Counterfeit Drugs: Domestic & Import

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Overview

- Scope of Drug Counterfeiting
- Regulation of Wholesale Distributors
- Model Rules for the Licensure of Wholesale Distributors
- Verified-Accredited Wholesale Distributors™ (VAWD™) Program
- State Efforts to Address Counterfeit Drugs

Are counterfeit drugs more prevalent in developing countries or industrialized countries?

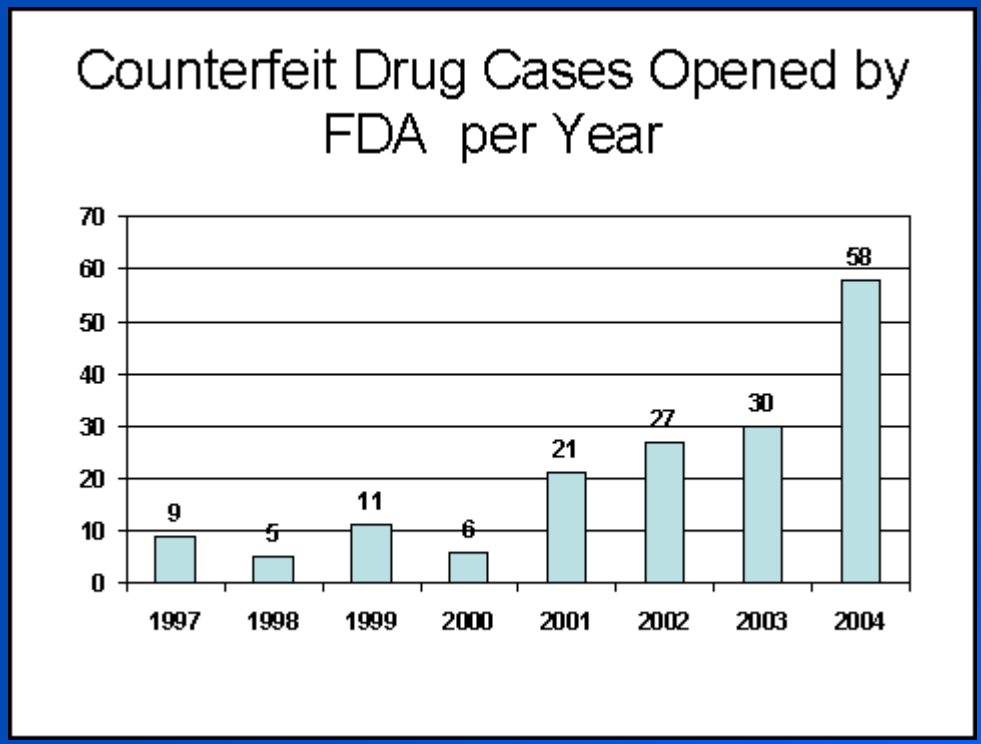
Prevalence of Drug Counterfeiting

- According to the World Health Organization (WHO):

  A. Industrialized Countries: 22%

  B. Developing Countries: 78%

  - Africa: 50-60%
  - Mexico: 40%
  - Brazil: 30-40%
  - India: 15-20%



Combating Counterfeit Drugs: A Report of the Food and Drug Administration Annual Update (May 18, 2005)

2004 Incidences of Counterfeit, Stolen, and Diverted Drugs

Where drug incidents occur				
Countries with the most incidents in 2004:				
	Fake	Diversion[1]	Theft	**Total**
USA	32	30	14	**76**
Colombia	41	15	4	**60**
China	56	3	0	**59**
Russia	40	8	2	**50**
India	36	3	0	**39**
Peru	21	4	0	**25**
Ukraine	23	1	0	**24**
Brazil	3	4	12	**19**
Israel	17	1	0	**18**
Mexico	6	5	6	**17**
U.K.	14	2	1	**17**

1 — Drugs which have been illegally diverted to a different market, population or region than was initially intended.

Source: Pharmaceutical Security Institute

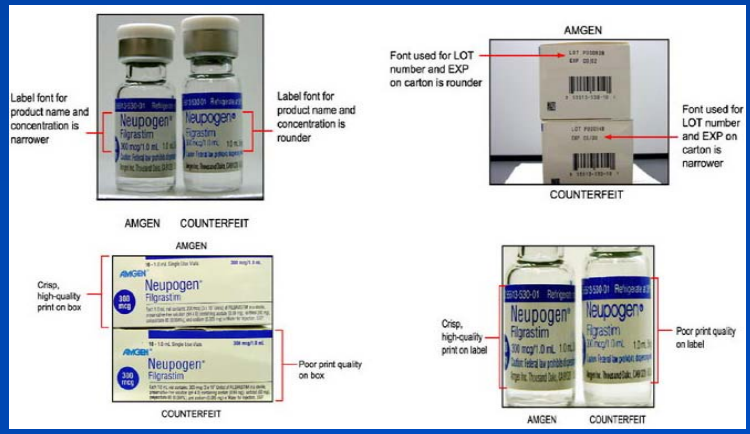
What is a Counterfeit Drug?

- According to the US Food, Drug, and Cosmetic Act:

  " [A] drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark…of a drug manufacturer, processor…or distributor other than the person…who in fact manufactured, processed…or distributed such drug and which thereby falsely purports or is represented to be the product of…. such other drug manufacturer, processor…or distributor."

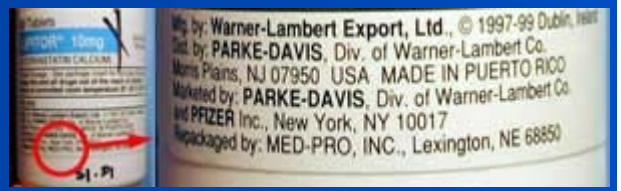
Counterfeit Categories (according to WHO)

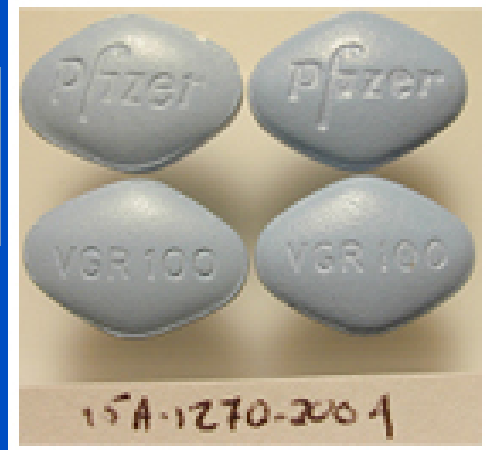
- Fake Packaging, Correct Quantity of Correct Ingredient (Clone)
- Fake Packaging, Wrong Ingredient
- Fake Packaging, No Active Ingredient
- Fake Packaging, Incorrect Quantity of Correct Ingredient
- Genuine Packaging, Wrong Ingredient
- Genuine Packaging, No Ingredient
- Genuine Packaging, Incorrect Quantity of Correct Ingredient


Label font for product name and concentration is narrower
Label font for product name and concentration is rounder
AMGEN
COUNTERFEIT
Font used for LOT number and EXP on carton is rounder
Font used for LOT number and EXP on carton is narrower
COUNTERFEIT
AMGEN
Crisp, high-quality print on box
Poor print quality on box
COUNTERFEIT
Crisp, high-quality print on label
Poor print quality on label
AMGEN
COUNTERFEIT


Authentic
Fake
Serostim® 6 mg
Serono

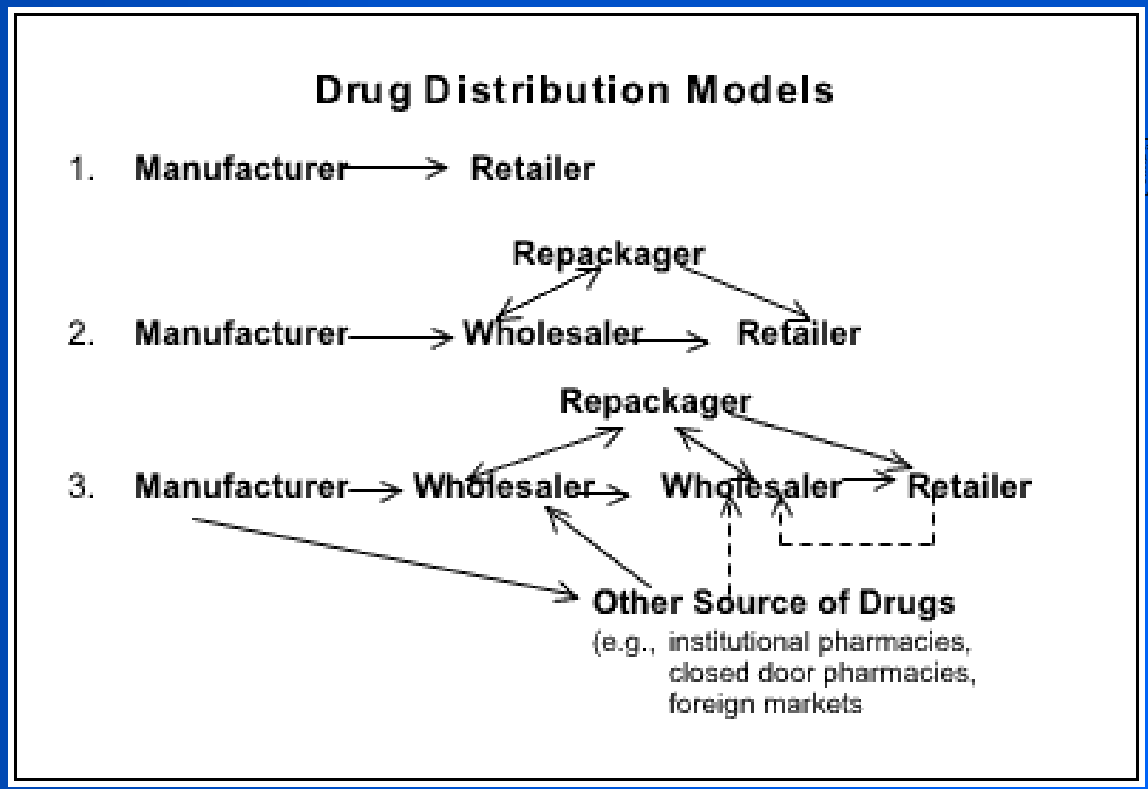

Photos: Mexican Border Pharmacies Found to be Selling Counterfeit Pharmaceuticals - Microsoft Internet Explorer
U.S. Food and Drug Administration
Photos: Mexican Border Pharmacies Found to be Selling Counterfeit Pharmaceuticals
Generic "Evista"
Counterfeit Lipitor


Mfg. by: Warner-Lambert Export, Ltd., © 1997-99 Dublin, Ireland
Dist. by: PARKE-DAVIS, Div. of Warner-Lambert Co.
Morris Plains, NJ 07950 USA MADE IN PUERTO RICO
Marketed by: PARKE-DAVIS, Div. of Warner-Lambert Co.
and PFIZER Inc., New York, NY 10017
Repackaged by: MED-PRO, INC., Lexington, NE 68850


Pfizer
Pfizer
VGR 100
VGR 100
15A-1270-2004


Authentic PROCRIT Vial: There are no imperfections found on the edges of the label.
Counterfeit Product Vial: A notch may appear in the black colored bottom edge of the label under the words "LOT" and "EXP".
LOT P004582
EXP 02/04
02/04

How are Counterfeit and Diverted Drugs Introduced into the Drug Distribution System?



FDA's Counterfeit Drug Task Force Interim Report, October 2003

Federal Regulation of Wholesale Distributors

- Prescription Drug Marketing Act (PDMA) of 1987, Prescription Drug Amendments (PDA) of 1992
  - Banned the Sale of Drug Samples and Drug Coupons
  - Banned Reimportation (limited exceptions)
  - Set Requirements for Sample Distribution and Storage
  - Required State Licensing of Wholesale Distributors
  - Required Identity Statements for Sales (pedigrees) by Unauthorized Distributors of Record

State Licensing of Wholesale Distributors

- State Boards of Pharmacy
- Renewal Schedule: One to Two years
- Out-of-State Wholesale Distributors
- Regulatory Challenges
  - Limited Board of Pharmacy/State Agency Resources
  - Lack of Uniformity of States' Regulation

NABP Commission to Combat Counterfeiting

- FDA Counterfeit Drug Task Force (July 2003)
- NABP Task Force on Counterfeit Drugs and Wholesale Distributors (October 2003)
- NABP Model Rules for the Licensure of Wholesale Distributors (February 2004; revised March 2005, June 2006)

NABP Model Rules on the Licensure of Wholesale Distributors

- Extensive Application and Criminal Background Check of Applicant
- No Operating from a Place of Residence
- $100,000 Surety Bond (or other equivalent means)
- Personnel Requirements: Designated Representative
- Introduced Prohibited/Criminal Acts
- Pedigree Requirements
- Authentication
- Due Diligence

NABP Task Force to Develop Recommendations on Electronic Pedigrees

- Primary Objective:
  - Gain consensus from state boards of pharmacy and other applicable state regulatory agencies regarding the necessary components for electronic pedigrees
- Recommendations:
  - Electronic pedigree records all transactions and distributions of a product beginning with manufacturer until final sale and distribution to the pharmacy
  - Implementation of electronic pedigrees by December 2007
  - Specified data elements of electronic pedigrees:
    - Drug name, amount of drug, dosage form, dosage strength, lot/control numbers, NDC (optional), name of manufacturer
    - Dates of transactions, sales invoice numbers
    - Name, address, telephone, number, e-mail address, VAWD #, state license number of each entity involved in the chain of custody
    - Certification that each recipient has authenticated the pedigree and information included within the pedigree is true
    - Name and address of each person certifying delivery or receipt of the drug

NABP Verified-Accredited Wholesale Distributors™ (VAWD™) Program

- Primary Objective
- Based upon NABP Model Rules, State and Federal Laws
- VAWD Criteria:
  - Licensure, Facility, Personnel, Recordkeeping, Authentication/Verification, Returned/Damaged/Outdated Products, Policies and Procedures
- Accreditation Process
  - Step 1: Application (licensure verification/clearinghouse screening)
  - Step 2: Policy and Procedure Evaluation
  - Step 3: Facility Inspection
  - Step 4: Award Accreditation

VAWD Accredited Facilities

- CVS/pharmacy's Distribution Center Indianapolis, IN
- Harvard Drug Group, Indianapolis, IN
- Harvard Drug Group, Livonia, MI
- US Oncology Inc., Fort Worth, TX
- Saddle River Marketing Concepts, Paramus, NJ

Wholesale Distributor Legislation
State Activity – Legislation Passed

- Arizona
- California
- Florida
- Indiana
- Iowa
- Mississippi
- Nebraska
- Nevada
- New Jersey
- New Mexico
- Oklahoma
- Texas
- Vermont
- Virginia

Wholesale Distributor Legislation State Activity: NABP's Involvement

- NABP:
  - Provides background and education to the boards
  - Reviews legislation/regulations and provides feedback
  - Testifies, upon request, before the board, at committee hearings, etc

Conclusion

- Patients
- Pharmacists
- Industry Stakeholders
- Regulators

Questions?

- Visit the NABP website at www.nabp.net
  - VAWD Accreditation Program and Criteria
  - NABP Model Rules for the Licensure of Wholesale Distributors