

FDA



Office of Criminal  
Investigations

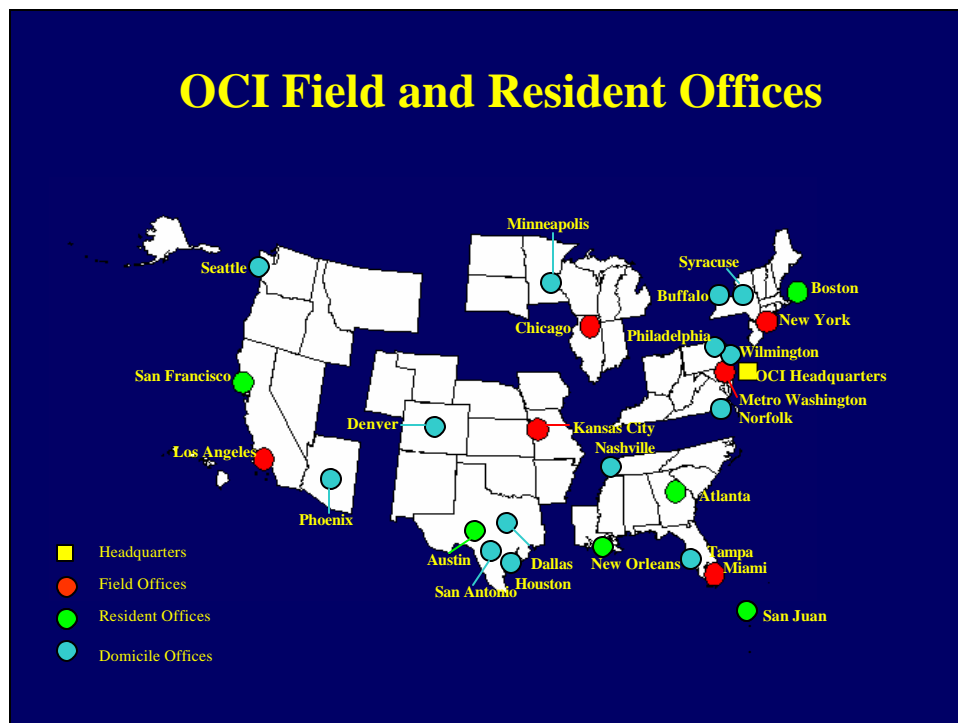


**Established in March 1992 by the  
Commissioner, with the urging of  
Congress, in response to concerns of  
increased criminal violations of the Act**



## OCI Mission Statement

The mission of the Office of Criminal Investigations (OCI) is to investigate suspected criminal violations of the Federal Food, Drug, and Cosmetic Act (FDCA); the Federal Anti-Tampering Act (FATA); and other statutes including applicable Title 18 violations; and to collect evidence to support successful prosecutive actions through the federal or state court systems as appropriate.



## OCI PERSONNEL



**180 Special Agents (Apr. 2002 estimate)**

**9 Technical Personnel  
(Analysts, Computer Techs, Electronic Techs)**

**33 Support Personnel**

**222 Total OCI Personnel**

## OCI Special Agents



\* Average federal law enforcement experience - Managers - 22 years  
Special Agents - 12-1/2 years

**“TASK FORCE OF TALENTS”**

\* Training

Primary Criminal Investigator training

OCI Special Agent Training Program (SATP-FLETC)

FDA Food and Drug Law Course

Continuing education programs:

Financial Crimes, asset forfeiture, Internet investigations,  
continuing legal education, interviewing techniques, management and  
leadership training, computer forensics, money laundering, self  
defense tactics, etc

## Investigative Case Support



### Investigative Analysis Branch (IAB)

- \* experienced investigative analysts
- \* utilize a host of research/analytical tools, public, commercial, and law enforcement information systems
- \* compile preliminary investigative summary
- \* conduct criminal history searches

### Technical Support

- \* provide training, equipment and complex technical installations

### Polygraph Examiners

- \* Certified agent polygraph examiners

### Asset Forfeiture Program

### Seized Computer Evidence Recovery Specialist (SCERS) Program

## INVESTIGATIVE JURISDICTION



### Federal Food, Drug, and Cosmetic Act (FDCA)

**Title 21, United States Code,  
& related Acts**

### Federal Anti-Tampering Act (FATA)

**Title 18, United States Code § 1365**

### **And related violations of Title 18 U.S. Criminal Code**

**Title 18, United States Code § 1001**

**Title 18, United States Code § 371**

**Title 18, United States Code § 1341**

**Title 18, United States Code § 1343**

## Investigative Course



- \* **Identify and investigate suspected criminal violations of the Federal Food, Drug, and Cosmetic Act (FDCA), Public Health Service Act (PHSA), and related Title 18 United States Code violations**
- \* **Compile evidence of these violations**
- \* **Present the findings to the U.S. Attorney's Office with venue**

## General Areas of Enforcement



- \* **Manufacturing and sale of counterfeit and unapproved drugs**
- \* **Illicit prescription drug diversion**
- \* **Product substitution crimes**
- \* **Product Tampering**
- \* **Schemes involving fraudulent health treatments**
- \* **New drug application fraud**
- \* **Fraud associated with clinical investigations**
- \* **Frauds involving FDA regulated products**

## ORIGIN OF CASES



- **FDA Centers & ORA**
- **OCI Proactive Initiatives, Informants, Spin-offs from other cases, etc.**
- **Other Foreign & Domestic Law Enforcement & Intelligence Agencies**
- **Other Foreign & Domestic Regulatory & Public Health Agencies**
- **Regulated Industry**
- **General Public**

## Industrial Problems



- False Tampering Complaints
- Internal Tampering
- External Tampering
- Sabotage (Internally and Externally)
- Extortion (Internally and Externally)

## OCI/Center Liaison



Facilitate communication between OCI Field and Center

- \* Is manufacturer registered with FDA?
- \* What is the manufacturer's record/status with FDA?
- \* Is product approved/unapproved?
- \* Advise/Expertise on interpretation of regulations
- \* Expert witness

## JOINT FEDERAL INVESTIGATIONS



## **FEDERAL AGENCY LIAISON**



**OCI Designated by the Commissioner as the Point of Contact and Conduit for Information Flow between the FDA and the Intelligence Community: CIA, FBI, NSA, etc.**

## **CT Related Investigations**



- **Product Tampering**
- **Manufacturing and sale of counterfeit and unapproved drugs and other products**
- **Illicit prescription drug diversion, and diversion of other regulated products**
- **Product substitution crimes**
- **Other fraud schemes involving FDA regulated products**
- **Any FDA related crimes that may finance terrorism**



## OTHER OCI CT ACTIVITY



Continue to develop and maintain professional relationships with domestic and foreign law-enforcement agencies to receive and act on any information regarding criminal or terrorist activity.

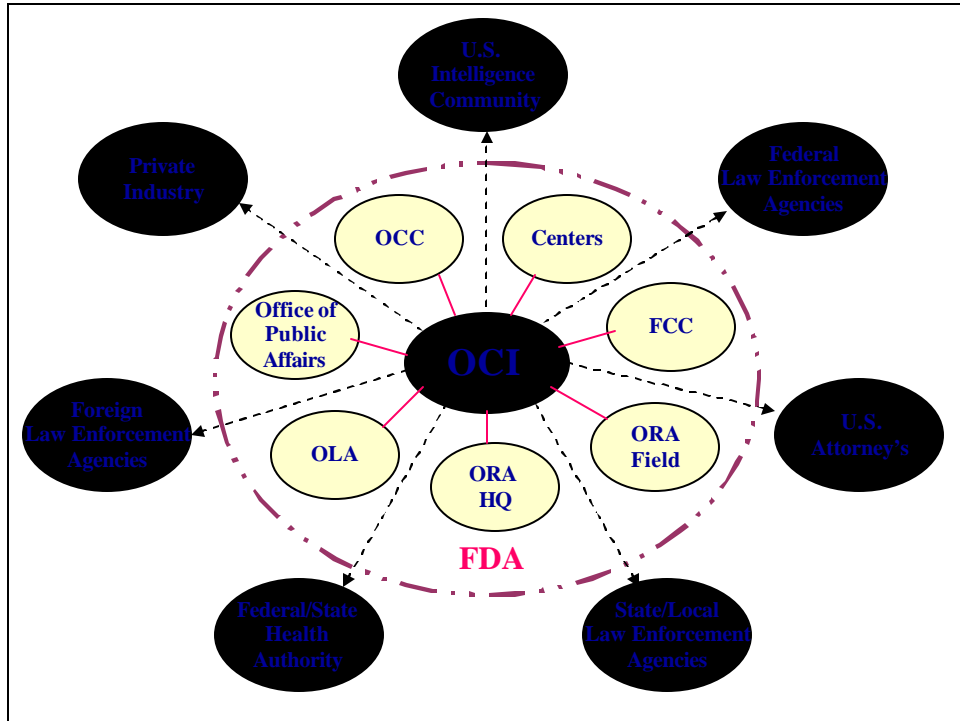
Interaction with security professionals associated with domestic and multi-national regulated firms and trade organizations to provide advice, establish and maintain open lines of communication, and learn about problems encountered or foreseen in domestic or foreign operations.

Threat assessments in connection with foreign travel.

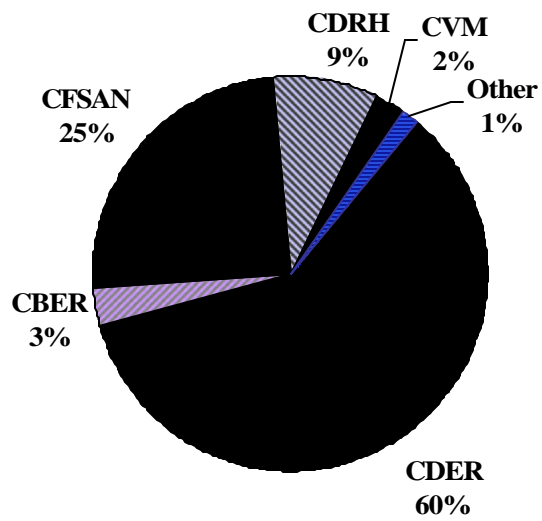
## Joint Terrorism Task Force Participation



56 JTTFs Nationwide



## Historical Case Distribution by Center



## ORIGIN OF CASES



- **FDA Centers & ORA**
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- Other Foreign & Domestic Law Enforcement & Intelligence Agencies**
- **Other Foreign & Domestic Regulatory & Public Health Agencies**
- **Regulated Industry and General Public**

## OCI FY 93 to August 2002



**Criminal Cases = 2741**

**Arrests = 2515**

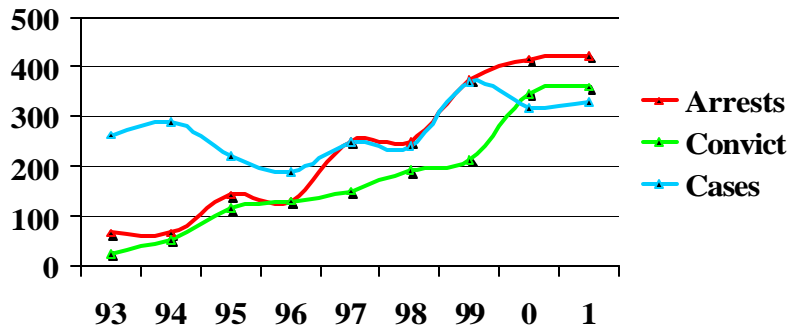
**Convictions = 1956**

**Over \$1.16 Billion Fines and Restitution**

**Over \$65.2 Million in Asset Forfeiture**



## Cases Opened/ Arrests/Convictions by FY



### OCI Headquarters

(301) 294-4030



**Terry Vermillion, Director**

**Horace Coleman, Deputy Director Investigations**

**Rodney Turner, Special Agent in Charge, IOD**

## OCI Field Offices



*	<b>Chicago</b>	<b>(630) 769-5520</b>
*	<b>New York</b>	<b>(201) 547-3851</b>
*	<b>Los Angeles</b>	<b>(949) 366-4600</b>
*	<b>Kansas City</b>	<b>(913) 541-7400</b>
*	<b>Miami</b>	<b>(954) 476-5400</b>
*	<b>Metro Washington</b>	<b>(301) 902-1500</b>