Detection and Deterrence of Counterfeiting
US FDA Experience

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FDA Components typically involved in counterfeit cases

- Office of Criminal Investigation (OCI)
- FDA Laboratories
- Center for Drug Evaluation and Research or Center for Biologics Evaluation and Research
  - Risk analysis
  - Compliance
- Office of the Commissioner
- Office of Regulatory Affairs
  - Regional offices
  - Recall office
  - Crisis Management
- Press office
- Lawyers
- International affairs

FDA/Office of Criminal Investigation Field and Resident Offices

Headquarters

6 Field Offices

6 Resident Offices

13 Domicile Offices

Counterfeit drug cases opened by FDA's Office of Criminal Investigations per fiscal year

A counterfeit drug case in the U.S. may involve….

- Food and Drug Administration
- Federal Bureau of Investigation (FBI)
- Drug Enforcement Administration
- Immigration and Customs Enforcement (ICE)
- U.S. Marshal Service
- Secret Service
- State/Local law enforcement
- State/Local regulatory agencies
- Department of Justice
- Others…

U.S. Intelligence Community
Private Industry
Federal Law Enforcement Agencies
FOOD AND DRUG ADMINISTRATION
FDA
OFFICE OF
US
CRIMINAL INVESTIGATIONS
SPECIAL AGENT
Foreign Law Enforcement Agencies
U.S. Attorney's
Federal/State Health Authority
State/Local Law Enforcement Agencies

Legal theories for prosecution

- Federal Food Drug and Cosmetic Act
  - Counterfeit Drugs
  - Misbranded, Adulterated or Unapproved Drugs
- Trafficking in Counterfeit Goods (Reg. Trademark)
- Federal Fraud Statutes
- Money Laundering
- Smuggling / Customs Violations

Statutory Penalties

Counterfeit Drugs

21 U.S.C. § 331(i)

- **1-year misdemeanor & significant fines**
  - **21 U.S.C. § 333(a)(1)**

- **2nd offense or intent to defraud:**
  - **3-year felony & significant fines**
    - **21 U.S.C. § 333(a)(2)**

Statutory Penalties

U.S. Federal Criminal Code

Trafficking in Counterfeit Goods or Services

18 U.S.C. § 2320

- **Individuals**
  - **10-year felony; $2 million maximum fine**
    - **First offense**
  - **20-year felony; $5 million maximum fine**
    - **Second offense**
- **Businesses**
  - **$5 million maximum fine**
    - **First offense**
  - **$15 million maximum fine**
    - **Second offense**

Policy Coordination in U.S.

- Intra-Governmental Working Group on Counterfeit Medical Products
  - FDA
  - Commerce
  - Trade
  - Patents/Trademark
  - Homeland Security
  - State Dept
  - Justice Dept
- Public/Private Sector Working Group
- FDA Counterfeit Drug Initiative

WHO Assessment Questions in Tool for Evaluating National Situation

National collaboration

- *Is there a national medicines anti-counterfeiting taskforce?*
- *Is there collaboration with and involvement of key stakeholders in the control of counterfeit medicines?*
  - Customs……..
  - Police……..
  - Judiciary……..
  - Pharmaceutical manufacturers…….
  - wholesalers and other distributors……..
  - Retail pharmacies and other dispensing outlets….
  - Health Professional and their Associations……..
  - NGOs……...
  - Consumers…….

WHO Assessment Questions in Tool for Evaluating National Situation

- *Is the collaboration with stakeholders formalized?*
  - If Yes Explain how……..
- *What is the level of their involvement?*
- *Is there a comprehensive national plan of action involving government agencies (NMRA, Customs, Police and Judiciary), pharmaceutical manufacturers, wholesalers and other distributors, retail pharmacies and other dispensers, health professionals and their associations, consumers, non-governmental and international organizations for combating counterfeit medicines?*
- Are there enough resources to support medicines counterfeit strategies?
  - If Yes; how much (% allocation against need)?
    - Financial Resources…….
    - Human Resources……..

Summary/Conclusion

- Effective detection/deterrence requires:
  - Many agencies
  - Multiple disciplines
  - Various levels of government
  - Public/private sector cooperation
- Efforts to evaluate country-specific capabilities have led to the development of a useful assessment tool
- Counterfeiting will continue to be both a major economic and public health issue that requires close international cooperation and regular interaction