

FDA Law Enforcers Protect Consumers' Health

Inside the Office of Criminal Investigations

When it comes to fighting crime, most Americans think of the FBI, state troopers, sheriffs' agencies, and police departments. Much less known is a battle waged against certain kinds of criminals by law officers whose badges identify them as "FDA-Special Agent."

The men and women of FDA's Office of Criminal Investigations (OCI) represent the consumers' front line against companies and individuals who endanger the public's health. These criminals carry out unlawful actions involving pharmaceuticals, foods, and other products regulated by FDA. OCI focuses on violations of two laws—the Federal Food, Drug, and Cosmetic Act and the Federal Anti-Tampering Act.

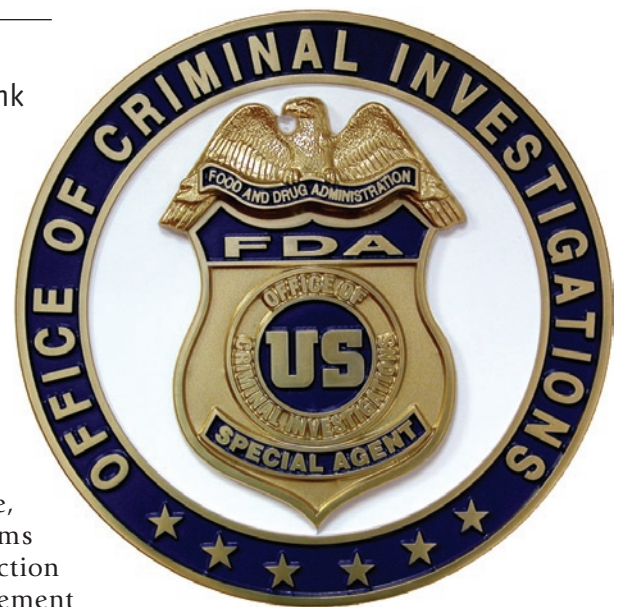
The Role of Special Agents

FDA's Special Agents are stationed in multiple cities throughout the continental United States and Puerto Rico. "We operate much like every other federal law enforcement organization," says Terry Vermillion, founding Director of OCI.

"We gather facts and present them to the local U.S. Attorney's Office," he says. "The U.S. Attorney's Office determines if and who will be prosecuted and OCI does the investigative work to support the effort."

Special Agents:

- come to FDA mostly from other federal law enforcement agencies, such as the U.S. Secret Service, Immigration and Customs Enforcement, Postal Inspection Service, and Drug Enforcement Administration
- bring years of prior federal criminal investigative experience using traditional law enforcement methods, professional contacts, and investigative techniques
- investigate FDA-related crimes typically involving counterfeit, unapproved or illegally diverted drugs, product tampering and substitution, fraudulent health treatments, and allegations of fraud in new drug applications and clinical trials
- have all the legal powers and capabilities of a well-equipped federal law enforcement organization



- have federal statutory authority to obtain and execute arrest and search warrants, carry firearms, and gather evidence to enforce United States criminal law
- obtain specialized training as polygraph examiners, computer forensics examiners, firearms instructors, and technical surveillance specialists (if selected to do so)

A Collaborative Approach

FDA's Special Agents frequently investigate criminal wrongdoing by large companies. If these investigations lead to prosecution, the guilty

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officers and employees often receive federal prison sentences, while the company can expect to receive multimillion-dollar fines and restitution payments.

Many times when OCI initiates an investigation, other federal law enforcement agencies that have a jurisdictional interest will join the investigation. Many OCI cases have an international aspect. Since being founded in 1992, OCI has developed good working relationships with many foreign law enforcement counterparts, which aid in bringing criminals outside the United States to justice.

Field investigations are enhanced by OCI's skilled investigative analysts and technical specialists. In addition, the FDA's Forensic Chemistry Center in Cincinnati, Ohio, provides valuable forensic laboratory support by performing many different laboratory tests related to suspect products involved in OCI investigations.

Examples of Investigations

In a typical year, FDA's Special Agents will investigate about 1,000 criminal cases resulting in the arrests of hundreds of suspected violators of public health laws.

On average, 200 criminal suspects are convicted each year as the result of OCI investigations. From 1993 to present, OCI has made 4,593 arrests that resulted in 3,546 convictions and more than \$5.7 billion in fines and restitutions.

Overcharging for Zoladex: OCI, working with several other agencies, uncovered a massive conspiracy to

overcharge Medicare, Medicaid, and other providers for a drug for prostate cancer. The company paid more than \$291 million in fines and restitution to U.S. and state governments.

Illegal schemes for Serostim: After OCI's Special Agents discovered a conspiracy to commit health care fraud by bribing doctors and using other illegal methods to market a treatment for AIDS, the company paid \$704 million in criminal fines and restitution to the U.S. Treasury.

Illegal promotion for OxyContin: A major pharmaceutical company and three executives were convicted for having falsely labeled, promoted, and illegally marketed a potent pain reliever. The company paid fines and restitution totaling more than \$600 million.

Counterfeit drugs: Beginning in 2005, an OCI counterfeit drug investigation has resulted in the indictment of three businesses and 24 individuals for their involvement in a \$42 million conspiracy to manufacture and sell counterfeit Lipitor and other drugs that they manufactured in a Costa Rican lab. To date, 20 have been convicted.

Internet case: On April 12, 2006, two men were sentenced in the Southern District of Indiana Federal Court to 77 months incarceration after pleading guilty to introducing a misbranded drug into interstate commerce. Dextromethorphan (DXM), a cough suppressant, was sold over

the Internet through their Web site. This case started in 2005 when five young people died after consuming DXM that they had ordered through the Web site.

Clinical investigator fraud: An investigation by OCI and the Veterans Affairs Office of Inspector General resulted in the conviction of a Veterans Affairs' employee who claimed to be a physician but in fact was not. This employee falsified documentation of a clinical drug study and recklessly enrolled patients who did not qualify under the study protocol. The defendant's criminal negligence caused the death of one patient by falsely documenting the results of blood chemistry analysis. The defendant was prosecuted and sentenced to 71 months federal incarceration.

Food contamination: The president of a cold storage distribution company was convicted and sentenced to one year of federal incarceration. The company paid hundreds of thousands of dollars in restitution for reboxing and relabeling food tainted by an ammonia leak at the cold storage facility. The contaminated food was delivered to an Illinois elementary school, causing 43 students and staff to become hospitalized.

Illegal drug diversion: In 2006, father and son owners and operators of a Florida pharmaceutical wholesale distributorship were sentenced to 18 years and 25 years incarceration, respectively. They also paid more than \$27 million in restitution for

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their involvement in an illicit diversion scheme to buy and sell millions of dollars of illegally obtained medications used to treat AIDS, cancer, hemophilia, and other ailments. This scheme defrauded the Medicaid and Medicare programs of more than \$45 million.

Faulty surgical devices: OCI agents were instrumental in securing the conviction of two company executives who had fraudulently sold surgical sterilizing devices that caused eye damage in 18 patients, one of whom lost sight in one eye.

Unlicensed flu vaccine: In 2005, OCI agents arrested a person in Texas who administered counterfeit influenza vaccine. Agents also brought about a federal conviction of a smuggler who tried to sell the foreign, unlicensed flu vaccine to hospitals.

Contaminated pet food: In 2007, OCI initiated this investigation after FDA received numerous reports that contaminated pet food was injuring and killing pets nationwide. The products were contaminated with melamine, an ingredient that is not approved for use in human or pet food. In February 2008, a federal grand jury in Kansas City, Mo., indicted two Chinese companies and their two top executives along with an American company and its owners on charges including introducing adulterated and misbranded food into interstate commerce. Pet food manufacturers had to recall more than 150 brands of dog and cat food across the nation.

Fraudulent cures: In 2005, OCI began investigating several Web sites selling fraudulent cures for various diseases. The Web sites, which were operated by a Dutch national, contained fictitious articles from nonexistent doctors, fictitious testimonials from purported customers, and claims that the products were FDA-approved when they were not. In December 2005, based on evidence gathered by OCI, the defendant received but ignored a court order prohibiting him from producing and selling his products. He was indicted for criminal contempt, misbranding drugs, conspiracy, and mail and wire fraud. In 2008, he was sentenced to 210 months incarceration.

How to Report Suspected Crime

OCI has six field offices and six resident offices located throughout the United States and Puerto Rico. Field offices are located in New York; Washington, D.C.; Miami; Kansas City, Kan.; Chicago; and Los Angeles. Resident offices are located in San Francisco; Austin, Texas; New Orleans; San Juan, Puerto Rico; Atlanta; and Boston.

Consumers can alert OCI to suspected criminal activity involving FDA-regulated products by contacting the OCI office located in their region:

OCI headquarters: 240-276-9500

New York: 201-547-3851

Washington, D.C.: 240-276-9400

Miami: 954-476-5400

Los Angeles: 949-366-4600

Kansas City, Kan.: 913-384-7400

Chicago: 630-769-5520


San Francisco: 510-637-3480

Austin, Texas: 512-349-2599

New Orleans: 985-871-5152

San Juan, Puerto Rico:
787-281-4863

Atlanta: 404-253-2317

Boston: 978-531-5850 

This article appears on FDA's Consumer Health Information Web page (www.fda.gov/consumer), which features the latest updates on FDA-regulated products. Sign up for free e-mail subscriptions at www.fda.gov/consumer/consumerenews.html.

For More Information

FDA Law Enforcers Crack Down on Illegal Botox Scammers
www.fda.gov/consumer/updates/botox081308.html

FDA's Office of Regulatory Affairs
www.fda.gov/ora/

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