

Pharmaceutical Waste: Fish Don't Need Anti-Depressants

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Take Home Messages

- USGS Study found pharmaceuticals at detectable levels in many U.S. surface waters!
- First manage for P2, then dispose of properly.
- Pharmacists not always conversant in waste regulations (and may need support).

Looming Issue: Drugs in Waters

- USGS Study finding pharmaceuticals in streams...
- ...though not present at therapeutic doses
- Potential adverse impacts:
 - ✓ Water quality degradation
 - ✓ Endocrine disruption (physical, mental, sexual development)
 - ✓ Antibiotic resistance
 - ✓ Public perception

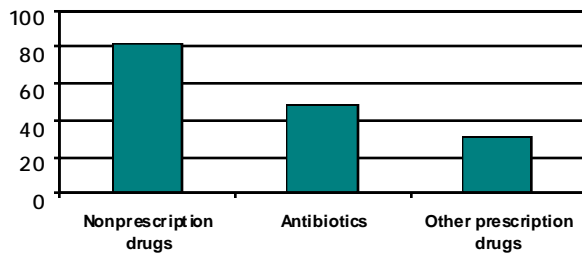


- First nationwide reconnaissance of occurrence of pharmaceuticals, hormones, other organic wastewater contaminants (OWCs)
- 139 streams in 30 states, analyzed for 95 different OWCs
 - ✓ Many OWCs: 82 of the 95 OWCs detected in at least one stream sample
 - ✓ Widespread: One or more OWCs found in 80% of stream samples
- 13% of streams had more than 20 OWCs

* <http://toxics.usgs.gov/pubs/OFR-02-94/index.html>



USGS Stream Survey¹: Frequency of Detection by Drug Class



¹ Streams susceptible to contamination were sampled (139)



Below the Dose/Response Curve: Endocrine Disruptors

- Endocrine Disruptors:
 - ✓ Disrupt hormone regulation in the body
 - ✓ Interfere with the normal function of the endocrine system (glands including thyroid, adrenals, ovaries, testicles)
 - ✓ Mimic hormones
 - ✓ Affect reproduction, development, and behavior
 - ✓ Multi-generational effects.



Below the Dose/Response Curve: Endocrine Disruptors

- Do not follow the normal dose/response curve.
- Active at much lower doses, especially in the fetus and newborn.
- Estradiols, progesterone, testosterone.
- Questions: Evidence of human effects at low concentrations?

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Antibiotic Resistance

- Ampicillin-resistant bacteria found in every U.S. river tested in a 1999 study
 - ✓ 4 - 59% of population resistant
 - ✓ All Ohio River samples, contained E. coli with some degree of resistance to penicillin, tetracycline, and vancomycin in a 2000 study
 - ✓ Samples containing the highest levels of antibiotics also contained bacteria with greatest resistance



Pathways to Sewers



Human Waste



Dumping in Sinks and Toilets



Showering and Handwashing



Overview of Pharmaceutical Disposal for Hospitals

- Radioactives
 - ✓ special handling
- RCRA hazardous waste
 - ✓ must be hauled off as hazardous waste
- Solid waste
 - ✓ some flexibility



Recommended Disposal Strategy

RCRA Hazardous



RCRA Hazardous Waste

IV bags with salts/nutrients



Sewer

Everything Else



Medical Waste



Minimizing Pharm Waste

- Minimize inventory to extent feasible
- Rotate inventory - use oldest stock first
- Centralized disposal of physician's samples
- Avoid unnecessary prescriptions, especially antibiotics
- Use pharmacy reverse distribution



Minimize Hazardous RX Waste Generation?

- Inherent limitations on substitution of a less hazardous drug since the hazardous nature of the chemical often provides the therapeutic effect
- Tighter inventory control to reduce outdate generation, both original manufacturers' containers and repacks
- Single dose vials vs. multiple dose vials
- Patient specific oral syringes vs. 10 cc. repacks (e.g. choral hydrate for pediatric use)
- Reformulation of heavy metal concentration, especially mercury and m-cresol as preservatives

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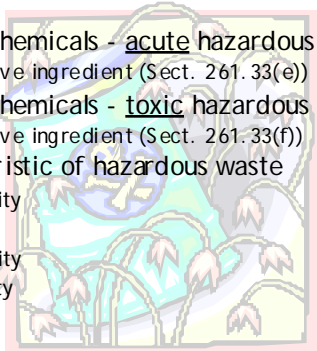
What Pharms Can Be Sewered?

- Up to individual POTWs
- Generally okay to sewer solutions in IV bags containing only:
 - ✓ saline solution
 - ✓ lactate (i.e., Ringer's)
 - ✓ nutrients such as glucose (i.e., D5W)
 - ✓ vitamins
 - ✓ potassium
 - ✓ other salts and electrolytes



Which Discarded Drugs Become Hazardous Waste?

- P-listed chemicals - acute hazardous waste
 - ✓ Sole active ingredient (Sect. 261.33(e))
- U-listed chemicals - toxic hazardous waste
 - ✓ Sole active ingredient (Sect. 261.33(f))
- Characteristic of hazardous waste
 - ✓ Ignitability
 - ✓ Toxicity
 - ✓ Corrosivity
 - ✓ Reactivity



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When is an Outdated Drug a Waste?

- At the time and place the decision is made to discard it
- Two EPA guidance letters to the industry:
 - ✓ Merck & Co., 1981
 - ✓ BFI Pharmaceutical, 1991
- Enables shipping of potentially creditable outdates to a reverse distributor as product
- PROHIBITS the shipping of waste-like items, such as unused IVs, partial vials

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Federal Waste Generation Status

- Large Quantity Generator (LQG): generates more than 1000 kg/month of hazardous waste or >1 kg/month "P" listed waste.
- Small Quantity Generator (SQG): Generates <1000 kg/month but >100 kg/month of hazardous waste & < or = 1 kg/month "P" listed waste.
- Conditionally Exempt Small Quantity Generator (CESQG): Generates < or = 100 kg haz waste/month, < or = 1kg P listed waste/month

Bottom Line? Know your status.

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P-Listed Pharmaceutical Waste

- Arsenic trioxide* P012
- Epinephrine P042
- Nicotine P075
- Nitroglycerin P081
- Phentermine (CIV) P046
- Physostigmine P204
- Physostigmine Salicylate P188
- Warfarin >0.3% P001

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P-Listed Pharmaceutical Waste



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U-Listed Pharmaceutical Waste

- Chloral Hydrate(CIV) U034
- Streptozotocin* U206
- Chlorambucil* U035
- Lindane U129
- Cyclophosphamide* U058
- Saccharin U202
- Daunomycin* U059
- Selenium Sulfide U205
- Melphalan* U150
- Uracil Mustard* U237
- Mitomycin C* U010
- Warfarin <0.3% U248

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U-Listed Pharmaceutical Waste



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Chemotherapy Waste

- Seven chemotherapy agents are U-listed; one is P-listed
- Medical waste hauler protocols for “Chemo Waste”
 - ✓ Empty vials, syringes, IV’s
 - ✓ Treated as infectious medical waste preferably through regulated medical waste incineration
- If not empty, should be placed into Hazardous Waste container
- “Empty” for U-listed waste means all contents removed that can be removed through normal means
 - ✓ 3 ml allowance in common practice is a misunderstanding of the definition of “RCRA empty”

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Chemotherapy Residue: Infectious and Hazardous

- If chemo IV bag has been hung, is not completely used and can be separated from patient exposed sharp without exposing the employee, remove and dispose as RCRA hazardous waste
- If chemo residue cannot be removed safely, dispose in trace chemotherapy container (yellow/white) as infectious chemo waste
- No consensus yet on this issue among hazardous waste regulators



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Chemotherapy Residue: Infectious and Hazardous

Chemo Waste



Empty vials,
 syringes, IVs,
 tubing, gowns,
 gloves, etc.

Hazardous Waste

Residue or bulk chemo in vials,
 unused IV's, P, U, toxic D



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Characteristic of Ignitability

- Aqueous Solution containing 24% alcohol or more by volume & flash point < 140° F.
- Hazardous Waste Number: D001
- Rubbing Alcohol
- Topical Preparation
- Injections



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Characteristic of Corrosivity

- An aqueous solution having a pH < or = 2 or > or = to 12.5
- Examples: Primarily compounding chemicals
 - ✓ Glacial Acetic Acid
 - ✓ Sodium Hydroxide
- Hazardous waste number: D002

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Characteristic of Toxicity

- Approximately 40 chemicals which meet specific leaching concentrations
- Examples of potential toxic pharmaceuticals:

✓ Arsenic	✓ m-Cresol
✓ Barium	✓ Mercury (thimerosal)
✓ Cadmium	✓ Selenium
✓ Chloroform	✓ Silver
✓ Chromium	
✓ Lindane	

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Examples of Pharmaceuticals Exhibiting the Characteristic of Toxicity

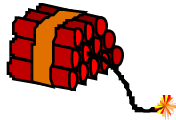


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Characteristic of Reactivity

- Meet eight separate criteria identifying certain explosive and water reactive wastes
- Nitroglycerin formulations may be considered exempt as of August 14, 2001 under FR: May 16, 2001. States must still adopt.
- Hazardous Waste Number : D003



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How Can a RCRA Hazardous Waste Be Identified?

- Web-based database enabling search by product for waste management recommendations
- Search by NDC, product or generic name, active ingredient
 - ✓ Recommendations citing federal regulations and recommended waste streams
 - ✓ State regulation alerts if more stringent than federal
 - ✓ Risk Management alerts based on professional knowledge (e.g. chemotherapy agents not regulated at the state or federal level)

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Where Should a RCRA Hazardous Waste Be Stored?

- Hazardous Waste Storage Accumulation Site:
 - ✓ Same locked area as mercury, xylene, formaldehyde, lab chemicals
 - ✓ Maximum storage time: 90 or 180 days based on generator status



RCRA Hazardous Wastes Must Be Properly Labeled!

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How Should a RCRA Hazardous Waste Be Disposed?

- Either contract with a hazardous waste broker or develop internal expertise for:
 - ✓ Lab packing
 - ✓ Manifest preparation
 - ✓ Land ban preparation
- Contract with a federally permitted RCRA hazardous waste incineration facility (TSDF: Treatment, Storage & Disposal Facility)

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What About Non-Hazardous Drugs?

- Segregate into a non-red, non-yellow container, such as beige or white with blue top (California Pharmaceutical Waste)
- Label "Non-hazardous Pharmaceutical Waste - Incinerate Only"
- Dispose at a regulated medical waste or municipal incinerator that is permitted to accept non-hazardous pharmaceutical waste



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Benefits of a Comprehensive Hazardous Waste Disposal Plan

- JCAHO Environment of Care Performance Improvement Initiative
 - ✓ New 2004 Standards - see both Medication Management and Environment of Care
- Reduces EPA liability and risk exposure to a minimum
- Protects employees and patients
- Demonstrates responsible care in dealing with hazardous substances, hazardous wastes

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What About Household Pharms?

- Non-controlled substances
 - ✓ Take to a household hazardous waste roundup
- Controlled substances
 - ✓ Mix with undesirable trash and put out with regular trash
- **NO DRUGS DOWN THE DRAIN**



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Resources

- www.pharmecology.com
- Pharmaceutical Waste: <http://www.h2e-online.org/tools/chem-pharm.htm>
- "Safely Managing Hazardous Materials and Hazardous Waste," ASHP Clinical Midyear, 2001, Handouts on CD-Rom
- RCRA On-Line www.epa.gov/rcraonline
- RCRA Hot Line 1-800-424-9346
- Improper Discard of Toxic Drugs Hurts Environment, Leads to Fines, AJHP, Vol 58, #17 September 1, 2001 pp 1576-1578.

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Resources

- Pharmaceutical Waste Survey, King County, Washington State, April 29, 2003, <http://www.metrokc.gov/hazwaste/pubs/studies.html#pharmwastesurvey>
- Your Risks in Handling Outdated and Unusable Drugs: A Guide to JCAHO and Regulatory Standards. Capital Returns, Inc., 1998 Call 1-800-950-5479
- A Guide on Hazardous Waste Management for Florida's Pharmacies, www.floridacenter.org.
- Guidelines for Reverse Distributors: Minimum Federal Regulatory Standards, www.returnsindustry.com

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Key Issues to Cover Today

- Concerns about Pharmaceuticals in the Environment?
 - ✓ US Geological Survey Study
 - ✓ Health Impacts
- Current EPA RCRA Requirements
 - ✓ P and U Listed, Other RCRA Haz. Waste Characteristics and Non-Hazardous Waste
- Waste Planning, JCAHO and Resources