

FDA Criminal Unit Guards Public Health

When it comes to protecting the public, most people think of their local fire, police, and sheriff’s departments, state troopers, and the FBI.

What’s less known is that the Food and Drug Administration (FDA) also has a team of criminal investigators—called special agents—who are protecting public health as part of the Office of Criminal Investigations (OCI).

These agents are charged with protecting \$1 trillion worth of food, drugs, cosmetics, and other FDA-regulated products from theft, counterfeiting, fraud, tampering, and false advertising as spelled out in these federal laws:

- **Food, Drug, and Cosmetic Act and amendments:** These laws establish safety and purity standards for almost all food products and ensure the safety and effectiveness of all drugs, medical devices, animal drugs, and biological products—including blood, vaccines, and tissues for transplantation. The law was passed in 1938 after 107 people died from taking a new, liquid form of Elixir Sulfanilamide, commonly prescribed for streptococcal infections. In the rush to market the medication, the drug maker did not test the liquid formula for safety.
- **Anti-Tampering Act:** The law prohibits tampering with consumer products. It was passed in 1983 in response to the deaths of nine people who took Tylenol spiked with cyanide.

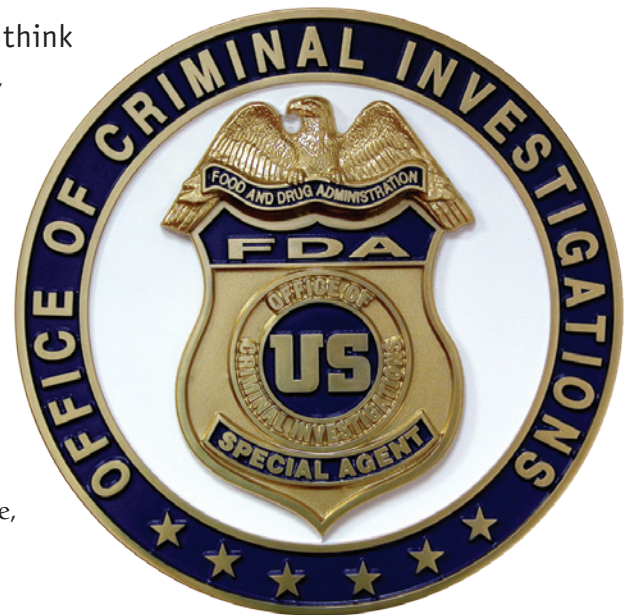
“These laws enable the FDA to protect the American people from dangerous products that threaten the public health. Office of Criminal Investigations (OCI) special agents make it possible for families to have confidence in the safety of the drugs, medical devices, and foods they buy,” says Thomas P. Doyle, OCI’s acting director.

Role of Special Agents

Doyle says the agency’s special agents operate much the same as other law enforcement investigators, but they use specialized knowledge and training to investigate violations of food and drug laws across the United States and Puerto Rico.

These agents are responsible for gathering information in civil and criminal investigations and presenting it to the local U.S. attorney’s office. The U.S. attorney determines if a case will be prosecuted; and, if it is, FDA’s law enforcement officers gather evidence to support the prosecution.

- In general, these agents
- come to FDA mostly from other federal law enforcement agencies, including the U.S. Secret Service, FBI, Immigration and Customs Enforcement, the Postal Inspection Service, and the Drug Enforcement Administration;



- obtain and execute arrest and search warrants, carry firearms, and gather evidence to enforce U. S. laws; and
- obtain specialized training as lie detector examiners, computer forensics examiners, firearms instructors, and technical surveillance specialists (if selected to do so).

Agency Collaboration

OCI frequently investigates allegations of criminal wrongdoing by large companies and their officers. If an investigation leads to prosecution and conviction, the guilty officers sometimes receive federal prison sentences, and the company may be ordered to pay millions of dollars in fines and restitution.

In some cases when OCI begins



What OCI Investigates

- Manufacture and sale of counterfeit or unapproved drugs/devices
- Promotion of FDA-approved drugs and devices for unapproved uses
- Health care fraud
- New drug application fraud
- Clinical investigator fraud
- Product substitution
- Product tampering
- Compromises to the blood supply
- Adulteration and/or misbranding food
- Internet fraud
- Importation of unapproved drugs/devices
- Manufacture, sale, distribution of unapproved drugs/devices
- Illegally diverting medicines and other FDA-regulated products, which are then sold for a different purpose than they were produced for (for example, stealing product samples and then selling them to a nursing home)

an investigation, other federal law enforcement agencies that have jurisdiction will join the probe. Many of these cases stretch beyond U.S. borders into other countries. Since being founded in 1992, OCI has developed good working relationships with many foreign law enforcement agencies, which assist 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 tests on products that are the subject of investigations.

FDA Investigations

Each year, OCI investigates about 1,200 criminal cases that result in the arrests of about 300 criminal suspects. From 1993 through November 2010, agents made 5,702 arrests that resulted in 4,748 convictions and more than \$11 billion in fines and restitutions.

OCI is also involved in preparing civil cases for trial—many of which are coupled with criminal cases and result in huge settlements.

For example, a subsidiary of pharmaceutical giant GlaxoSmithKline in October agreed to plead guilty to criminal charges and pay \$150 million in fines and restitution in a criminal case that also involved a civil lawsuit. The case revolved around the manufacture and distribution of four adulterated drugs at a now-closed plant in Puerto Rico. Under the terms of the agreement in the civil case, GlaxoSmithKline agreed to pay more than \$600 million to federal and state governments for false claims made to Medicaid and other health care programs.

According to court documents, SP Pharmco Puerto Rico Inc. failed to guarantee that two medications were free of contamination, while a manufacturing defect caused the double-layered Paxil CR (a controlled released anti-depressant) to split. In addition, Avandamet—used to treat diabetes—did not always have the FDA-approved mix of active ingredients.

Report a Crime

Doyle says OCI wants consumers' help in exposing crimes involving FDA-regulated products and bringing the perpetrators to justice. Among

the most serious crimes under OCI's jurisdiction are: health care fraud; manufacture and sale of counterfeit or unapproved drugs or devices; drug theft; product tampering and substitution; fraudulent health treatments; and contamination of food products.

"American consumers should not have to be concerned about the safety of the foods and drugs they use," he says.

If you suspect criminal activity involving an FDA-regulated product, contact the nearest OCI location (www.fda.gov/ICECI/CriminalInvestigations/ucm123034.htm). Visit OCI to send a report online (www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm).

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