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**Counterfeit Drugs:  
Issues, Explanations, and Avoidance Tools**

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**Prescription Drugs**

- Prescription drugs are a critical part of health care.
- Use:
  - 1,500,000,000 drugs were prescribed through physician offices.
  - 139,000,000 drugs were prescribed through hospital outpatient departments.
  - 196,000,000 drugs were prescribed through hospital emergency departments.
- >3,500,000,000 prescriptions filled annually.
- Prescription drugs represent big bucks: ~\$200-250 billion in revenues annually.

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**Problem: Counterfeits**

- Benefit of drugs accrue only if legitimate.
- WHO study found that a significant fraction of drugs sold worldwide are fake.
- Scope of problem is unknown. But ...
- Up to 60% of drugs in developing countries are counterfeit.
- Up to 20% of drugs sold in some developed countries counterfeit.
- Up to 10% of all drugs around the world are counterfeit.
- Estimated sales: \$32-38 billion/year—\$88-96 million/DAY.

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### Bad Medicines in the USA

- Here, for example:
  - 2002: 110,000 vials of inappropriately stored low dose Epogen relabeled as higher dose;
  - 2003: 180,000 fake bottles of Lipitor recalled when found to be counterfeit;
  - 2003: FDA blitz inspections of foreign drug imports found 88% were unapproved drugs with safety issues;
  - 2004: FDA discovered Mexican drugs imported by US citizens were fake;
  - 2005: FDA issues warning on fake Lipitor, fake Viagra, and fake unapproved osteoporosis drug from Mexico.
  - 2006: FDA finds Canadian internet pharmacy drug source in Bahamas selling fake drugs to US.

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### Public Health Issue

- Surgeon General's December 2004 report: only 16.9 FTE FDA inspectors covering all int'l mail facilities—and 20 million packages come in each year.
- *Business Week* February 2005 reports huge market in fake products including medicines.
- Pharmaceutical Security Institute Report May 2005 on counterfeiting, theft, and drug diversion worldwide finds US 1st with reported problems—second year in a row.
- Canada reports 7 deaths from counterfeit drugs purchased from Hamilton, Ontario pharmacy.
- FDA guesstimates ~<1% or less of all US drugs fake or counterfeit.
- In combination with WHO estimates, assume 0.1% tainted drugs, 3,500,000 to 350,000,000 prescriptions potentially affected.

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### What Kinds?

- Back in the bad ole days, it was lifestyle drugs: Viagra.



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## What Kinds?

- Now ...
- AIDS/HIV therapy, over-the-counter pain medications, antibiotics, insulin, cholesterol drugs, hormone replacement therapy, over-the-counter flu medications, cancer drugs, anti-arthritis drugs, cardiac drugs, anti-parasitic drugs, antihistamines ... and more that are undiscovered.
- Gone from lifestyle drugs to lifesaving drugs.



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## What Harm?

- **Wrong ingredient.**
  - Patients harmed by fake drug ingredient; harmed by not being treated for disease.
  - Also results in increased resistance requiring second or third line therapies.
  - Vial for antibiotic relabeled with fake label as another, more expensive antibiotic with different bacterial coverage.

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## What Harm?

- **Wrong concentration/dose.**
  - Too high/too low harms patient.
  - Cancer patient needing Epogen gets diluted form (with contaminated water as diluting agent).
  - Purported Botox actually highly concentrated *botulinum* toxin not intended for human use results in paralysis and hospitalization (and near death).

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### What Harm?

- **No ingredient.**
  - Patients harmed by not being treated; and by material used to fake drug.
  - Bacteria-laced water as IV antibiotic or pediatric cystic fibrosis inhalant.
  - Toxic yellow road paint to get color imitating authentic drug, floor wax and boric acid to mimic consistency.

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### Why?

- **Money.**
  - Cash flows incredible; millions of US\$ sales/year.
  - Mark Kolowich who ran Internet pharmacy for fake drugs in USA had > US\$500,000 sales/month.
  - Epogen low-dose vials relabeled as high-dose versions; low dose sells for US\$22 a bottle, high-strength bottle US\$445; 800 boxes reached market netting criminals \$48 million profit.

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### Why?

- **Terrorism and International Crime.**
  - FDA, Royal Canadian Mounted Police, and British Intelligence warn that counterfeit drug sales funding international crime and terrorist activities.
  - FDA also warns that terrorists targeting drug supplies to harm citizens:
    - Baz Mohammad.
  - Al Qaeda; Hezbollah suspected of raising funds through counterfeit sales:
    - DOJ Joint Task Force on Terrorism.
  - International crime syndicates:
    - Russian mafia; Latin America drug lords entering market.
  - State-sponsored crime activities:
    - North Korea.
  - Individuals:
    - Former illicit drug dealers, Julio Cruz.

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### Why?

- High Profit Margins and Easy Production.
- What normal production facilities look like:



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### Why?

- Pill may cost \$0.01 but may be sold for \$0.30—which is still cheaper than regular drug.
- Materials cheap: yellow road paint; concrete powders; boric acid; nonsterile facilities; unskilled labor.
- Illicit drug production requires producing real thing.
- No skilled workers necessary (and outsourcing available!).



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### Why?

- Easy Sales and Distribution.
  - Cloaking device: Internet.
    - Only 0.02% of “Canadian” Internet sellers in Canada.
  - Night markets, other nontraditional sources.



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### Why?

- **Law/Low Penalties. For example:**
  - Latin America: Unanticipated side effect of illicit drug crackdown; illicit drug production now penalized by tough sentences: 10-15 years in slammer.
  - Penalties for counterfeit drug production 6 months at most, and out on bail in a few days.
  - Same story in Europe and Asia: <6 months or even just a fine.
  - EU and Asia larger penalties for violating intellectual property rights, *not* threat to public health.

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### Why?

- **Wholesaler gray market.**
  - Between 1-10% of drugs sold in USA in the “gray market” before it gets to final pharmacy and patient.
  - Gray market is secondary wholesale market where drug resale occurs.
  - Resale occurs between three major wholesalers and ~6000 secondary wholesalers to shed excess supplies, arbitrage prices, address cash flow, deal with impending expiration.
- Gray market represents weakness in drug supply chain, allowing tainted or fake drugs into chain.
- Importation expands gray market to importers and suppliers from other countries.

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### Why?

- **Technology limited.**
  - For example, radio-frequency identification tags.
- **Problems:**
  - 27% tags read incorrectly by manufacturer.
  - Up to 21% read incorrectly at wholesaler level.
  - Costs for readers and devices.
  - Data standardization problem along distribution chain and between hemispheres.
  - Debate on ownership of information.
- And regardless of type—RFID, DNA markers, laser etching, holograms, tamper-proof labels, embossing, thermo-reactive ink—all just track packaging *not the product*.
- Counterfeiters have already mimicked packaging effectively.

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## Where?

- **Examples:**
  - UK counterfeiting operation: 500,000 pills/day selling across Europe;
  - UK: cialis, viagra reductil, zantac.
  - Netherlands: wholesalers duped into supplying counterfeits into supply chain.
  - Italy: licensed medicines dealer distributing counterfeit GI drugs.
  - French counterfeiting operation: seizure of 542,000 fake pills.
  - Spain: six labs producing counterfeit steroids, hormones, cancer drugs; producing 20,000 fake doses/hour sold in Italy, France, Portugal.
  - Canada: 4-7 deaths in Hamilton, Ontario associated with counterfeit hypertension/cardiac medicines.

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## Implications

- **Creates:**
  - tremendous problem for importation, including Canada and EU;
  - unreliability of purchases over the Internet;
  - high risks going over the border to buy medicines; and
  - almost impossible detection and tracking of fake meds.

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## US Issues: Law

- **Law—Bad Incentives:**
  - Counterfeiting a *label* with trademark 10 years in slammer; counterfeiting *drugs* only up to 3 years.
  - Difficult to reach offshore Internet sources for accountability.
  - Difficult to enforce law due to limited resources and international cooperation.
- **State importation purchasing programs require hold harmless agreements, e.g., Illinois, Minnesota, Washington.**
- **Pharmaceuticals not earmarked for domestic use *not* subject to country's safety laws!**

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## US Issues: Medicine

- **Medicine: ignorance regarding the risks associated with counterfeits; no index of suspicion.**
- **Medicine: Fake drugs the perfect crime:**
  - packaging thrown away;
  - “drug” metabolized or excreted;
  - human variation in response may “explain” different or lack of effect;
  - no index of suspicion of different effect or death of ill patients;
  - no standard testing of drug levels or other verifications of drug authenticity.

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## Strategy: Education

- **Education: Need to raise awareness of potential for counterfeits.**
- **Education: Need to proactively get information on detected counterfeit.**
  - Safemedicines.org email alert system.
  - www.safemedicines.org.




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## Strategy: Education

- **Safety Checklist: SAFE DRUG:**
  - S amples
  - A ppearance
  - F eel/taste
  - E valuate
  - D octor contact
  - R emove
  - U navailable
  - G ive details
- www.safemedicines.org




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## Strategy: Penalties

- Support increased penalties.
- Consideration of life imprisonment and drug trafficking penalties appropriate.
- H.R. 780, The Counterfeit Drug Prevention Act of 2007: 20 years to life imprisonment.

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## Safety First

- No program relying on external sources such as importation or the Internet before demonstrated adequate and effective safeguards in place.
- Maxine Blount, survives breast cancer then gets fake epogen.
- 192,000 dead in China in 2001 due to counterfeits.
- 500 children dead around world due to counterfeit cough syrup [made with antifreeze].

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## Overall

- Counterfeit drugs big business and tremendous public health issue.
- Patient must protect themselves through knowledge of potential sources of harm, detection, and vigilance.
- Support increased penalties for perpetrators.
- Safety first!

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