U.S. Food and Drug Administration
Protecting and Promoting Public Health
www.fda.gov

FDA Efforts: Counterfeit Drugs

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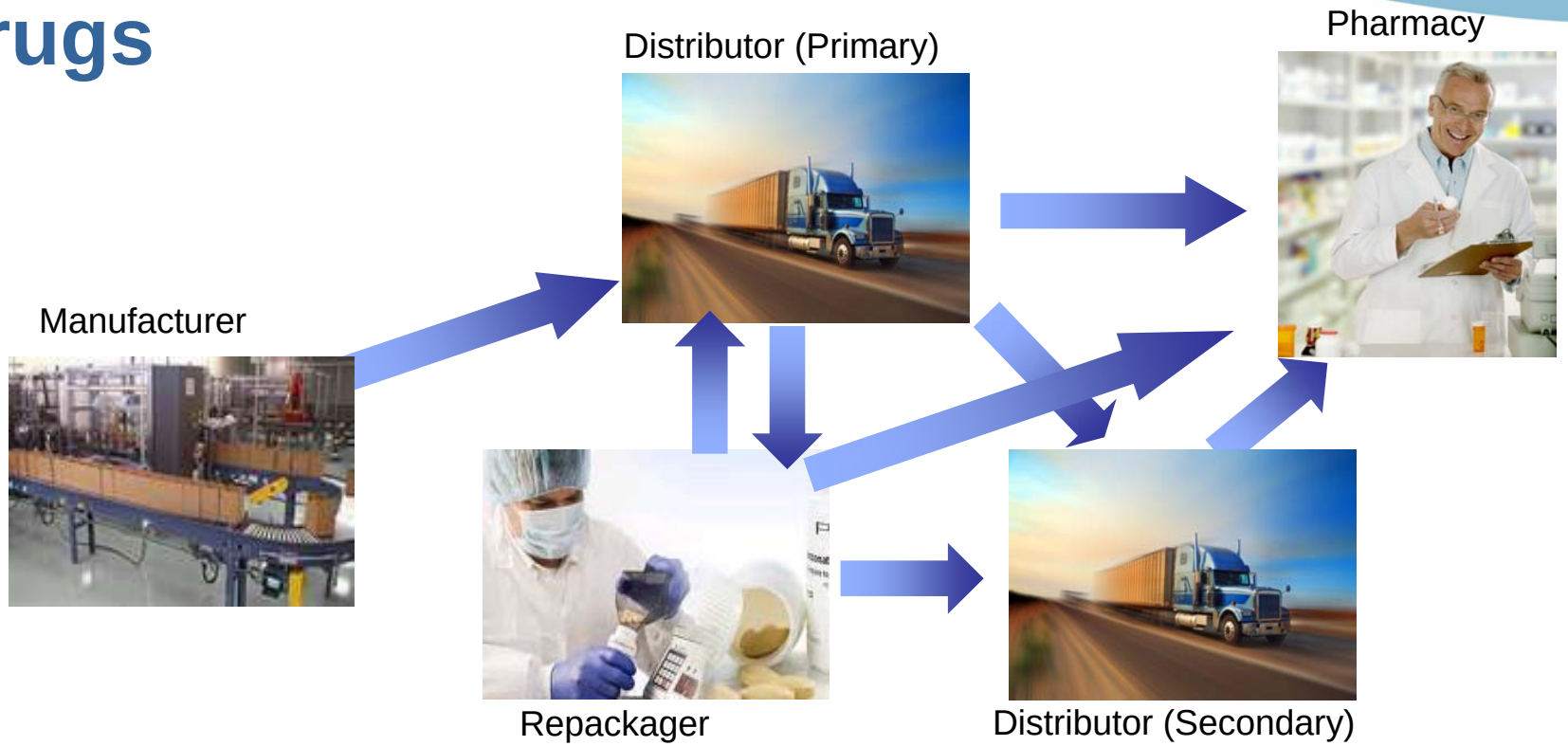
Overview

- The basics
- What's needed?
- What's being done?
- Pharmacist's role

Supply Chain for Finished Drugs



Complexity of the supply chain is increased by:

- Multiple participants
- Globalization of supply chains
- Criminal activities such as diversion, cargo theft, and counterfeiting
- Rules that vary by state

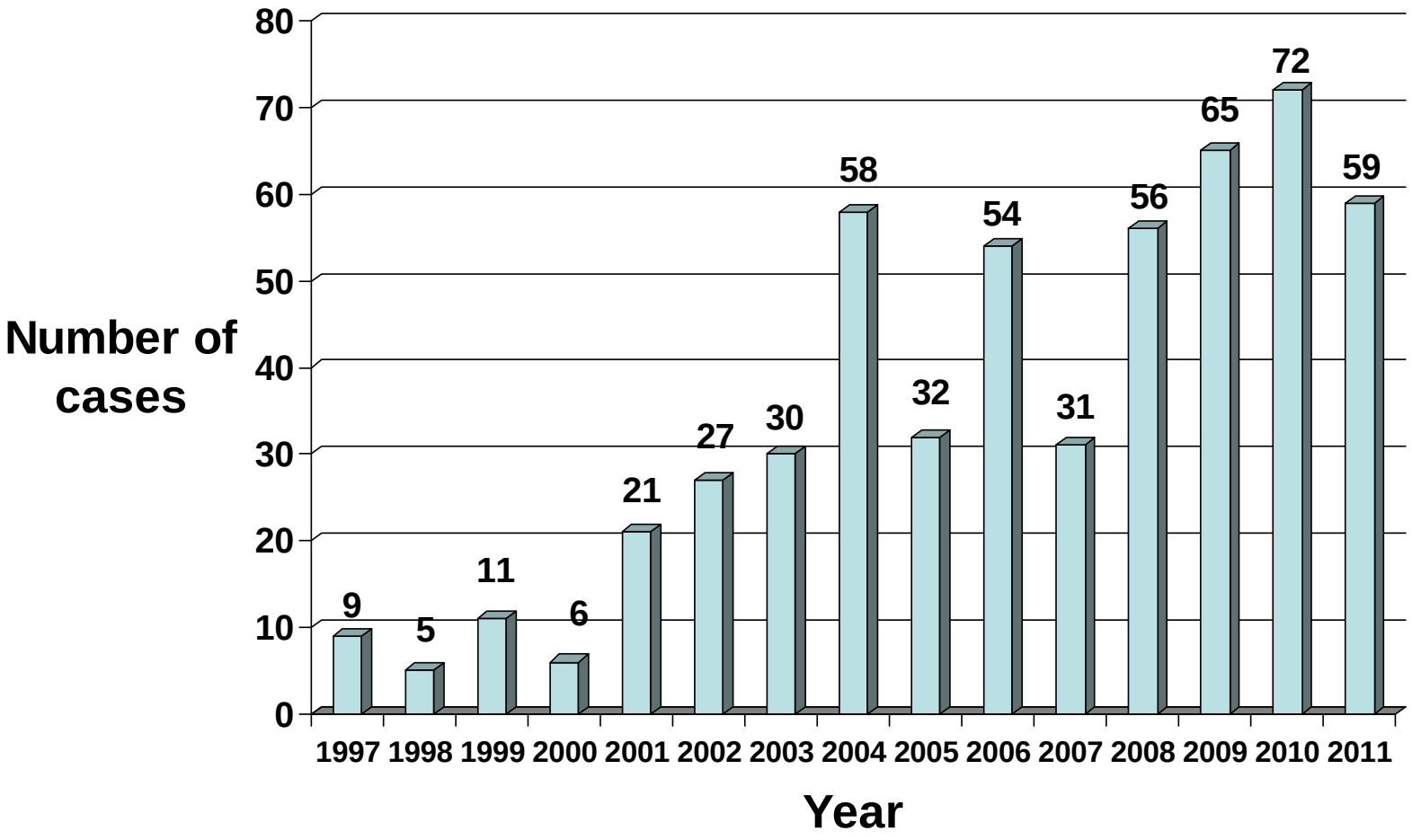
Example of vulnerabilities in the supply chain:

- Stolen products reintroduced
- Counterfeit/falsified drugs sold to suppliers
- Diverted drugs resold
- Other adulterated/misbranded drugs introduced

What is a Counterfeit Drug?

- U.S. law defines counterfeit drugs as:
  - "drug which, or container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a manufacturer, processor, packer, or distributor other than the person or persons who in fact manufacture, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor."
- Can apply to both brand name and generic products, or the bulk ingredients used to make the product.
- May include products without the active ingredient, with an insufficient or excessive quantity of the active ingredient, with the wrong active ingredient, or with fake packaging.

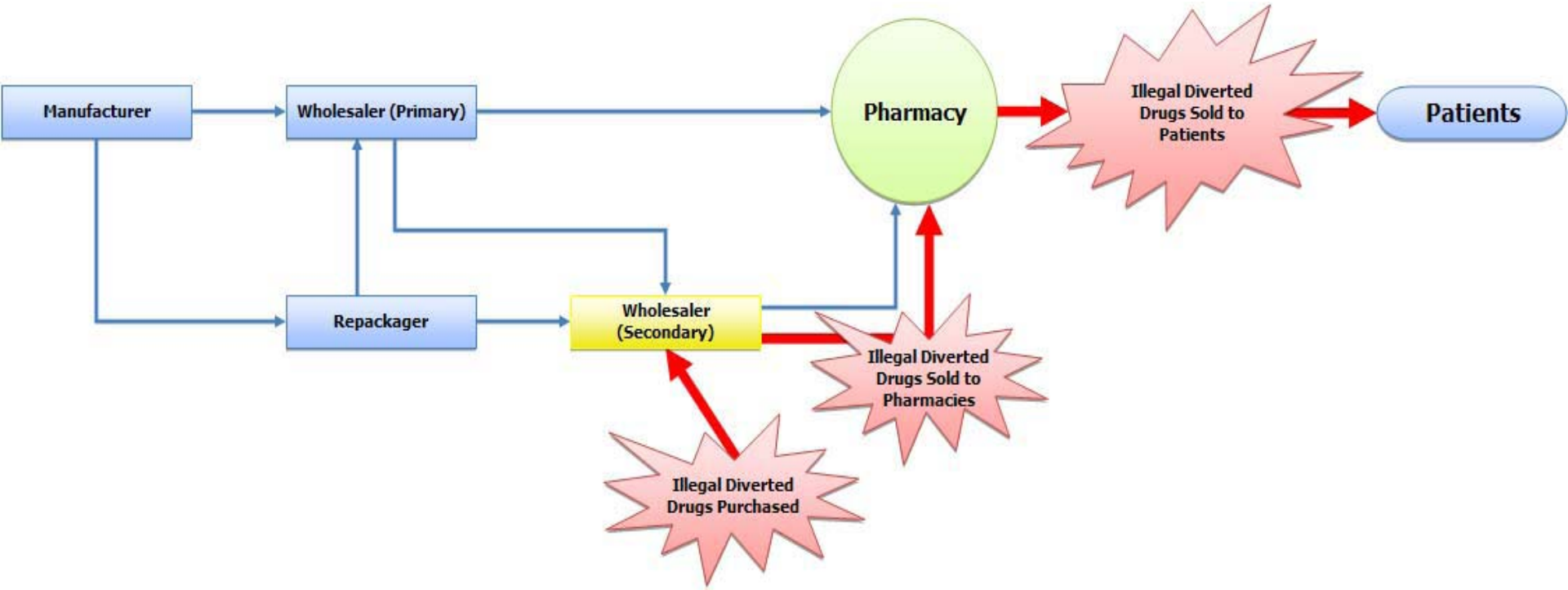
Counterfeit Drug Cases Opened by FDA's Office of Criminal Investigations per Fiscal Year



Preliminary Review of OCI Cases

Report Highlights

- **Examples of diversion and counterfeit schemes**



- **Drug products involved (solid oral dosage forms)**
- **Type of entities involved (wholesalers, pharmacist, doctor etc.)**

Compromised Integrity: Recent Supply Chain Threats

Counterfeit

- Counterfeit Roche Avastin
- No active ingredient
- Medical clinics notified
- Only Genetech Avastin is FDA-approved in U.S.
- Evaluation ongoing

Authentic

Images from Genentech, Inc.

Compromised Integrity: Supply Chain Threats

Authentic alli Sample Counterfeit alli Sample

- Counterfeit Alli - OTC drug with dangerous Rx drug ingredient

Authentic alli Sample Counterfeit alli Sample

Counterfeit/Falsified, Diverted or Stolen or Unapproved Drugs may be Dangerous

- May contain harmful ingredients
- May be ineffective (contain no or little drug)
- May cause adverse events (due to ingredients or wrong strength)
- May have lost potency (due to improper storage)
- May be expired
- May be produced under filthy conditions…etc.

= harm to public health

What's FDA doing to protect public health?

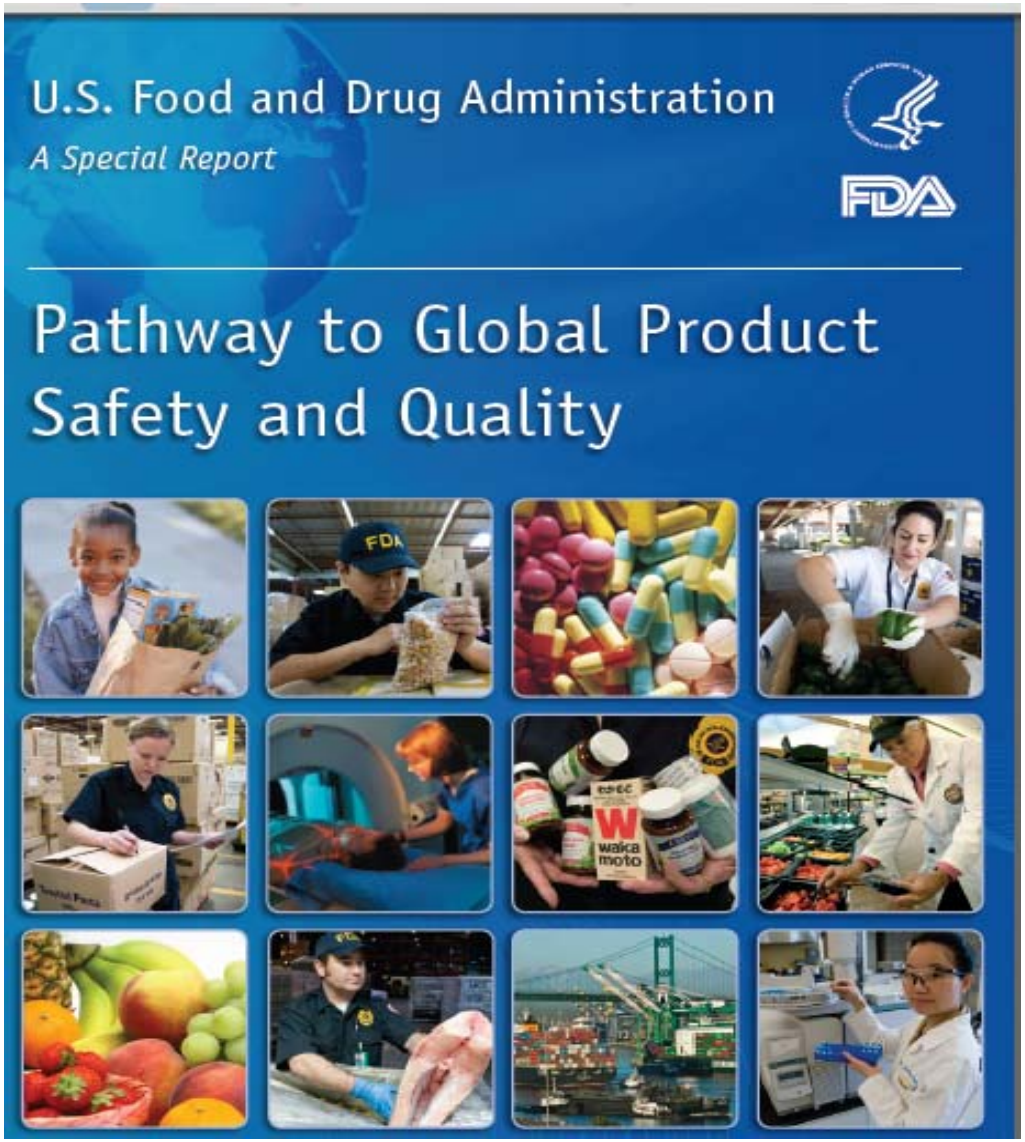
Building Supply Chain Integrity to Ensure Patient Safety (1)

- Transparency and accountability in the supply chain – up and down
- Better enforcement and regulatory tools
- Stakeholder responsibility
- Surveillance/monitoring
- Increased vigilance and awareness
- Educate consumers

(continued)

Building Supply Chain Integrity to Ensure Patient Safety (2)

- Collaboration/cooperation – domestic and international
- Harmonize/Converge internationally
- Share scientific and technical expertise with fellow foreign regulators
- Training programs in regulatory disciplines internationally
- Strengthen global detection, surveillance and assessment systems
- Support development of innovative information systems


U.S. Food and Drug Administration
A Special Report
FDA
Pathway to Global Product Safety and Quality

New Office of Drug Security, Integrity, and Recalls (ODSIR)

- Enhanced and targeted resources
- Address increasing supply chain threats
  - Intentional adulteration, cargo theft, counterfeiting, diversion, other
  - Focus on life-cycle of the product from drug components through to the finished dosage from delivered to the patient
- New and coordinated approaches, policies and enforcement strategies

Recalls **Drug Shortages**	**Imports** **Exports**	**Drug Supply Chain Integrity**

Transparency and Accountability

- **Know what is in the drug supply chain and who is handling the drugs**
- **Current: Pedigree** – documenting each sale or transaction of the product
  - Knowledge of:
    - What drug? How much?
    - Who they bought it from and when
    - Who they sold it to and when
    - Other information
- **Future/Ideal: Track and Trace & Authentication**
  - National, Uniform tracking and tracing
  - All supply chain stakeholders participate
  - Check the unique serial number on each package
  - Check security features – e.g., hologram, color-shifting ink, taggant

Overview of a Track and Trace System

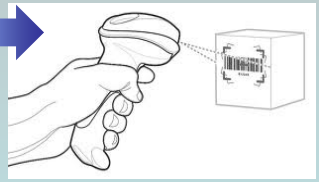
or

Manufacturer/ packaging line

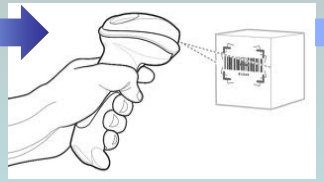
Distributor

Distributor

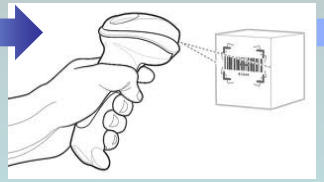
Pharmacy



- Serialize
- Record SNI and product info



- **Track** product
- **Authenticate**



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Track and trace database
centralized or decentralized (distributed)

Track and Trace System Goals

- Help to preventing the introduction of counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs
- Facilitating the identification of counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs
- Providing accountability for the movement of drugs by supply chain participants
- Improving efficiency and effectiveness of recalls

Where Track and Trace Can Help

Distributor (Primary)

Pharmacy

Stolen Levemir sold to distributors

Manufacturer

Repackager

Distributor (Secondary)

Heparin (recall)

Counterfeit Lipitor

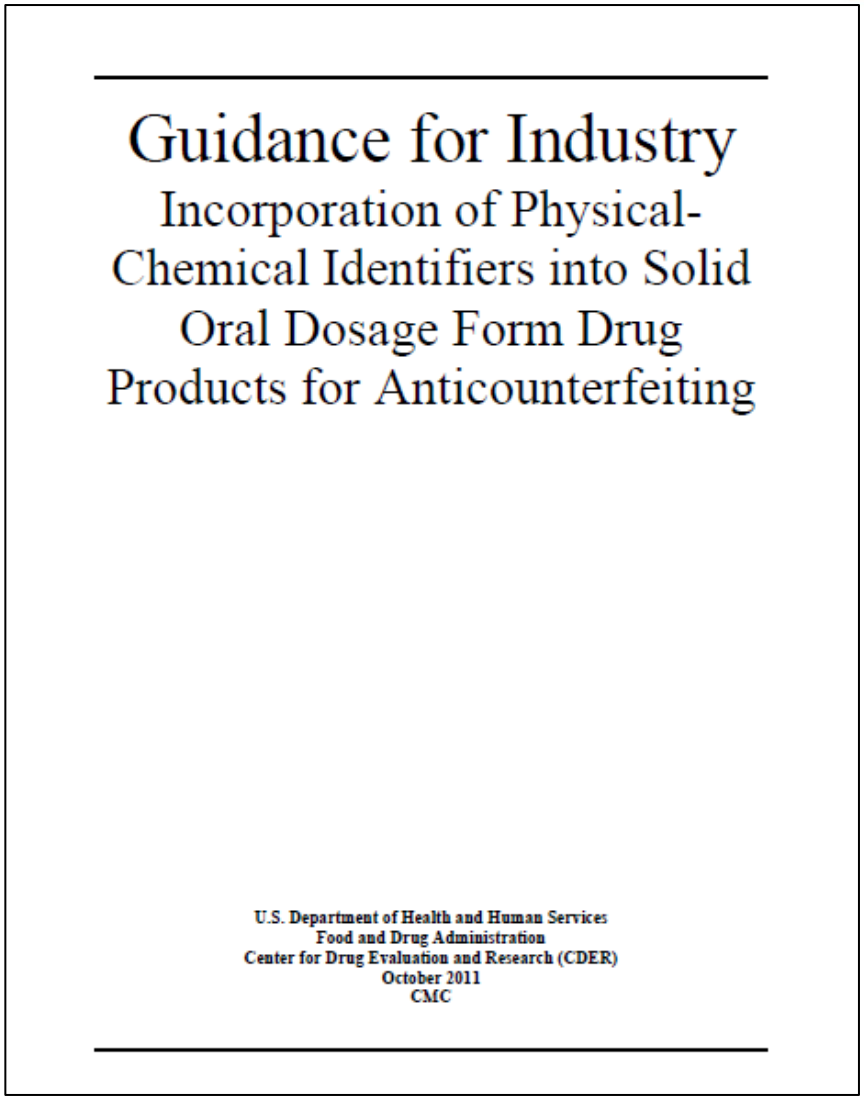
Counterfeit Avastin

Stolen Eli Lilly drugs that may be introduced into the supply chain

Florida pharmacists trying to introduce diverted medicare / medicaid drugs into the supply chain

Physical-Chemical Identifiers Final Guidance

- Pharmacological and Toxicological considerations
- Should not adversely affect the identity, strength, quality, purity, potency, or bioavailability
- Final Guidance released October 2011
  - http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM171575.pdf



Guidance for Industry

Incorporation of Physical-Chemical Identifiers into Solid Oral Dosage Form Drug Products for Anticounterfeiting

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
October 2011
CMC

Collaboration and Cooperation (1)

- Inter-governmental efforts
  - FDA/ US Commerce anti-counterfeiting task force
  - White House efforts
  - Federal Agencies:

    FBI – Federal Bureau of Investigations

    ICE – Immigration and Customs Enforcement

    CBP – Customs Border Protection

    DEA – Drug Enforcement Agency

    DoS- Department of State
- Private/public partnerships/collaborations
- State Medical and Pharmacy Boards, non-governmental organizations, consumer groups, trade associations, etc.

Collaboration and Cooperation (2)

- International efforts
  - World Health Organization
    - International working group
    - WHO/FDA cooperative agreement
      - To support building global capacity for the surveillance and monitoring of counterfeit/falsified medicines and supply chain threats
  - Operation Pangea IV
    - INTERPOL led global operation targeting internet websites supplying illegal and dangerous drugs;
    - 81 countries participated

  - APEC Roadmap for Global Medical Product Quality and Supply Chain Integrity
    - identify a path forward toward regulatory convergence of practices necessary to ensure the integrity of marketed medical products

Communication and Education

- FDA Counterfeit Alert Network (CAN) - partnership with organizations to disseminate alerts and support public education
- Educational messages and public notification for healthcare providers, consumers/patients, and industry on FDA Website
- FDA Press Releases http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/default.htm
- MedWatch - Safety Alerts

  http://www.fda.gov/Safety/MedWatch/default.htm

Pharmacist's Role

- **Minimize the risk of and exposure to counterfeit medical products**
  - Know who you are doing business with
  - Stay informed
  - Safeguard products
  - Destroy empty packages/containers
- **Be vigilant**
  - Inspect the product and packaging
  - Know high risk products
  - Consider counterfeits if:
    - New/unusual side effects
    - Lack of therapeutic effect
    - Products tastes/smells abnormal
    - Patient experiences pain, burning, redness at injection site
- **Counseling patients about counterfeit medical products**
  - Encourage patients to shop only at US licensed pharmacies
  - Tell you patient if you dispense a drug that may look different from their previously dispensed drug
  - If paying for meds is a problem, counsel on assistance program and generics, rather than buying online
- **Report Suspect Counterfeit medical products to**

? QUESTIONS ?

CDER/Office of Compliance/ODSIR Webpage
http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/default.htm

Counterfeit Medicines Webpage
http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/CounterfeitMedicine/default.htm

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