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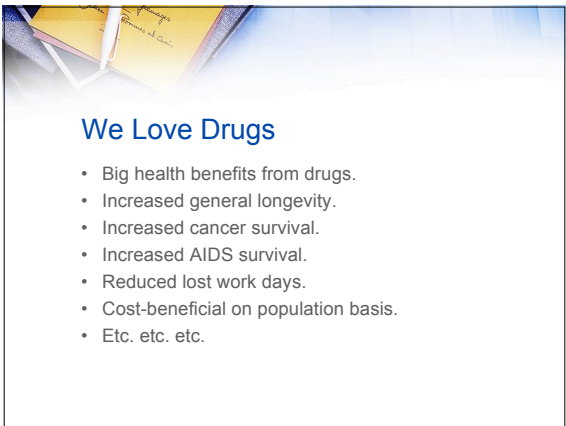
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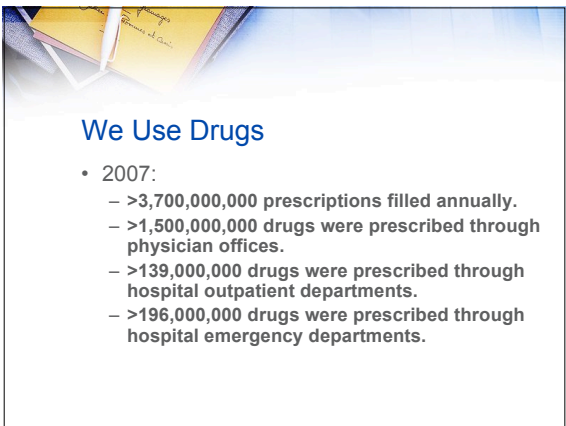
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### We Spend A Lot Too

- 2007: \$286.5 billion.
- Est. 2015: \$446.2 billion—\$1.2 billion/day.

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### What's the Problem?

- Bad guys.
- Supply chain holes allow scum to introduce fake drugs into the system.
- WHO estimate: \$40 billion annually—that's \$132 million/DAY.
- Increase up to \$75 billion annually by 2010.

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### How?

- Gray Market and the Internet.
- ~90% of US distribution through simple system:

Manufacturer → 3 Wholesaler(s)\* → Retailers

\*Big 3: AmerisourceBergen, Cardinal, McKesson.

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## Gray Market

- But ... ~10% of drugs sold in USA in the "gray market" before it gets to final retailer and patient.
  - Gray market is secondary wholesale market where drug resale occurs.
  - Resale occurs between big 3 major wholesalers, ~6000 secondary wholesalers, pharmacies, hospitals, nursing homes, clinics, and others to shed excess supplies, arbitrage prices, address cash flow, deal with impending expirations.
- US allows repackaging of drugs.
- Result: dozens of hands touching drugs, multiple changes in packaging, movement of drugs across places, people, and time without record—allows easy introduction of counterfeits.

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## The Internet

- No regulatory reach or accountability for Internet sellers.
- Highly limited ability to detect offshore criminals for prosecution.
- Sources for drugs include countries notorious for fakes, e.g., China and India.
- Important note 1: State Internet purchasing programs have hold harmless clauses as condition for use.
- Important note 2: Materials passing through a country, e.g., Canada, UK, not earmarked for domestic use not subject to that country's safety laws.

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## Creativity

- Types:
  - Total fakes—packaging to product.
  - Total substitution—real drugs en route to another market replaced completely with fake stuff using real packaging.
  - Hybrid—real drugs (or forms with active ingredient) mixed with counterfeits (i.e., salting) to fool testers.
- Materials used include boric acid, concrete powder, toxic yellow road paint.
- Counterfeiters highly sophisticated in mimicking labels, packaging, and documentation in different languages—including use of same packaging and labeling equipment as actual manufacturers.



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### Can't Tell Just By Looking

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### Except Behind the Scenes

No need for this ...

Just this. ...

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### Solution?

- Pedigree.
  - "A drug pedigree is a *statement of origin* that identifies each *prior sale, purchase, or trade of a drug*, including the date of those transactions and the names and addresses of all parties to them."
  - Prescription Drug Marketing Act (PDMA) §503(e)(1)(A) (1987).
  - Assuming accuracy, helpful in determining where drug is, who has touched it, and where it ended up.

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### Issues

- Feds:
  - No full federal pedigree requirement in place yet!
  - Pedigree mandates delayed half a dozen times.
  - Back in the bad old days [1987] thought was: use paper [the rule since 2006].
    - Problem: you, me, my 11 year old nephew, Photoshop, and a laser printer can make paper pedigree.
    - Problem: counterfeiters who can make pills, labels, holograms, etc. can buy Photoshop and a laser printer too.
    - And ... documents get lost, paper takes space, delay in creation and tracking, and the vast amount of records generated difficult to deal with for audit purposes.
      - Typical wholesaler ships 2 million packages a day.

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### Issues

- New thought:
  - Feds and states think: electronic pedigree [e-pedigree].
  - Assuming accuracy, addresses issues of paper problems, delay in information transfer, and provides real-time tracking and tracing.
  - Feds propose requiring e-pedigree in 2007.
    - Delayed by lawsuit and injunction.

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### Issues

- California moves forward.
  - In response to big counterfeit cases in Pennsylvania [18 million doses of fake Lipitor], fake Procrit in supply chain in 2002-2003.
  - Gray market cases.

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## California Law

- E-pedigree
  - Passed in 2004, e-pedigree by 2007.
  - Delayed once by Board of Pharmacy to 2009.
  - Delayed again by Board of Pharmacy to 2011.

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## Why the Delay?

- Law's requirements—not ready for prime time; devil in details.
- Challenges in:
  - Electronic record practicalities.
  - Mass serialization.
  - Costs of implementation.
  - Privacy issues.
  - Other concerns.

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## Why the Delay?

- Law requires:
  - “an electronic record, containing information regarding each transaction resulting in a change of ownership of a prescription drug, from sale by manufacturer, through acquisition and sale by a wholesaler, until final sale to a pharmacy or person furnishing, administering, or dispensing the prescription drug.”
    - Electronic record from beginning to end of the chain—every link must be outfitted with relevant technology.
    - Different than traditional pedigree requirements, which started with distributors, not manufacturers.
    - One size fits all: no differentiation between, e.g., chemical pills and injectables.

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### Why the Delay?

- Law requires:
  - that manufacturers “mass serialize” all products, i.e., place a unique number on every unit of sale, whether that is a pill bottle, a case, or a pallet for track and trace purposes.
    - Must use “interoperable technology” throughout chain; however, currently no federal or California state standard exists for use throughout supply chain.
    - Debate as to what is best; example: Cardinal says Ultra-high Frequency is best; AmerisourceBergen says High Frequency.

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### Why the Delay?

- Law does not provide for assumption of costs.
  - **How will rural and inner city independent pharmacies absorb costs?**
    - Estimates between \$30K to 80K to equip pharmacy to fulfill e-pedigree law.
    - Small pharmacies don't have lawn furniture to cross subsidize costs.
    - Serve most vulnerable patient populations—so risk of policy failure on these groups.

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### Why the Delay?

- Law does not take into account privacy issues.
  - **Question: if mass serialization down to unit dose given to patient, will unethical marketers attempt to gain access to information on medication bottles?**
    - Who will be the owner, guardian and steward of the information?

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## Other Concerns

- Order of technological adoption:
  - “As a pharmacist, I’m not going to invest in technology or new systems until I know what the distributors are going to do.”
  - “As a wholesaler, I’m not going to invest in technology or new systems until I know what the manufacturers are going to do.”
  - “As a manufacturer, I’m not going to invest in technology or new systems until I know what the federal and international requirements are going to be.”
  - “We [pharmacists, wholesalers, manufacturers] don’t want 50 different standards across 50 states.”
    - Note: FDA Amendments Act of 2007 mandates federal e-pedigree standard by 2010.

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## Other Issues

- Big oversight: all e-pedigree efforts focus on tracking and tracing cardboard, not product.
  - Counterfeiters have mimicked product and packaging well.
  - They can mimic technology as well as disable protections.
  - Recall: repackaging drug products legal in US!

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## Other Issues

- The big, giant, huge, 800 pound gorilla, large pink elephant in the room:
  - E-pedigree drug safety efforts don’t take into account the problem of fakes via the Internet.
    - E-pedigree addresses gray market; but all big 3 wholesalers no longer purchase in gray market—increased scrutiny has reduced problem.
    - Attention to gray market has shifted counterfeit sales to Internet and non-traditional sources.

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## Reform

- E-pedigree a good idea.
  - Board of Pharmacy should mandate supply chain participation in development of e-pedigree standards.
  - State should work with FDA to create workable *national* standards.
- California legislature should see e-pedigree as beginning of drug safety efforts, not end.
  - Legislature should ban Internet sales of drugs except those accredited by National Association of Boards of Pharmacy Verified Internet Pharmacy Practice Site (VIPPS) program.
    - VIPPS requires valid prescription, inspections, privacy rules, and compliance with applicable federal and state laws.
  - Legislature should penalize (criminal and civil) any credit card company executing a non-VIPPS sale of drugs over the Internet.

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## Overall

- Drug safety an important policy issue.
- E-pedigree good in theory, but not yet ready for prime time.
- California Board of Pharmacy should work with feds and mandate industry determination of technology standards.
- California Legislature should ban non-VIPPS Internet drug sales, and impose penalties on credit card companies that execute these transactions.

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