

Safe Drug Disposal: Blueprint for the Future



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Agenda

- Regulatory considerations, barriers and successes
 - DEA
 - State boards
 - EPA, states
- Environmental considerations,
- Funding considerations
- Slowing down waste generation volumes



Pharmaceutical Waste: The Big Picture

- Environmental Costs
 - Endocrine disruption of aquatic species, amphibians
 - Unknown impact on humans
- Direct Societal Costs
 - Cost of production, distribution, wastage of unused prescription and OTC drugs
- Public Safety Costs
 - Availability of opioid and other controlled substances to young people
 - Poisonings and death
- Indirect Societal Costs
 - Disruption of family, work place, economy



The Unintended Epidemic

- From 2000 to 2006, number of deaths due to unintentional overdose in the US more than doubled from 32 deaths/day to 72/deaths per day
- Ohio's death rate grew from 2.9/100,000 in 1999 to almost 13/100,000 in 2008
- Task Force report addresses issues related to treatment, law enforcement, public health, regulation
- Public health: Facilitate the proper disposal of prescription medication
 - Addresses primarily one-day collection events
- Public health issues are one aspect of larger pharmaceutical waste picture



*Ohio Prescription Drug Abuse Task Force, October 1, 2010,
<http://www.odh.ohio.gov/features/odhfeatures/drugod/drugoverdose.aspx>

Focus on Unwanted Consumer Medications

- Recommendations for landfilling after mixing with undesirable substance
 - <http://www.smarxtdisposal.net/>
 - http://www.whitehousedrugpolicy.gov/publications/pdf/prescription_disposal.pdf
 - Take-back surveys have documented that over 50% of respondents would have retained the unwanted meds in their homes had the event not been available
- FDA site continues to recommend flushing of most commonly abused/dangerous drugs
 - <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm>



Consensus: Collection Options are Needed

- One time/periodic community collection events
- Permanent collection facilities
 - Law enforcement kiosks
 - Pharmacy kiosks
 - Household Hazardous Waste facilities
- Mail-back options
 - Maine Mail-back to state DEA
 - Concerns about other “don’t ask, don’t tell” programs that rely on consumers to differentiate controlled substances from other drugs
- Need DEA regulatory guidance



DEA National Drug Disposal Day

- Operated by regional Special Agent in Charge or other state DEA representative – disposal operations planned varied
- Law enforcement take-back programs only – compliant with existing CSA regulation
- Over 4,000 registered programs across the country; 121 tons collected nationally
- State environmental regulations considered
- DEA covered cost of disposal, some free disposal
- Examples:
 - Six New England state collected 25,810 pounds
 - Waste-to-energy incinerator used for disposal
 - CO, WY, MO - ? More info to come
 - Industrial waste landfill used for disposal



Current DEA Regulations

- DEA Controlled Substance Act
 - Closed loop system
 - Outside the loop – ultimate users (residents)
- Colorado SAC regarding don't ask...don't tell programs

"It has been the experience of DEA that most people do not understand the difference between controlled substances, dangerous drugs, and over the counter medications. We do not recommend instituting take-back programs which instruct the public to deposit "non-controlled items only." There is no way for the program to guarantee that outcome and, therefore, may allow controlled substances to go into the possession of unauthorized persons."
- DEA response to another vendor regarding destruction

"Mixing a controlled substance with chemicals, absorbent materials, or other undesirable substances does not invalidate its status as a controlled substance nor may the controlled substance be considered "destroyed" at that point."



Current DEA Regulations

➤ DEA response to WM regarding possession:

“Based on the above, you asked if reasonable measures were taken to exclude controlled substances from a household pharmaceutical waste program, could the program assume it would not be subject to requirements of the CSA and its implementing regulations. If a pharmaceutical waste program comes into possession of a controlled substance, even inadvertently, and has no legal authority to possess the substance, the program is in illegal possession of the material and subject to CSA provisions.”



Senate Hearing on the CSA: June 30, 2010

- Senate Special Committee on Aging: Drug Waste and Disposal
 - Committee Chairman: Senator Herb Kohl (D-WI)
- Consensus: CSA needs to be amended
- Senator Kohl pushing FDA to amend guidance to eliminate sewerage recommendation



Secure and Responsible Drug Disposal Act of 2010 (S.3397)

- Passed by Congress on September 28, 2010
- To amend the CSA to provide for the take-back disposal of controlled substances in certain instances
- Findings:
 - Unintentional overdose deaths involving Rx opioids increased 114% from 2001 to 2005
 - Number of treatment admissions for Rx opioids increased 74% from 2002 to 2006
 - (related) Violent crime and property crime has increased in all regions of the US over the past 5 years
 - Teens abuse Rx drugs more than any illicit drug except marijuana
 - Drugs most often found in the home



Secure and Responsible Drug Disposal Act of 2010 (S.3397)

- Findings cont:
 - Long-term care facilities face a distinct set of obstacles to the safe disposal of controlled substances (not a DEA registrant, not able to use reverse distribution)
 - Act gives the Attorney General authority to promulgate new regulations, within the framework of the Controlled Substances Act, that will allow patients to deliver unused pharmaceutical controlled substances to appropriate entities for disposal in a safe and effective manner consistent with effective controls against diversion
 - The goal of the Act: to encourage the Attorney General to set controlled substance diversion prevention parameters that will allow public and private entities to develop a variety of methods of collection and disposal of controlled substances...in a secure, convenient and responsible manner.



Secure and Responsible Drug Disposal Act of 2010 (S.3397)

- Section 302 of the CSA (21 U.S.C.822) is amended by adding at the end of the following:
 - “(g)(1) An ultimate user who has lawfully obtained a controlled substance in accordance with this title may, without being registered, deliver the controlled substance to another person for the purpose of disposal of the controlled substance if-
 - “(A) the person receiving the controlled substance is authorized under this title to engage in such activity; and
 - “(B) the disposal takes place in accordance with regulations issued by the Attorney General to prevent diversion of controlled substances.



What Should DEA Regulations Encompass? Or, The Devil's in the Details....

- Consider new “registration” category for receipt, management and disposal of controlled substances: “Disposer” category
- Require an inventory and security procedures for containers of consolidated returns, but not at the capsule/tablet level of detail
- No ARCOS reporting
- Form 41 modifications for witnessed incineration
- Consideration of other forms of non-recoverable disposal such as microencapsulation at industrial landfills
- Enable current DEA registrants to add new registration with appropriate security concerns addressed
- Enable waste disposal companies to become registrants under “Disposer” category



Scenarios Eligible for “Disposer” Registration

- Retail pharmacies
- Reverse distributors
- Mail-back receipt locations at incineration facilities
- Law enforcement facilities



Other Potential Barriers

- State Boards of Pharmacy/Controlled Substances Boards
- State environmental protection agencies
- DOT: USPS/FedEx/UPS



State Boards of Pharmacy/CS Boards

- Will each state need to adopt the federal rules?
- Will states have the option to ignore the new regulations?
- Example: some states currently require law enforcement to take possession of all collected drugs, not just controlled substances
- PA requires one-day registration as a reverse distributor to conduct a collection event
- Many state boards of pharmacy will need to change rules to enable pharmacies to accept drugs back into the facility



Security of Transport for Collected Meds

- Kiosk collection:
 - Packaging from kiosk documented by two responsible parties
 - Package tracked and traced through receipt by final disposer
- Consumer mailback:
 - Advance notification or call-tag type system
 - Package tracked and traced to final disposer
- Reverse distributor:
 - Advance notification or call-tag type system
 - Packages tracked and traced without opening through system and final witnessed burn (manage all as controlled substances)
- Community event:
 - Law enforcement continues to take controlled substances; other drugs shipped by waste vendor



State Environmental Protection Agencies

- Household generated drugs are exempt from hazardous waste regulations at the federal level
 - EPA's Resource Conservation and Recovery Act does not apply at any point along the disposal process
 - RCRA requires that businesses (which often include long term care facilities) identify and manage drugs that meet the definition of a hazardous waste according to complex rules that parallel the CSA with cradle-to-grave reporting requirements
- Some states require that drugs that are collected centrally come under RCRA and must either:
 - Be segregated for disposal (too costly)
 - Or managed as hazardous waste (also costly!)
 - WA, ME, MN, NH
 - Maine and New Hampshire provided a one-time exemption for DEA event



Dept of Transportation

- Some prohibitions against “waste” being transported by common carriers like FedEx, UPS
- USPS able to do so with certain packaging requirements
- Maine mail-back program has demonstrated safety of consumer mail-back option



The Elephant in the Room

- What is the most cost effective method for conducting take-back programs?
- How does convenience (e.g. mailback) compare to permanent kiosks?
- Who pays?
 - Public vs private
 - Product stewardship
 - Shared responsibility
 - Manufacturer only



Barriers to One-Day Collection

- Time to plan (location, marketing, transport, and disposal)
- Accessibility (central location, time of year, weather)
- Staffing (law enforcement, pharmacists, other volunteers)
- Containers
- Segregation of waste
 - Some programs sort controlled from non-controlled
 - Some programs treat all as controlled
- Transportation – near existing disposal infrastructure
- Cost (who pays, who provides in-kind costs)



Practical Experience and Disposal

- Consumer Options for disposal
 - Drain (easy, costs nothing)
 - Trash (easy, costs nothing for resident)
 - Collection activity (event or permanent)
 - More complex and higher cost
- Collection Operator Options for disposal
 - Landfill (MSW, Industrial waste, Hazardous waste)
 - Waste-to-Energy incineration
 - Medical Waste incineration
 - Hazardous Waste incineration



Waste Management Option: Microencapsulation

- Micro Secure™
Waste Management developed Micro Secure™ microencapsulation technology to treat smaller-sized hazardous debris. Micro Secure™ involves coating hazardous debris with a custom-tailored mixture of proprietary sealing agents, thus preventing them from interacting chemically with the surrounding environment. Micro Secure™ is the preferred treatment for smaller-sized hazardous debris that can be fully coated on all surfaces, both exterior and interior.
- Possible cost-effective, environmentally friendly alternative to incineration
- http://www.wmdisposal.com/services/micro_macro_encapsulation.asp



Disposal Cost Considerations

- Available treatment methods in order of descending costs
 - Hazardous waste incineration: \$.95 to \$4.95/lb
 - Regulated medical waste incineration: \$.60 to \$.90/lb
 - Waste-to-energy incineration: \$.05 to \$.10/lb
 - Industrial landfill “sequestration”: \$.075 to \$.10/lb
 - Municipal landfill management : \$.01 to \$.03/lb
- Transportation costs will vary based on location



Viewing the Problem Through Another Lens*

- A “Pipeline of Opportunities”
 - Design: of pharmaceuticals to include environmental concerns
 - Approval: process to include more stringent environmental impacts
 - Production: process could benefit from a pollution prevention assessment
 - Use: Over-prescription of pharmaceuticals in humans and over-use of antibiotics in animals is a core contributor to pharmaceuticals in the drinking water/environment
 - Discharge and Disposal: End-of-pipe problem without easy answers
 - Collection initiatives important first step



*Dosed Without Prescription: Preventing Contamination of Our Nation’s Drinking Water, NRDC White Paper, December, 2009, http://docs.nrdc.org/health/files/hea_10012001a.pdf

Contributors to Overuse

- Physician behavior: Over-prescriptions
 - Antibiotics
 - Pain medication for temporary conditions such as surgery, dental procedures
- Manufacturer marketing techniques
 - Direct-to-consumer advertising
 - 2003: \$22.1 billion on physicians, \$3.2 billion on consumers
- Insurance plans
 - 90 day supplies result in extensive wastage
 - Maine now requiring a 15-day starter supply for commonly wasted drugs
- Rates of wastage vary but figures between 30% and 50% have been noted in the literature



Summary

- Amendment to CSA removes one significant barrier to consumer drug collection programs
- State board of pharmacy and state controlled substance boards will play a significant role in enabling cost-effective programs to be developed
- Environmental considerations will also play a role; some compromises may be needed to insure public safety is served
- The causes of left-over meds need to be addresses not only from a public safety perspective but also to reduce unnecessary healthcare spending



Resources

- Ohio Prescription Drug Abuse Task Force, October 1, 2010, <http://www.odh.ohio.gov/features/odhfeatures/drugod/drugoverdose.aspx>
- Dosed Without Prescription: Preventing Contamination of Our Nation's Drinking Water, NRDC White Paper, December, 2009, http://docs.nrdc.org/health/files/hea_10012001a.pdf
- EPA Draft for Public Comment available at: http://water.epa.gov/scitech/wastetech/guide/unusedpharms_index.cfm
- WMHS PharmEcology Services
www.pharmecology.com
FAQs, state and federal waste regulations, subscription search engine
PharmE® Waste Wizard identifies RCRA hazardous waste plus NIOSH hazardous drugs, among additional criteria



Questions?

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