EPA Comments on the Development of Safe and Effective Drug Collection and Disposal Methods

Robert W. Dellinger, Division Director
Materials Recovery and Waste Management Division
Office of Resource Conservation and Recovery
U.S. EPA
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Introductory Remarks

• Active Pharmaceutical Ingredients (APIs) have been found in low concentrations in the environment potentially exposing wildlife and humans

• EPA and DEA share a common goal to protect public health

  – DEA works to prevent drug diversion to people

  – EPA works to prevent drug diversion to the environment and thus indirectly to people

• Our agencies can collaborate to prevent diversion to both people and the environment
Introductory Remarks (Cont.)

• Our collaboration should focus on making drug take-back programs available and easy to execute in a safe manner

• EPA is working to stop flushing of drugs where appropriate and drug take back programs can help keep drugs out the environment

• EPA has awarded two grants for take-back programs which we will discuss later and drafted Best Management Practices for Unused Pharmaceuticals at Health Care Facilities
Overview—EPA Recommendations

• Develop a national set of options for take-back programs

• Ensure that collected controlled substances are managed and disposed of in accordance with environmental regulations

• Clarify current destruction/disposal methods and approve additional methods

• Streamline recordkeeping requirements for take-back programs
Development of Take-Back Options

• EPA encourages flexibility in the new DEA regulations to allow for various approaches to drug take-back programs

• Providing a choice of take-back options will help communities overcome obstacles that their geographical locales may present or that their individual residents may experience

• Some options include but are not limited to:
  – Mail-back programs
  – Consumer returns to DEA registrants (including but not limited to reverse distributors)
  – Secured boxes at pharmacies and/or other locations
  – Any combination of the above

• EPA awarded two successful grants to test different approaches for prudent disposal of unwanted pharmaceuticals
EPA Grant: RxMEDS

• RxMEDS - Regional Excess Medication Disposal Service
  – St. Louis Metro Region
• Returns by users to pharmacies
• Collected 244,708 capsules, tablets and suppositories over an 12 month period
• Unable to obtain permission to collect controlled substances
• All collected drugs were incinerated
• No instances of diversion, theft, etc.
• [http://www.epa.gov/aging/grants/winners/archs.htm](http://www.epa.gov/aging/grants/winners/archs.htm)
EPA Grant:
Safe Medicine Disposal for ME

• Mail-back program
  – Univ. of ME, ME DEA, US Postal Service, other partners
  – Collected 2,373 lbs of drugs during the grant period
    • 2,123 lbs – non-controlled substances
    • 250 lbs – controlled substances
  – Take-back program still in operation post-EPA grant
    • 20,000 mailers available at approx. 150 sites
    • Collecting over 100 lb a week
    • Funding in place through 2011
  – No instances of diversion, theft, etc
  – Secure delivery to Maine Drug Enforcement Agency for data collection & destruction
    • All non-controlled drugs are incinerated as HWs
    • Controlled drugs are witness-incinerated as municipal solid waste at a waste-to-energy facility
  – Final report issued in April 2010: www.safemeddisposal.com
Environmental Regulations

• Once collected, unwanted controlled substances and other unwanted pharmaceuticals must be managed in accordance with all applicable federal, state, and local environmental regulations.

• Federal environmental regulations lay out the baseline standards:
  – States may have more stringent or broader regulations than federal EPA.

• EPA comments focus upon the federal regulations as they apply to disposal of household (ultimate user) pharmaceutical waste:
  – Resource Conservation and Recovery Act (RCRA)
  – Clean Air Act (CAA)
RCRA

- Non-hazardous wastes, such as municipal solid waste, are regulated under Subtitle D of RCRA (local and state level)

- Hazardous wastes are regulated under Subtitle C of RCRA
Are Pharmaceuticals HW Under RCRA?

• A waste is hazardous if:
  – It is specifically listed by EPA; or
  – It exhibits a characteristic of HW

• Only a very small percentage of pharmaceuticals are regulated HW
  – 3 listed hazardous wastes are also DEA controlled substances

• The regulations applicable to HW pharmaceuticals depends on the type of generator
  – Household, conditionally-exempt small quantity generator, small quantity generator or large quantity generator
Applying RCRA to Households

- Household hazardous wastes (HHWs) are exempt from federal Subtitle C regulations (40 CFR 261.4(b)(1))
  - When Congress enacted RCRA, it indicated that HW regulations should NOT apply to households
  - Exemption applies even when HHWs are collected
  - Some states do have more stringent requirements and regulate HHW once collected and consolidated (e.g., PA)
  - EPA recommends that collected pharmaceutical HHWs be managed and disposed of as HW
CAA

• No air standards apply directly to the ultimate user (i.e., household) who disposes controlled substances

• Certain CAA regulations may apply if the controlled substances are disposed of in landfills or incinerated
  – EPA has issued emission standards for:
    • Hazardous waste incinerators (under section 112(d) of the CAA)
    • Solid waste incinerators (under section 129 of the CAA)
      – Hospital, medical and infectious waste incinerators
      – Municipal Waste Combustors (large and small)
      – Other solid waste incinerators
    • Municipal solid waste landfills (under sections 111 and 112 of the CAA)
Additional Destruction and Disposal Methods

• EPA suggests DEA:
  – Discourage the sewering of household controlled substances except in the few instances where FDA recommends flushing
    • FDA recommends sewering for a short list of drugs that are extremely dangerous to those for whom the drug has not been prescribed (e.g., children and pets)
  – Define what constitutes destruction and identify DEA-approved methods
    • Destruction methods must also be in accordance with all federal, state and local environmental regulations
Expand Disposal Options for Non-DEA Registrants

• It is EPA’s understanding that long-term care facilities (LTCFs) often dispose of unwanted controlled substances by sewering
  – LTCFs employees are typically not DEA-registrants, and as a result they cannot:
    • Return controlled substances to the LTCF pharmacy;
    • Transfer controlled substances to a reverse distributor; or
    • Transfer to a DEA-registrant for disposal

• EPA recommends that DEA allow LTCFs to become DEA-registrants or authorize them to return/transfer controlled substances in order to expand their disposal options
Recordkeeping Requirements

- EPA recommends that DEA
  - Streamline or modify the recordkeeping requirements for take-back programs

- Current recordkeeping requirements could present obstacles to take-back organizers because inventory and recordkeeping requirements for controlled substances are applied in various ways
  - Pill-by-pill identification
  - Separation and tracking prior to disposal
Summary

• In development of regulations, EPA recommends that DEA:
  – Develop a set of flexible options for pharmaceutical take-back programs
  – Ensure destruction/disposal of pharmaceuticals is in accordance with all federal, state, and local environmental regulations
  – Define allowed additional destruction methods and disposal options
  – Streamline recordkeeping requirements for take-back programs
Conclusion

• Thank you for inviting us to comment

• We look forward to working together on this issue

• For more information, please contact Lisa Lauer at 703-308-7418