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Reverse Pharmaceutical Distribution Regulatory overview

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Reverse Distribution Core Functionality

- Centralizes outdated drugs into a finite number of warehouses which can be monitored for compliant processing procedures
- Returns millions of dollars to the healthcare industry from pharmaceutical manufacturers each year
- Removes outdated drugs from the market in a systematic fashion, thereby reducing diversion possibilities
- Could provide the infrastructure for national consumer take-back programs in the future

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Proposed Universal Waste Rule

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Impact of Universal Waste Regulations

- Applies ONLY to 4% to 5% of drugs in the marketplace that are RCRA hazardous waste
- Some state currently have added pharmaceuticals to universal waste regulations
- Some care and custody issues; unanticipated consequences
- Does not address other 95% of drugs

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Benefits of the Proposed Universal Pharmaceutical Waste Rule

- Enables hospitals to avoid becoming large quantity generators due to P-listed drugs
- Eliminates necessity to document P-listed drugs
- Enables continued reverse distribution of outdated drugs that will become hazardous waste but may be creditable
- Enables easier household collection in states where central collection facilities bring hazardous waste back into regulation
- Removes any concerns about using RDs as a national take-back model

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Concerns

- Does not all address all issues: legitimate environmental concerns such as “non-hazardous drugs”
- Hazard of not listing over 100 chemotherapy drugs as hazardous waste
- Cost of disposing of all waste pharmaceuticals as universal waste may be cost prohibitive

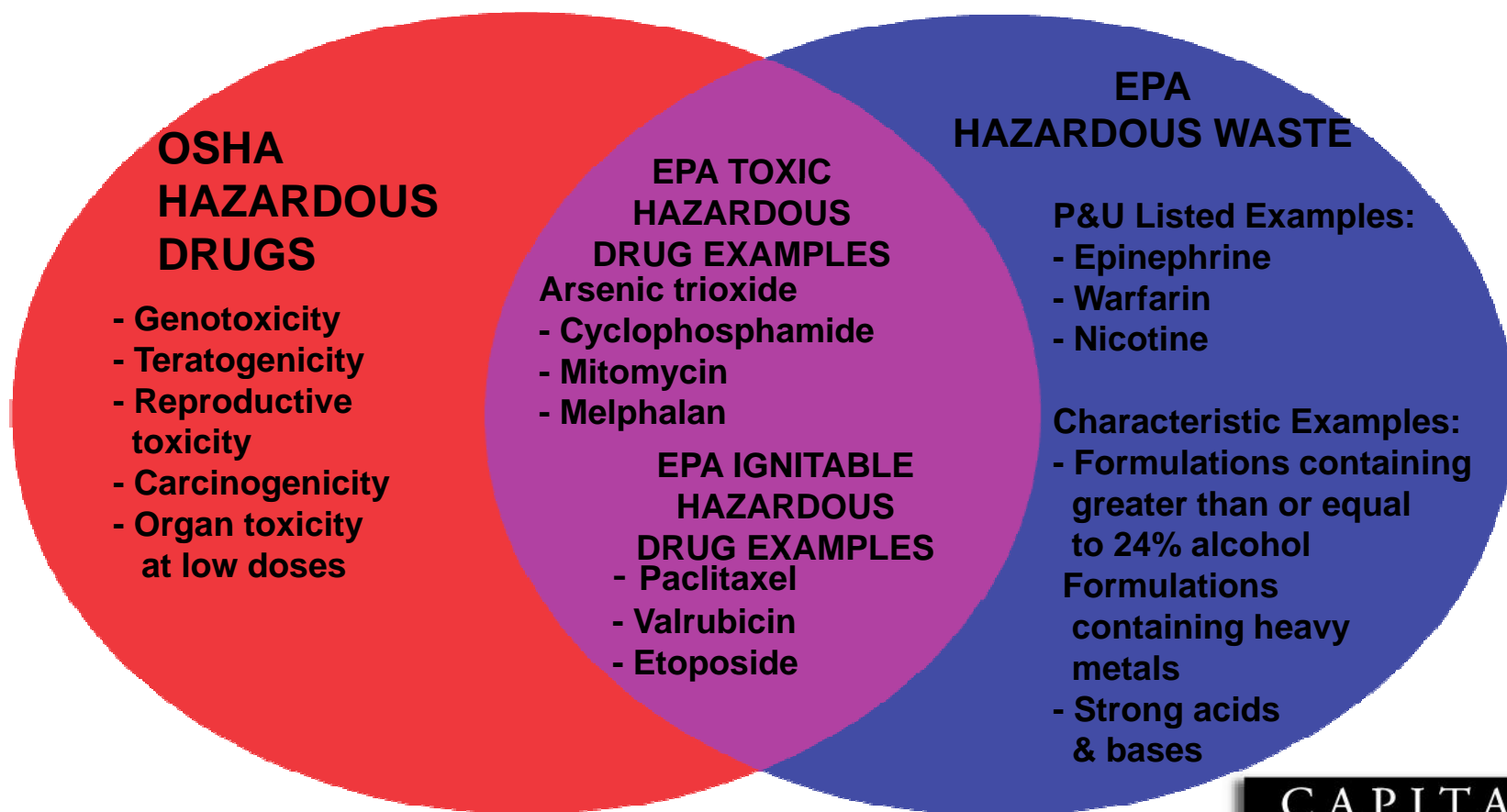
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OSHA vs. RCRA (Reproduced with permission from PharmEcology)



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Concerns

- Reverse distributors are required to inventory all drugs received into their warehouse
 - FDA 21CFR205.50 Guidelines for wholesalers
 - State Boards of Pharmacy
- This required inventory process would expose employees to potentially infectious materials and hazardous drugs, such as chemotherapy

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Food and Drug Administration Rules

- Inventory requirements
- Requirements for lot and expiration date tracking
- Segregation of product if forward donation of indated product
- Recall management: product segregation
- Pedigree requirements



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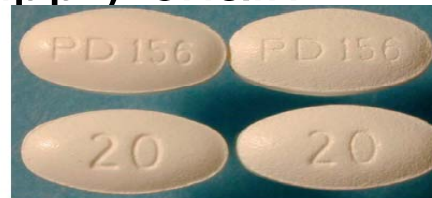
Counterfeit Detection



- COUNTERFEIT DRUGS: THE UNTOLD STORY

-Vials of medicine prescribed for a 16-year-old boy recovering from a liver transplant arrived in the mail from a national pharmacy chain. The shots were painful and didn't seem to work. But Tim continued to take the medication, unaware it contained only 5 percent of the active ingredient. It had been counterfeited.

-Pfizer recalls 18 million Lipitor tablets in 2003 due to counterfeit in the U.S. supply chain.



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Aside from a difference in their thickness, the counterfeit Lipitor® (left) is virtually indistinguishable from the authentic tablets.



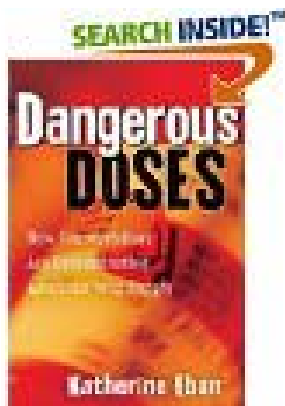
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Counterfeit Detection

- Lot and expiration date
- RFID
- Serial Number
- Bar code



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Drug Enforcement Administration



- **Controlled Substances Act**
- **Separate registration for reverse distributors**
- **Common reporting in reverse distribution:**
 - Arcos
 - 222 Form (CSOS)
 - Form 41
 - Form 106



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Department of Transportation

- Shipping product to a reverse distributor
 - “Product” – shipped via “consumer commodity”.
- Reverse distributor shipping product vs. waste
 - Shipped to manufacturer or other reverse distributor

Shipping as waste



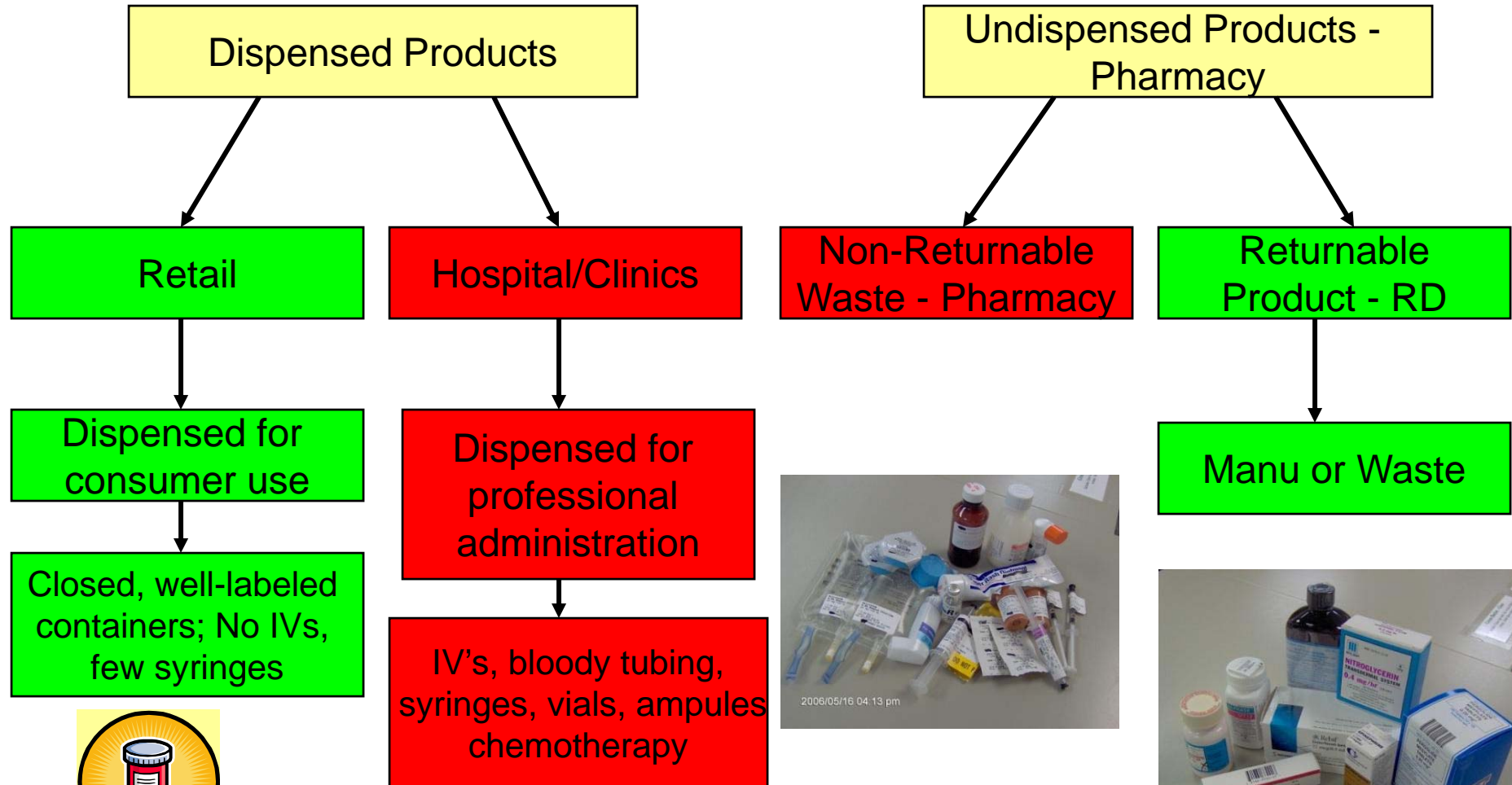
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Unused meds vs. waste



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Consumer Med Returns



- Reverse Distributors an option for mail back from consumers.
- Pilot conducted in two Wisconsin counties.
- National model info:
- <http://www.mainebenzo.org/documents/consumertakebackmodel102>



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Recommendations

- Educate healthcare facilities on pharmaceutical waste management.
- Consider other drugs that need to be considered hazardous: NIOSH list.
- No sewerage of drugs!
- Consider the financial impact to healthcare
- Be aware of definitions:
 - Undispensed product versus dispensed product.
 - Hospital versus Retail Pharmacy

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Questions?

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