Why is Pharmaceutical Waste a Problem?

Arleen Lim, REHS
County of San Diego
Department of Environmental Health
Hazardous Materials Division
Review conducted to evaluate the U.S. EPA’s process to identify and appropriately classify pharmaceuticals as hazardous waste and to ensure their safe disposal.

“general lack of awareness by the health care industry of RCRA regulatory requirements.”

http://www.epa.gov/oig/reports/2012/20120525-12-P-0508.pdf
Why is Pharmaceutical Waste a Problem?

Defining Hazardous Waste Pharmaceuticals

- **In 1980, EPA identified approximately 31 chemicals** used as pharmaceuticals that met the RCRA hazardous waste criteria but EPA has **not updated its list since that time**.

- OSHA lists 61 pharmaceuticals on its hazardous drug list which remains a primary reference for identifying drugs that should be handled as hazardous waste.

- The latest version of the NIOSH Drug Alert list published in 2010 includes 157 drugs that are considered hazardous.

- The FDA has approved an average of 30 new drugs each year since 1996 (approximately 480 new drugs).
Why is Pharmaceutical Waste a Problem?

Defining Universal Waste Pharmaceuticals

- In 2008, EPA proposed an amendment to the Universal Waste Rule to address pharmaceutical wastes.

- However, no action on the Rule has occurred since the close of the public comments period in 2009.

- EPA staff stated that “due to substantial negative public comments received on the 2008 universal waste proposal, the Agency is developing a revised proposal for regulation of hazardous waste pharmaceuticals at healthcare facilities.”

- EPA anticipates the proposal will be available for public comment in spring 2013. [http://www.epa.gov/osw/hazard/generation/pharmaceuticals.htm](http://www.epa.gov/osw/hazard/generation/pharmaceuticals.htm)
What about non-RCRA Pharmaceuticals?

- The **most commonly used** types of drugs included: asthma medicines for children, central nervous system stimulants for adolescents, antidepressants for middle-aged adults, and cholesterol lowering drugs for older Americans.

http://www.cdc.gov/nchs/data/databriefs/db42.htm#frequently
How big is the problem?

- “The United States still leads the world in pharmaceutical production, accounting for 39% of world production”\(^1\)

- “Americans consume 80% of opiate painkillers produced in the world.”\(^2\)

- 48% percent of Americans have taken at least one prescription drug in the past month\(^3\)

- In 2007-2008, 1:5 children and 9:10 older Americans reported using at least one prescription drug in the past month\(^4\)

- U.S. hospitals and long-term care facilities annually flush approximately 250 million pounds of unused pharmaceuticals down the drain\(^5\)

- U.S.G.S. conducted a study of 139 streams across the country during 1999-2000 and detected pharmaceutical compounds in 80% of the streams sampled.\(^6\)
What does that mean?

The majority of prescription medications are left to each individual state to regulate. Some states do not regulate pharmaceutical waste at all.

- **Controlled substances**: Federally regulated by DEA per the Controlled Substance Act of 1970

- **RCRA hazardous waste (5%)**: Federally regulated by EPA per the Resource Conservation and Recover Act of 1976

- **All other pharmaceutical waste**: No federal regulations
  - **California**: Regulated by CDPH per the Medical Waste Management Act
    - Non-RCRA/”California Only” pharmaceutical waste (24%)
    - Solid Waste
  - **Other States**: USEPA Where You Live - State Medical Waste Programs and Regulations: [http://www.epa.gov/osw/nonhaz/industrial/medical/programs.htm](http://www.epa.gov/osw/nonhaz/industrial/medical/programs.htm)
2010 Top Ten Most Prescribed Drugs in the U.S. per Billion

- Hydrocodone: 131.2 billion
- Generic Zocor: 94.1 billion
- Lisinopril: 87.4 billion
- Generic Synthroid: 70.5 billion
- Generic Norvasc: 57.2 billion
- Generic Prilosec: 53.4 billion
- Azithromycin: 52.6 billion
2010 Top Ten Drugs based on Waste Regulation

- Controlled Substance: DEA regulated (19%)
- All other Pharmaceuticals: State Regulated (81%)

563.6 billion prescriptions
Misunderstanding leads to mismanagement
A five month investigation by the Associated Press discovered that pharmaceuticals, including antibiotics, hormones, pain killers, and anti-seizure compounds, have been found in public drinking water supplied to over 40 million Americans across the US.

http://hosted.ap.org/specials/interactives/pharmawater_site/

- “Drugs found in drinking water” – USA Today 3/2008

  http://www.medicalnewstoday.com/articles/100038.php

  http://docs.nrdc.org/health/files/hea_10012001a.pdf
Aquatic species are the most susceptible organisms for toxicity effects. They are highly sensitive to the slightest environmental variance. As such they are key indicators for determining the health of an environment.

“evidence of feminization of fish caused from exposure to birth control and hormone replacement therapies.”

“drugged minnows appeared lethargic and took twice as long to react to stimulus, making them much more vulnerable to predators” (Raloff, 2008)

“United Kingdom has found that pharmaceutical waste runoff of antidepressant drugs like Prozac, causes shrimp and other crustaceans five times more likely to swim toward the light and ultimate demise.” (Benson, 2012)
Pharmaceutical Waste Environmental Impact

Global Pharmaceutical Waste Research

PubMed Search for “Pharmaceutical Waste” results in over 1,000 journal articles published in the last 5 years

- Environmental contamination with hazardous drugs in Quebec hospitals (Bussières, 2012)
- Quantitative study of controlled substance bedside wasting, disposal and evaluation of potential ecologic effects (Mankes, 2012)
- The effect of aeration on the removal of wastewater-derived pharmaceutical residues from groundwater (Burke, 2012)
- Evaluation of i.v. medication waste (Kerr, 2012)
- Soil persistence and fate of carbamazepine, lincomycin, caffeine, and ibuprofen from wastewater reuse (Williams, 2012)
- Chemical healthcare waste management in small Brazilian municipalities (Ferreira, 2012)
- Tracing pharmaceuticals in a municipal plant for integrated wastewater and organic solid waste treatment (Jalic, 2012)
Down Stream Effects

- **Local Impact**: A study of the Tijuana Estuary has shown the presence of antibiotic resistant bacteria caused by “natural” selection from storm water runoff (Cummings, 2008).

- **State Impact**: Drugs have been detected in the drinking water supplies of 24 major metropolitan areas including southern California (AP, 2008)

- **National Impact**: The U.S. Geological Survey (USGS) showed pharmaceutical contamination in national waterways (Barnes et al., 2008).

- **International Impact**: Pharmaceutical contaminants can also make their way into our oceans and food sources as illustrated by antidepressant detection in fish (Raloff, 2008; Bai, 2008).
Antibiotic Resistance

Selective Pressure

- Private Residences
- Long Term Care Facilities
- Hospitals and Clinics
- Drug Research and Production
- Farm and Aquaculture Industry
- Food Industry
- Sewage and Waste Water Treatment

Antibiotic Resistant Superbug
Antibiotic Resistance

Global Environmental Pollution Research

- Urban wastewater treatment plants as hotspots for the release of antibiotics in the environment (Rizzo, 2012)

- Molecular diversity of antibiotic-resistant gram-negative bacteria found in wastewater environments in China (Xia, 2012)

- Pathogenic Escherichia coli Strains in the Yeongsan River Basin of South Korea (Jang, 2012)

- Heavy metal driven co-selection of antibiotic resistance in soil and water bodies impacted by agriculture and aquaculture (Seiler, 2012)

- Phenotypic antibiotic resistance of Escherichia coli and E. coli O157 isolated from water, sediment and biofilms in an agricultural watershed in British Columbia (Maal-Bared, 2012)
Antibiotic Resistance

Environmental Selection

- “findings indicate that several conventional wastewater management practices are not effective in the complete removal of antibiotics, and their discharges have a large potential to affect the aquatic environment.” (Batt, 2006)

- “If (antibiotic resistance) genes were not present in the pathogenic bacteria, they must have originated in the environmental bacteria” (Alonso, 2001)

- In effect, the antibiotics that are not able to be removed from wastewater treatment is artificially selecting the environmental organisms that already posses the resistance gene to survive exposure, there by increasing the their prevalence in nature and human exposure.
Hope for the future?

Resource for health care facilities

- [http://practicegreenhealth.org/](http://practicegreenhealth.org/)

---

**Pharmaceutical Waste**

- Background
- Pharmaceutical Management Basics
- Pharmaceutical Management Team
- Formulary Review
- Management Approaches
- Hazardous Pharmaceuticals
- Common P-Listed Pharmaceuticals
- Common U-Listed Pharmaceuticals
- Selected chemotherapy agents by brand name
Hope for the future?
Recent Legislation - CA

- **California AB 1442**: Pharmaceutical Waste
  - Officially defines “pharmaceutical waste” for the purposes of the Medical Waste Management Act
  - Does not include pharmaceuticals sent to a reverse distributor
  - Chaptered 9/28/12

- **California SB 1329**: Prescription Drugs: Collection and Distribution Program (home generated)
  - Authorizes county board of supervisors or public health officer to establish a repository and distribution program for persons in need of financial assistance to be managed by local health
  - Chaptered 9/28/12
  - Not yet established in San Diego County
Hope for the future?

Recent Legislation - Federal

- **Federal SB 3397**: Secure Drug Disposal Act of 2010 (home generated): a patient may now deliver unused portions of a controlled substance to an authorized entity for destruction in accordance with regulations without a DEA
  - Enacted on 10/12/10

- **Federal HR 1677**: Drug Free Water Act of 2011: Requires EPA to convene a task force to develop recommendations on Pharmaceutical Waste disposal and public education strategy
  - Introduced 5/2/11; not enacted

- **Federal HR 2546**: Medical Waste Management Act of 2011: Amends the Solid Waste Disposal Act to revise the definition of "medical waste"
  - Very similar to CA Medical Waste Management Act
  - Introduced 7/11/11: not enacted
Hope for the future?

Increase public awareness

- **WA HR 1370:** Requires pharmaceutical companies to dispose of pharmaceutical waste delivered to drop off locations.
  - Introduced 1/19/11

- **Sharps Compliance Safe Medication Disposal Program:** Customers can buy Safe Medication Disposal Program envelopes at any Walgreens for $3.99, and postage is included in the cost of the envelope.
  - [http://youtu.be/7-XZ7Wgs_08](http://youtu.be/7-XZ7Wgs_08)
“Collection and analysis should not be allowed to consume resources if action does not follow it”

(Foege, 1976, p.29)