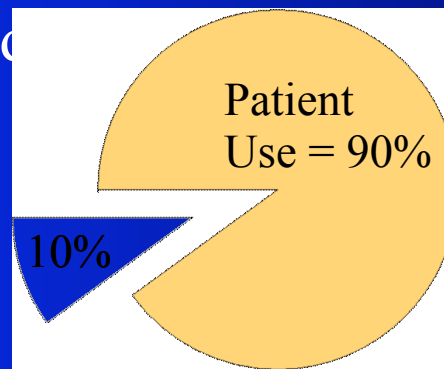


1. Given that we know there are unwanted & expired medicines being generated, what issues and concerns are raised for your company?

- We want patients to trust that they have safe and environmentally-sensible options for managing unused medicine
- Decisions based on science & data – **Some PIE Perspective**
 - Pharmaceutical detected in drinking water avg <20 ppt
 - 20 parts per trillion is about 1 second in 1,600 years
 - Caffeine is detected at 25 parts per trillion in drinking water
 - recommended daily water intake of 2 to 3 liters
 - Takes a person >2000 years for a cup of coffee equivalent
 - Ibuprofen is detected in some surface water at 1000 ppt
 - Takes a person >180 years to intake a single dose
 - It takes 7 years to get the allowable daily intake (ADI)
 - Significance of unuse



1. Given that we know there are unwanted & expired medicines being generated, what issues and concerns are raised for your company?

- PhRMA is concerned about patients not taking their medicine properly.
 - Medicines are valuable products designed to be effective when taken as directed by physicians.
 - A RAND study published in the Annals of Internal Medicine found that 50% of all quality problems in the use of medicines was accounted for by underuse.
- We are concerned about accidental poisonings and prescription drug abuse, but:
 - it is unknown whether the cause is medicines currently in use, unused or expired medicine
 - the root cause of these issues are not solved by disposal programs but by programs that address safeguarding all drugs at home (active prescriptions; OTC products; and unused medicine awaiting disposal)
- PhRMA partners on poisoning and abuse issues with:
 - DARE
 - Partnership for Drug Free America
 - Partnership for Safe Medication Use

2. Please describe your company's involvement with take-back programs for unwanted medications in other countries or the U.S?

- Drivers of take back programs differ globally
- Packaging directives forced by limited landfill capacity affected all industries & were the drivers of the first programs
- In Europe
 - ✓ – extensive use of old and poorly designed landfills helped drive the establishment of take back programs
 - there is no operational requirements or guidance on advertising, management or finance
 - there are no performance requirements
 - in 2007 19,000 tonnes collected from 8 schemes reporting
 - 13,000 from France includes packaging
 - 3 from Ireland
 - 1,000 each from the other 6 countries reporting
 - some locations incinerate all household trash and don't solicit participation
 - disposal cost ranged from \$600 to \$6000 per tonne of material destroyed
 - no data on recover rates
 - ✓ – Participation varies (estimates e.g. UK 20%, Austria 1%, France 80%)

2. Please describe your company's involvement with take-back programs for unwanted medications in other countries or the U.S?

- **PhRMA is a trade association that represents research-based pharmaceutical companies.**
- **We are aware that our members participate in take-back programs in other countries, but do not think that take-back is necessarily the right solution for the US.**
 - **Other countries do not have the same landfill technology as the US.**
 - **Most of the trace amounts of medicine in environment is from human use and metabolite.**
 - **The Drug Enforcement Agency enforces rules and regulations to prevent drug diversion and abuse.**
 - **Much liability is built into the US healthcare system.**

3. What is your vision of a comprehensive approach for addressing the issues and concerns regarding unwanted pharmaceuticals?

- As a basic concept, product stewardship initiatives should follow the well established hierarchy
 1. Reduce (don't generate the waste in the first place)
 2. Reuse
 3. Recycle
 4. Dispose
- Any effort should be cost effective
- Any effort should take into consideration local disposal technologies and cultural (likely participation rates)

Patient safety dictates that any medicine dispensed to the general public that goes unused be disposed

3. Vision continued:

First - Reduce (don't ever generate the waste)

- First in the hierarchy because the most effective way to eliminate any impacts from waste is to have no waste.
- Why does medicine go unused - Top survey responses
 - medication change: not solving the problem or side effects
 - the condition has been resolved: feels better
 - the medicine has expired
- To be most effective we must understand why medicine is unused & investigate what can be done e.g.
 - use of manufactures sampling programs
 - dispensing of “as needed” medicines (i.e. pain killers)
 - check expiration dates, package sizes and consider personal use history when purchasing OTC products.

3. Vision continued: Last - Disposal

- **Disposal options for US consumers**

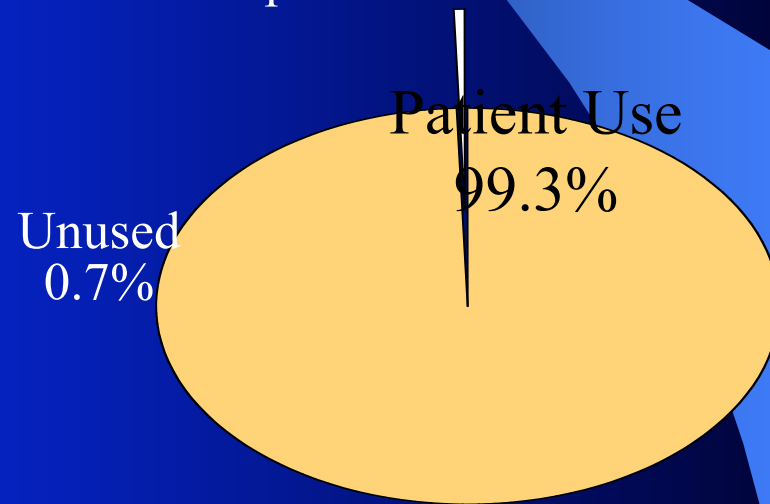
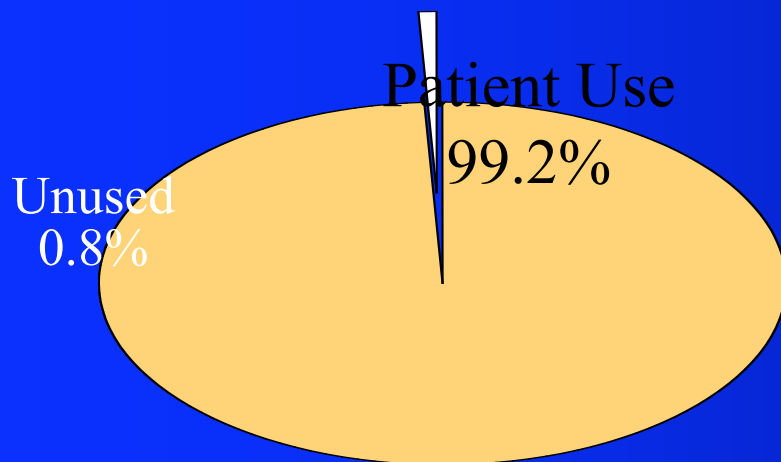
- ❌ drain disposal
- ✓ household trash disposal
- ✓ collection for incineration

- **Household trash**

- 15% incinerated
- Impact on PIE

- **Take back for incineration**

- 20% participation*
- Impact on PIE



- **Other environmental impacts need to be evaluated**

- take back: carbon footprint, air emissions, ash disposal
- trash: risk of leaking landfill liners, risk of groundwater contamination

3. What is your vision of a comprehensive approach for addressing the issues and concerns regarding unwanted pharmaceuticals?

- **Educate the public not to use sewer disposal**
- **Educate & encourage proper disposal of unused medicines**
 - **household trash**
- **Concentrate on having less unused medicines**
 - **study the reasons medicines go unused**
 - **determine the root causes**
 - **work together (physicians, pharmacists, insurers, payers, manufacturers etc.) to address the root causes**

4. In what ways can you see your company participating in take-back and other management efforts for unwanted medications in WA state?

- Filling data gaps so that scientifically based effective public policies can be pursued
 - what % of medicine goes unused and why
 - likely participation rates in take back programs
- Investigations on why medicines go unused and how to reduce that amount
 - collect data
 - determine root causes
 - design solutions

4. In what ways can you see your company participating in take-back and other management efforts for unwanted medications in WA state?

- **Getting the word out about not disposing of medicines down the drain**
 - **SMARxT DISPOSAL™**
- **Continue studying PIE**
- **Study overall environmental impacts of take back for incineration versus household trash disposal**
 - **working with the Graham Sustainability Institute at U of Michigan**
- **Continue PhRMA partnerships on abuse and poisoning issues**