to 6 months home detention, 3 years probation, and a $5,000 fine for obstruction.

Controlled Substance(s)

Distribution of a Controlled Substance - www.pillsforyou.com

This case involves the investigation of James Hoffman, who was selling prescription drugs by operating an Internet website www.pillsforyou.com. The investigation of Hoffman began in Wilmington, North Carolina, but was transferred to Pittsburgh, Pennsylvania after Hoffman agreed to provide information regarding ongoing criminal activity in Pennsylvania.

On February 12, 2003, Hoffman was convicted of violating Title 21 U.S.C. 841(d) - Distribution of a Controlled Substance.

On July 13, 2004, Hoffman was sentenced to 15 months incarceration, followed by 3 years of supervised release.

On-Line Pharmacy Found Selling Controlled and Non-Controlled Prescription Drugs

This case was initiated based on information provided by the National Association of Boards of Pharmacy regarding an Internet website called No-Prescriptionpharmacy.com. This website offered for sale numerous controlled and non-controlled prescription drugs, such as Clenbuterol, Clomid, Valium, and Viagra, without any apparent requirement for an online consultation or a doctor's prescription. The domain registrant was identified as Alden L. Sears, residing in Berea, Kentucky.

Based on this information, two separate undercover orders were made from the website in April 2003. Both money orders were negotiated, however no products were received despite numerous email inquiries. In a joint operation with USPIS, search warrants were executed on Sears' residence in August, 2003, during which time numerous anabolic steroids were seized. Sears was arrested and charged with violating Title 18 U.S.C. 1341 - Mail Fraud. Sears was subsequently convicted of the charge.

This case was investigated by FDA's OCI and USPIS.

Fraud

Drugs Promoted for Treatment for Paraplegics or Quadriplegics Offer False Hope of Walking Again

This case was initiated based on information received from the FBI concerning the promotion and use of Neuralyn by Thomas Michael Vigil, and his wife, Beverly Vigil. Tom and Beverly Vigil owned and operated The Alternative Medicine and Biophysics Research Institute, Inc., Nampa, Idaho, and promoted Neuralyn on their website at www.neuralyn.com. More than 150 patients, most of them paraplegics or quadriplegics, paid up to $10,000 each to come to Nampa, Idaho, or affiliated clinics in Utah and Colorado, to be treated with Neuralyn.

Prospective patients were told that Neuralyn was 85 to 95% successful and could enable them to move or even walk again by re-generating nerve cells. The patients were also fraudulently told that Vigil was a medical doctor with training in biochemistry, that Neuralyn had undergone clinical studies, and that a patent application and FDA approval were pending.

Neuralyn was promoted as an all-natural substance made from plants from the Yucatan, but it actually contained a topical anesthetic that gave some patients temporary pain relief and led them to believe they were improving. Tom and Beverly Vigil charged $300 to $500 for a vial of Neuralyn for home treatment, claiming that the ingredients, production process, and costs of research and patent applications justified the high price. Both admitted, however, that the vials of Neuralyn cost them only $15 each.

After patients received the initial treatment in Idaho or at affiliated clinics, the Neuralyn was ordered from David Taylor, a pharmacist in Costa Mesa, California, who operated the D.T. Holistic Pharmaceutical Company.

On June 23, 2000, OCI and the FBI executed 4 federal search warrants in California, Idaho and Utah. Extensive documents and physical evidence supporting the production and sales of Neuralyn were seized.

On December 13, 2001, Taylor was convicted of violating Title 18 U.S.C. 371 - Conspiracy to Deliver for Introduction into Interstate Commerce a Misbranded Drug.

On January 9, 2002, a Federal Grand Jury, District of Idaho, returned a 28 count indictment charging Tom and Beverly Vigil with 1 count of conspiracy to commit wire fraud in violation of Title 18 U.S.C. 371 and 1343; 18 counts of wire fraud, and aiding and abetting wire fraud, in violation of Title 18 U.S.C. 1343 and 2; 1 count of conspiracy to deliver for introduction into interstate commerce, knowingly and with intent to defraud, a misbranded

drug, in violation of Title 18 U.S.C. 371; and 8 counts of delivering for introduction into interstate commerce, knowingly and with intent to defraud, a misbranded drug, and aiding and abetting the commission of that offense, in violation of Title 21 U.S.C. 331(a) and 333(a)(2) and Title 18 U.S.C. 2.

On January 15, 2002, Beverly Vigil was arrested on an outstanding warrant issued relative to the above indictment. During the arrest of Beverly Vigil, information was developed that her husband, Thomas Vigil, had fled to Mexico.

On September 24, 2002, Beverly Vigil was convicted of 2 counts of conspiracy as charged in the indictment.

On October 16, 2002, Taylor was sentenced to 5 years probation, ordered to pay $39,907 in restitution, and fined $5,000.

On June 16, 2003, Beverly Vigil was sentenced to 33 months incarceration; 3 years supervised probation, and ordered to pay $795,396 in restitution to the victims of her scam.

On October 11, 2003, Thomas Vigil was arrested by the Department of Homeland Security at the San Ysidro, California, Port of Entry on an outstanding warrant issued relative to the above indictment. Thomas Vigil was attempting to enter the U.S. from Mexico.

On March 25, 2004, Thomas Vigil was convicted of all counts as charged in the indictment. On August 24, 2004, Thomas Vigil was sentenced to 51 months incarceration, which represented the high end of the federal sentencing guidelines, 3 years supervised probation, and ordered to pay $810,541 in restitution to the victims of his scam. During the sentencing, Judge Winmill commented that this was the most egregious case of fraud he had seen in his seventeen years on the bench.

Pharmacy Compounding

Compounding Pharmacist Unlawfully Selling Impotence Products

This investigation involved a Miami, Florida based urologist, Dr. Carlos Nazir; a Cheshire, Connecticut based compounding pharmacist, David Gaudio, and several Internet and mail order companies that were unlawfully selling male impotence products known as Power Gel (combination of Phentolamine, Prostaglandin E1, and Papaverine, administered intraurethrally) and Vigor (oral Phentolamine).

The investigation, which included undercover purchases and search warrants, determined that the defendants unlawfully sold Power Gel and Vigor to thousands of customers

throughout the U.S. and Puerto Rico. Records further disclosed that they advertised the products as having no side effects and containing all natural ingredients.

Following are the judicial actions against the principals in this investigation as well as the Internet and mail order companies who were involved in the illegal activity.

On November 15, 2001, Alejandro Holch, and his business, Sports Telemarketing, were convicted of violating Title 21 U.S.C. 331(a)(1) and 333(a)(1) - Dispensing a Prescription Drug without a Prescription. On February 8, 2002, Holch was sentenced to 12 months probation and ordered to pay a $5,000 fine. Holch's corporation, Sports Telemarketing was also sentenced to 12 months probation and ordered to pay a $5,000 fine.

On December 12, 2001, Reynaldo Farinas, Vice President of Propharma, Inc., was convicted of violating Title 21 U.S.C. 331(a) and 331(a)(1) - Introduction into Interstate Commerce a Misbranded Drug; and Title 18 U.S.C. 2 - Aiding and Abetting. On February 25, 2002, Farinas was sentenced to 6 months probation and agreed to $25,000 in asset forfeiture.

On September 18, 2002, Gaudio was convicted of violating Title 21 U.S.C. 331(k) and 333(a)(2) - Dispensing a Prescription Drug without a Valid Prescription. On September 15, 2003, Gaudio was sentenced to 10 months incarceration, a $10,000 fine, and forfeited $150,000 to the Department of Justice, Asset Forfeiture Fund.

On November 15, 2002, Nazir was convicted of violating Title 18 U.S.C. 1341 and Title 18 U.S.C. 371 - Conspiracy to Commit Wire Fraud; Title 18 U.S.C. 1341 - Mail Fraud; Title 21 U.S.C. 331(a) and 333(a)(2) - Introduction into Interstate Commerce of Misbranded Drug (Power Gel and Vigor); and Title 18 U.S.C. 1956(h) - Conspiracy to Commit Money Laundering.

On the same date, Nazir was also convicted of charges associated with another investigation. In that case Nazir was convicted of violating Title 18 U.S.C. 1347 - Health Care Fraud (Medicaid Fraud), wherein he defrauded the government of over $1 million for prescription drugs (Neupogen) he purported to have provided to patients, but actually diverted. On November 14, 2003, Nazir was sentenced to 24 months incarceration and 3 years probation. Nazir was ordered to pay $1,022,232.60 in restitution to the State of Florida regarding the Medicaid fraud case.

On December 13, 2002, Francisco Munoz and Alberto Llona were convicted by a jury of Title 18 U.S.C. 371 - Conspiracy; Title 18 U.S.C. 1341 - Mail Fraud; Title 21 U.S.C. 331(a) and 333(a) - Introduction into Interstate Commerce of a Misbranded Drug; and Title 21 U.S.C. 331(k) and 333(a)(2) - Misbranding of Prescription Drugs after Shipment in Interstate Commerce. On November 14, 2003, Munoz and Llona were each sentenced to 51 months incarceration followed by 3 years probation. Munoz was also ordered to pay a fine of $12,500.

Illegal Pharmacy Compounding

This investigation was initiated based upon information obtained from the Southern Ohio Medical Center Pharmacy, Portsmouth, Ohio. The information revealed that the pharmacy had purchased 50 vials of the drug Sincalide (Kinevac) from a compounding pharmacy, Tricare Pharmacy Network, LLC, Lexington, Kentucky, without providing prescriptions as required by law. The Sincalide had labels bearing fictitious patient names, fictitious doctors names, and there existed potential sterility concerns; specifically the product arrived in powder form with instructions to keep the product frozen (although it was only cool), and sterility filters were included with instructions to add saline and inject the solution through the sterile filter.

Additional undercover purchases of prescription and controlled drugs both commercially available and unavailable were made from Tricare. The pharmaceuticals ordered were received bearing fictitious patient and doctor's names or were invoiced to disguise the drug that was shipped. Additionally, no prescriptions were ever required by or provided to Tricare.

In July, 2004, the Ohio State Board of Pharmacy and Tricare reached a settlement in which Tricare agreed to pay a $4,000 fine, receive a 1 month suspension and are prohibited from compounding and prescribing in Ohio without patient specific prescriptions. If they commit another offense there will be a total revocation of their Ohio pharmacy license.

On August 17, 2004, Gary Harris and Darren White, pharmacists at Tricare were convicted of violating Title 21 U.S.C. 331(k) and 353(b)(1) - Misbranding of a Drug after Receipt in Interstate Commerce. The 2 defendants were each fined $1,000.

Prescription Drug Marketing Act

Pediatrician Violates Prescription Drug Marketing Act (PDMA)

This case was initiated based on information received from the FBI’s Health Care Fraud Task Force in New Haven, Connecticut. The FBI reported that Dr. Jorge Elias, a pediatrician in Norwalk, Connecticut, allegedly committed a PDMA violation by selling and/or billing Medicaid and private insurance companies for prescription drug samples. Dr. Elias also committed health care fraud by billing Medicaid and private insurance companies for prescription drug vaccines that he received free of charge from the Vaccines for Children's (VFC) program administered by the State of Connecticut, Department of Public Health.

From December 2, 2003 to January 14, 2004, OCI's New York Field Office, the FBI's Health Care Fraud Task Force, New Haven, Connecticut, and the DHHS' OIG, Hartford, Connecticut, conducted an investigation which revealed that during the years 1995 to 2003, Dr. Elias received 3,000 free prescription drug vaccines per year from the State of Connecticut, Department of Public Health.

A review of Dr. Elias's patient billing records, provided by Medicaid and various private insurance companies, indicated that Dr. Elias billed for and was reimbursed for all the free prescription drug vaccines that he received, and that Medicaid and the private insurance companies paid Dr. Elias approximately $400,000 for these free vaccines.

On January 14, 2004, a federal search warrant was executed at Dr. Elias's office. Records and documents seized during the search documented that Dr. Elias did in fact bill for and was reimbursed for these free vaccines.

Dr. Elias was interviewed on January 14, 2004, incident to executing the search warrant. During this interview, Dr. Elias said he did not bill his patients, Medicaid, or private insurance companies for prescription drug samples. However, Dr. Elias did admit to billing Medicaid and private insurance companies for the free vaccines he received from the VFC program to offset the high cost of operating his office.

On May 28, 2004, Dr. Elias was convicted of violating Title 18 U.S.C. 1347 - Health Care Fraud.

On September 21, 2004, Dr. Elias was sentenced to 2 years probation, ordered to pay restitution in the amount of $222,920, and pay a fine in the amount of $30,000.

Illegal Sale of Repackaged Prescription Drug Samples

This case was initiated based upon information received from the Sterling Heights Police Department (SHPD), Sterling Heights, Michigan, concerning alleged violations of the PDMA by a local pharmaceutical sales representative, Larry Kozlowski. A search warrant had been executed at the home of Kozlowski. A large amount of repackaged prescription drug samples were seized along with discarded drug sample packaging. At the time of the warrant, Kozlowski was in California attending a business meeting at his employer, Alza Pharmaceutical Company. Kozlowski was a pharmaceutical sales representative for Alza Pharmaceuticals and was authorized to promote the sale of two Alza drugs known was Ditropan XL and Mycelex. FDA's OCI advised the SHPD that the sale of drug samples is a violation of the PDMA.

On February 16, 2000, Kozlowski advised his employer that the drugs found in his home were drug samples his wife had collected from an unknown source. Kozlowski was donating

them to World Medical Relief, Inc. (WMR), Detroit, Michigan. On the same date, FDA's Detroit District Office advised that WMR maintains a lawful pharmacy on their premises that is periodically inspected by FDA. OCI interviewed Carolyn George, Director, WMR, who stated that she would never accept repackaged drugs for donation. All donated drugs remain in their original packaging from the manufacturers and are usually donated by area doctors, not pharmaceutical sales representatives.

On February 23, 2000, OCI and SHPD interviewed Martin Newman, a pharmacist employed at the Plumbrook Pharmacy, Sterling Heights, Michigan. Newman claimed he did not know Kozlowski and that he would never purchase drug samples from anyone. The next day, Newman confessed that he purchased numerous stolen re-packaged drug samples from Kozlowski and had done so on a regular basis since 1997. Newman stated Kozlowski delivered the drugs to him every 6 weeks and he purchased them for 40% below the average wholesale price.

On February 24, 2000, OCI and SHPD interviewed Dr. Lionel Gale who stated he received repackaged drugs from Kozlowski. Dr. Gale then donated the drugs to a charity called Youth for Christ for shipment to Burkina Faso, Africa.

On May 3 and 8, 2000, Kozlowski was interviewed with his attorney present and made a full confession. During the course of his confession, he implicated his wife, Jodie, and other family members.

On May 25, 2000, Jodie Kozlowski was interviewed with her attorney present. She admitted her role in her husband's drug sample scheme.

On August 25, 2000, Robert Vandenberghe, a pharmacist, was interviewed and confessed to purchasing re-packed stolen drug samples from Kozlowski on several occasions. The purchase price for these drug samples was approximately $12,000.

On November 20, 2000, Vandenberghe was convicted of violating 1 count of Title 21 U.S.C. 331(t) - Sale of Drug Samples. Vandenberghe was later sentenced to 2 years probation and fined $1,000.

On November 27, 2000, Newman was convicted of violating 1 count of Title 21 U.S.C. 331(t) - Sale of Drug Samples. Newman was later sentenced to 2 years probation and fined $3,000.

On November 7, 2001, Larry Kozlowski was convicted of 1 count of violating Title 18 U.S.C. 1347 - Healthcare Fraud. Jodie Kozlowski was convicted of 1 count of violating Title 21 U.S.C. 331(t) - Sale of Drug Samples.

On February 11, 2002, a final order of forfeiture was signed which included 2 vehicles and over $700,000 in cash.

On December 15, 2003, Larry Kozlowski was sentenced to serve 9 months in a halfway house, fined $20,000, and received 3 years probation.

On December 18, 2003, Jodie Kozlowski was sentenced to 1 year probation and fined $1,000.

Smuggling

Firm Found Smuggling Counterfeit Hair Care Products

This investigation was initiated based on a referral from the ICE that Vincenzo Russolillo, d.b.a. Art Packaging and Hair Perfect Salons, 3587 NW 82nd Ave., Miami, Florida, imported approximately 15 containers of counterfeit Sebastian Shaper Hair Spray through the Port of Miami, Florida.

On May 13, 2004, Russolillo was convicted of violating Title 18 U.S.C. 371 - Conspiracy; and Title 18 U.S.C. 545 - Smuggling. Russolillo was sentenced to 78 months incarceration and 3 years supervised release. Russolillo was also ordered to pay restitution of $150,000 to the Matrix Company and $2,740,074 to Sebastian Hair Care.

The investigation also determined that Orlando Quinones used his companies International Commidity Network, Inc., and National Consumer Imports and Warehousing, Inc., to distribute the counterfeit goods throughout the U.S.

On February 25, 2003, Quinones was indicted by a federal grand jury in the Southern District of Florida on 3 felony counts of violating Title 18 U.S.C. 371 - Conspiracy; Title 18 U.S.C. 545 - Smuggling; and Title 18 U.S.C. 2320 - Trafficking in Counterfeit Goods.

On December 3, 2003, Quinones was convicted of these charges individually and on behalf of the companies.

On May 3, 2004, Quinones was sentenced to 37 months incarceration to be followed by 3 years probation. The companies International Commodity Network, Inc., and National Consumer Imports and Warehousing, Inc., were each sentenced to 1 year probation, assessed $1,600 in fines and International Commodity Network, Inc., agreed to forfeit $80,000 in assets to the ICE.

Anabolic Steroids from Thailand

This investigation was initiated in April 2002, when information was received regarding the shipment of 3,036 anabolic steroids from Bangkok, Thailand to Middlesex, New Jersey. The steroids were intercepted and detained by the U.S. Customs Service's (Customs) Los Angeles Field Office.

The recipient of the steroids was Anthony Malloy. Malloy was previously on record for the smuggling of prescription drugs from Mexico into the U.S.

USPIS conducted checks on the address located in Middlesex, New Jersey and determined the address to be a Mailboxes Etc.

During subsequent criminal history checks for Malloy it was revealed that he had been arrested several times for assault, harassment and narcotics. Malloy was also arrested in 1998 by the South Plainfield Police Department for the possession and distribution of anabolic steroids.

On April 30, 2002, Malloy was arrested outside the Mailbox Etc. facility in Middlesex, New Jersey after picking up the package of anabolic steroids. Assisting in the arrest was the Middlesex County Prosecutors Office, OCI, Customs, the Middlesex Boro Police Department and USPIS.

On October 25, 2002, Malloy was convicted of state felony charges.

On March 3, 2004, Malloy was sentenced to 5 years incarceration in a state penal facility and 2 years probation.

Smugglers Caught with Marijuana and Unapproved Ephedrine

On September 24, 2003, the ICE's Office of the Resident Agent in Charge, Blaine, Washington, informed OCI's Seattle Resident Office, that they would be conducting a marine enforcement activity on the Puget Sound later that day and evening. The ICE had obtained information that indicated smugglers were involved in using the Puget Sound water ways to smuggle narcotics and other contraband into the U.S. from Canada to by-pass the declaration of these goods.

On September 25, 2003, Mike Morcom was arrested in U.S. waters near Canada as he attempted to smuggle numerous large hockey-style bags into the U.S using a small rubber zodiac water vessel, under the cover of darkness. The bags contained approximately 275 pounds of marijuana and 170 pounds of suspected misbranded and unapproved ephedrine.

On November 21, 2003, Morcom was convicted of violating Title 21 U.S.C. 841(a)(1) - Distribution of a Controlled Substance.

On February 13, 2004, Morcom was sentenced to 37 months incarceration with 3 additional years of probation.

This was a joint investigation with the ICE, the U.S. Border Patrol, and the U.S. Coast Guard.

Tampering

Civilian Nurse Found Tampering with Demerol

This case was initiated based on information regarding the suspected tampering of vials of Demerol and morphine sulfate at the Evans Army Community Hospital located at Ft. Carson Army Base in Colorado Springs, Colorado.

On April 8, 2003, Ivan Segura, a civilian nurse employed at the hospital, was indicted by the federal grand jury in the District of Colorado on a 52 count indictment charging violations of Title 18 U.S.C. 1347 - Health Care Fraud; Title 18 U.S.C. 1365 - Tampering with a Consumer Product; and Title 21 U.S.C. 843 - Obtaining Controlled Substances by Deceit and Fraud.

On January 17, 2004, Segura was convicted of Title 18 U.S.C. 1365 - Tampering with a Consumer Product.

On August 17, 2004, Segura was sentenced to 60 months incarceration. Upon his release from prison, Segura will be placed under supervisory probation for a period of 36 months. Segura was also ordered to make restitution in the amount of $9,000.

OCI Investigates Tampering With Children's Tylenol

The case involves the substitution of Children's Tylenol (80 mg) chewable tablets with Extra Strength Tylenol tablets in 500 mg strength. The boxes and bottles were labeled as the Children's product; however the adult version strength was contained inside the bottles. Three of these bottles were placed on the shelf of a Giant Food Store in Pennsylvania. A consumer noticed the difference just prior to giving her child four of the tablets. Gehan Awad was subsequently identified as the individual who had tampered with the Children's Tylenol.

Awad was interviewed by OCI agents and subsequently admitted to substituting the Tylenol for monetary purposes.

Awad agreed to waive indictment and was convicted of violating Title 18 U.S.C. 1001 - False Statements.

On January 16, 2004, Awad was sentenced to 1 year probation.

Center for Food Safety and Applied Nutrition

Attempts to Import Betel Nuts Result In Fine and Restitution

This investigation was initiated based on information received from the U.S. Customs Service (Customs) that a 20-foot container of imported food items, container number 1636849, was on a Canadian Pacific Railway train en route from Montreal, Canada, through Detroit, with a final destination at the Canadian Pacific Railway Yard, Chicago, Illinois. The importer of record for the food items was Salwan Trading Company, Schaumburg, Illinois. The container contained Betel Nut products (a prohibited food product according to FDA's Import Alert #23-06, revised July 17, 1992). However, no Betel Nut products were listed on the invoice/manifest or any other documents required for import.

On June 12, 2000, at the Canadian Pacific Railway Yard, Chicago, Illinois, the contents of container number 1636849 and identified numerous boxes were examined and were imprinted with the words "Lijjat Papa Mumbai 80 Pkts X 200 gms." Approximately half of these boxes had stickers on them labeled, in part, "...Garlic Papad..." and half of the boxes did not have these stickers on them. An examination of 5 of the boxes with the stickers revealed that they contained a tortilla-type food product. However, an examination of 5 of the boxes without the stickers revealed that they contained crushed Betel Nut products. Samples of the Betel Nut products were obtained and subsequently analyzed.

The analyses of the samples determined that they contained arecoline, the alkaloid that causes cancer and makes Betel Nut products a prohibited food item in the U.S. An examination of the invoice and other documents, which accompanied this import, was subsequently presented to FDA and Customs in order to allow the products to be imported into U.S. commerce, revealed that the entry reportedly only consisted of various "assorted food products," imported from Veerprabhu Export House, Mubai, India. Surveillance revealed that the container was delivered to Salwan Trading Company.

A search was conducted at Salwan Trading Company. During the search, a large quantity of Betel Nut products in various packaging and form (whole, crushed, processed and packaged

with flavoring) and business records were seized. Also, during the search a customer was interviewed and admitted to having just purchased numerous types of packaged Betel Nut products from Salwan Trading Company. The Betel Nut products purchased by this individual were seized as evidence.

During the search, Ayodhia Salwan, Owner, Salwan Trading Company, was interviewed and initially stated that his company never sold Betel Nut products. However, after he was shown the large amount of Betel Nut products that were being seized, Salwan stated that he only sold Betel Nut products that had been laboratory tested, and released by FDA and Customs. Salwan stated that he was the individual who placed the orders to his overseas food suppliers, to include Veerprabhu Export House. When Salwan was shown the Betel Nut products in container number 1636849 and the accompanying documents that identified the contents of the container as "Lijjat Papa Mumbai" - food products, he stated that Veerprabhu Export House personnel placed the Betel Nut products in the shipment by mistake.

A review of the records identified 18 importations by Salwan Trading Company, during the period January 1997 to June 2000, suspected of containing Betel Nut products.

On November 24, 2004, Salwan Trading Company was convicted of violating Title 18 U.S.C. 542 - Entry of Goods by Means of False Statements. Salwan Trading Company was fined $16,000, and ordered to pay $4,753.73 in restitution to the U.S. government for avoiding Customs duties.

Smuggling Bottled Water with “Off” Taste

This case was initiated based upon a referral from FDA’s New Orleans District Office and information received from the U.S. Immigration and Customs Enforcement (ICE) regarding the sale of bottled water that was smuggled into the U.S. from Canada by WGM Marketing. The smuggled bottle water was believed to be adulterated as complaints were received indicating that the product had an “off” taste.

The investigation identified the manufacturer of the water as Clearly Canadian Beverage Corporation (CCBC) who contracted with Recycle Plus for the destruction of 1,556,568 bottles of water. Recycle Plus instead sold the bottled water either to itself or through Littlewolf Enterprises, Inc., to WGM Marketing, a company that specializes in selling distressed merchandise. CCBC advised the ICE that the water was an "off spec" problem dealing with a bad taste. CCBC informed the ICE that they became suspicious of Recycle Plus when they could not obtain verification of destruction and Recycle Plus’ subsequent reluctance to cooperate in the reconciliation of the inventory.

On July 31, 2003, the ICE executed a search warrant on WGM Marketing resulting in the seizure of approximately 317,568 bottles of Reebok Fitness Water. A constructive seizure

agreement was executed and signed by William McDaniel, owner of WGM Marketing, regarding the Reebok Fitness Water. During the execution of the search warrant, samples of the Reebok Fitness Water were taken by FDA for further analysis.

On April 2, 2004, WGM Marketing, represented by McDaniel, was convicted of Title 21 U.S.C. 331(a) - Introduction into Interstate Commerce of Adulterated Food; and Title 18 U.S.C. 545 - Smuggling. The company was later sentenced to 1 year probation, fined $15,000, and ordered to pay restitution of $11,049. McDaniel was instructed to take the necessary steps toward dissolution and effective termination of WGM Marketing.

Trafficking in Counterfeit Dietary Supplements

On October 3, 2001, information was received from the U.S. Attorney's Office, Eastern District of Philadelphia, and the Federal Bureau of Investigations (FBI) that Scott Knox and Theodore Sosangelis, the owners of East Coast Ingredients, 211 South Street, Philadelphia, Pennsylvania, were misbranding, distributing, and trafficking in counterfeit dietary supplement products.

Knox and Sosangelis conspired with 2 individuals from Canada, Derek Okukuro and Kent Mosur, to distribute counterfeit dietary supplement products through their company, East Coast Ingredients. They manufactured a different version of the dietary supplement products manufactured by Muscletech. They then placed counterfeit Muscletech labels on these counterfeit products, and distributed and sold these counterfeit dietary supplement products to customers who believed that they were purchasing legitimate Muscletech products.

Knox and Sosangelis were both convicted after bench trials. Knox was sentenced to serve 18 months incarceration and Sosangelis was sentenced to 3 years probation.

On January 23, 2004, Okukuro and Mosur were convicted of violating Title 18 U.S.C. 2 and 18 U.S.C. 2320 - Aiding and Abetting and Trafficking in Counterfeit Goods. Each were sentenced to 2 years probation, and ordered to pay restitution in the amount of $210,000.

Defendant Used Expired Ingredients in Dietary Supplements

This investigation was initiated in February 1998 based on information received from FDA's Milwaukee Resident Post regarding Shara Laboratories, a dietary supplement manufacturer in Wautoma, Wisconsin. Arnold Suresky was the principal owner of Shara Laboratories. Several former employees of Shara Laboratories alleged that dietary supplements were rebottled and relabeled using expired ingredients or less costly ingredients (product substitution). One product was labeled as containing 100% "Pur Gar, garlic powder."

However, the product contained another ingredient, “Triarco, garlic powder.” Suresky also instructed his employees to destroy and/or alter business records that were responsive to several Grand Jury Subpoenas.

On November 26, 2003, a Criminal Information was filed charging Suresky with violating Title 21 U.S.C. 331(a) and 333(a)(2) - Introduction and Delivery of a Misbranded Product into Interstate Commerce; and Title 18 U.S.C. 2 - Aiding and Abetting.

On January 9, 2004, Suresky was convicted and later sentenced and fined $90,000. Suresky also agreed that he would never hold any position, in any business, regulated by the Federal Food, Drug, and Cosmetic Act or the U.S. Public Health Service Act.

Food Service Found Selling Spoiled Meat to Rest Homes and Schools

This case was initiated based on regulatory inspections conducted by FDA and the North Carolina Department of Agriculture on Nichols Food Service, Inc., Wallace, North Carolina. Nichols Food Service, Inc. sells meat and poultry products to restaurants, rest homes, and schools in the states of North Carolina and South Carolina. The inspections performed discovered unsanitary conditions including putrid, moldy and spoiled meat and poultry, rodent excreta pellets and live roaches in the warehouse. As a result, charges were brought for causing federally inspected meat and poultry, suitable for human consumption, to become adulterated and misbranded.

On March 14, 2004, James L. Nichols, III, owner of Nichols Food Service, Inc. and Jeff Rand, Vice President of Operations, entered into Pretrial Diversion Agreements in the Eastern District of North Carolina. Nichols and Rand were convicted of violating Title 21 U.S.C. 331(k) - Mislabeling of Food, Causing Adulteration and Misbranding, and Title 21 U.S.C. 610(d) and 676 - Adulteration of Meat, Poultry, and Grain Products.

The agreements state their prosecution shall be deferred for a period of 18 months provided certain conditions are met. Nichols and Rand were ordered to complete 100 hours of community service and 80 hours of training to insure the sanitary practices of his company. Nichols was also ordered to pay a $5,000 fine. Nichols Food Service, Inc., et al., was ordered to pay $8,053 in restitution to the U.S. Department of Agriculture.

Importer Attempts to Circumvent FDA Imports

On February 14, 2001, this investigation was referred to OCI’s Los Angeles Field Office by FDA’s Southwest Import Division, located in Otay Mesa, California. The Southwest Import Division physically sampled 3 shipments of avocado product imported from Mexico by G

Products, Inc., (Owner/Alain Guizar) an importer based in San Diego, California. The laboratory analysis indicated that the shipments were contaminated with *Listeria Monocytogenes*. As a result of the positive *Listeria* readings, all entries or shipments of avocado that G Products, Inc. imported from the Mexican manufacturer were detained. However, Guizar advised that he exported 22 of the detained entries to Mexico, without formal notification to the U.S. Customs and Border Protection and FDA. Furthermore, in his efforts to import the avocado product and circumvent FDA, Guizar changed the names of the manufacturers (EPAMSA and COMISA), made false statements to FDA concerning the location of the shipments, and attempted to import a shipment of avocado product at a different port of entry, Calexico, California, and under a different importer's name (Sanitary Food Products).

On July 9, 2003, G Products, Inc., was convicted of violating Title 18 U.S.C. 542 - Entry of Goods by False Statement; and Title 18 U.S.C. 2 - Aiding and Abetting. Alain Guizar was convicted of violating Title 21 U.S.C. 331(k) and 333(a)(1) - Alteration of a Label While Article is Held for Sale after Shipment in Interstate Commerce; Title 21 U.S.C. 331(c) and 333(a)(1) - Receipt in Interstate Commerce of an Adulterated Food; and Title 18 U.S.C. 2 - Aiding and Abetting.

Benoit Guizar was convicted of violating Title 21 U.S.C. 331(k) and 333(a)(1) - Alteration of a Label While Article is Held for Sale after Shipment in Interstate Commerce; and Title 18 U.S.C. 2 - Aiding and Abetting. Tandeleya Guizar was convicted of violating Title 21 U.S.C. 331(c) and 333(a)(1) - Receipt in Interstate Commerce of an Adulterated Food; and Title 18 U.S.C. 2 - Aiding and Abetting.

On July 9, 2003, Tandeleya Guizar and Benoit Guizar were each immediately sentenced to 2 years probation.

On December 8, 2003, G Products, Inc., the corporation, was sentenced to 1 year probation and a $5,000 fine.

On March 1, 2004, Alain Guizar was sentenced to 5 years probation and a $3,600 fine.

Center for Veterinary Medicine

Defendant Found Selling Veterinary Steroids Without a Veterinary Prescription

This case originated upon a referral from OCI's Chicago Field Office. In October 2001, information was developed which revealed that John "Jack" Ward was again selling Vitamin

B complex injectables and veterinary steroids without a veterinary prescription to harness racing individuals at a racetrack in the vicinity of Columbus, Ohio. Ward had previously been convicted in a 2 count information for similar drug offenses in 1995, which resulted in his receiving probation.

During February 2002, information was developed which revealed that Ward and Carl Clyne were present at a Delaware, Ohio, horse auction and were offering to sell unapproved and misbranded veterinary drugs. During a subsequent meeting and undercover sting operation, Clyne sold a total of 7 vials of unapproved and misbranded injectable drugs which had been smuggled into the U.S. from Canada.

In the aftermath of the sting operation, Clyne agreed to cooperate in the investigation. Clyne gave consent to search his storefront operation located in Plain City, Ohio, which resulted in the seizure of approximately 40 cases of unapproved and misbranded veterinary drugs which had been smuggled into the U.S. from Canada. Clyne advised that Ward was the co-owner of the store front operation. Ward subsequently confessed to his complicity in the operation. On October 28, 2003, both Ward and Clyne were convicted of violating Title 21 U.S.C. 331(a) - Introduction of Misbranded Drugs into Interstate Commerce.

On January 9, 2004, Ward was sentenced to 3 years probation and 3 months home confinement. Clyne was also sentenced 1 year probation.

This case was investigated by OCI with assistance from Standardbred Investigative Services.

Impersonation of FDA Investigator

This case originated upon information from the Nassau County Police Department that Lewis Tacktill used an “FDA Investigator” badge to affect a vehicle stop in Nassau County, New York. The occupants of the car were two off duty New York City Police Department Officers. Assistance was requested to confirm or refute Tacktill’s employment with FDA and to authenticate and identify the badge confiscated at the scene.

On January 9, 2004, Tacktill was interviewed regarding his possession of the FDA badge. Tacktill admitted that he was not an FDA employee, but received the badge from his aunt, a former FDA employee. Tacktill was arrested and charged with a violation of the New York State Penal Law, Section 190.25 (3) - Criminal Impersonation in the Second Degree, a Class A Misdemeanor.

On January 9, 2004, Tacktill’s aunt was interviewed and advised that she retired from the FDA approximately 2 years ago. The aunt verified that she gave her nephew, Tacktill, the FDA badge approximately 30 years ago as a souvenir. She also advised that when she was

assigned to the Brooklyn, New York Office, years ago badges that were no longer in active use were distributed to select employees as souvenirs.

On February 13, 2004, Tacktill was convicted of disorderly conduct.

Substitution of Equine Drug

This case was initiated in August 2002 on a referral from FDA's Cincinnati District Office. The referral was based on a complaint received regarding a suspected tampering and sale of the equine drug Legend. William Skipper, a stable manager, was alleged to have tampered with and sold vials of Legend to a professional barrel racer. Skipper was interviewed and while he admitted to selling the pharmaceutical without a pharmacy or medical license, he denied having any knowledge that the drug had been tampered with.

Upon being interviewed a second time, Skipper admitted to the tampering. Skipper replaced the drug Legend with the equine drug Banamine, which he believed would be less harmful to the horse it was being administered to. It should be noted that Banamine is significantly less expensive than Legend. FDA's Forensic Chemistry Center analyzed the product and confirmed that the vials contained between approximately 1% and 10% of the stated amount of Legend, and also contained Banamine.

On June 18, 2004, Skipper was convicted of violating 1 felony state charge of Tampering with Drugs and 2 misdemeanor state charges of Sale of Adulterated or Misbranded Drugs.

Assault on FDA Consumer Safety Officers

On July 2, 2002, Anthony R. Dinitto, owner/operator of Dinitto Farms Dairy, Marcy, New York assaulted two FDA Consumer Safety Officers from the Syracuse Resident Post while they were conducting a tissue residue inspection.

On January 8, 2004, Dinitto was convicted of violating Title 18 U.S.C. 111(a) - Simple Assault on a Federal Officer.