



## Why is Pharmaceutical Waste a Problem?



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# + EPA Report on Hazardous Waste Pharmaceuticals

May 25, 2012



U.S. Environmental Protection Agency  
Office of Inspector General

12-P-0508  
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## At a Glance



### Why We Did This Review

We conducted this review to evaluate the U.S. Environmental Protection Agency's (EPA's) process to identify and appropriately classify pharmaceuticals as hazardous waste and to ensure their safe disposal.

### Background

The discovery of a variety of pharmaceuticals in water has raised concerns about potentially adverse environmental consequences of these contaminants. Studies have suggested the detection of pharmaceutical compounds in treated wastewater effluent, streams, lakes, seawater, drinking water, and groundwater, as well as in sediments and fish tissue. EPA has the authority under the Resource Conservation and Recovery Act (RCRA) to regulate hazardous waste pharmaceuticals (HWP) to ensure safe management and disposal practices.

For further information, contact our Office of Congressional and Public Affairs at (202) 566-2391.

The full report is at:  
[www.epa.gov/oig/reports/2012/20120525-12-P-0508.pdf](http://www.epa.gov/oig/reports/2012/20120525-12-P-0508.pdf)

### ***EPA Inaction in Identifying Hazardous Waste Pharmaceuticals May Result in Unsafe Disposal***

#### **What We Found**

Since 1980, EPA has not used its RCRA authority to determine whether pharmaceuticals may qualify as hazardous waste. EPA also has not established a process for the regular identification and review of pharmaceuticals that may qualify for regulation as hazardous waste. Without a regular process, EPA cannot provide assurance that pharmaceuticals that may pose a hazardous risk to human health and the environment have been identified. We identified eight chemicals found in pharmaceuticals that meet EPA's criteria for regulation as acute hazardous waste, but wastes containing these chemicals are not regulated as such. There are over 100 drugs that federal occupational safety organizations have identified as hazardous but may not have been reviewed by EPA to determine whether they may qualify as hazardous waste. EPA staff stated they have started examining these drugs for listing as hazardous waste. Further, the state of Minnesota recently noted that there has been a proliferation of pharmaceutical development since RCRA regulations were established. Our review has identified a risk that there are unknown but potentially dangerous unregulated HWP that may be unsafely disposed and released into the environment.

An additional challenge to ensuring the safe disposal of HWP is that some health care facilities, such as hospitals, may be unaware of federal hazardous waste regulations. The state of Minnesota, for example, has reported that there is a "general lack of awareness by the health care industry of RCRA regulatory requirements." This may result in mismanagement of hazardous 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. During our review, EPA staff informed us that the Agency has decided to develop another proposal for the regulation of hazardous waste pharmaceuticals at health care facilities. 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.

#### **What We Recommend**

We recommend that EPA establish a process to review pharmaceuticals for regulation as hazardous waste and develop an outreach and compliance assistance plan for health care facilities managing HWP.

- 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



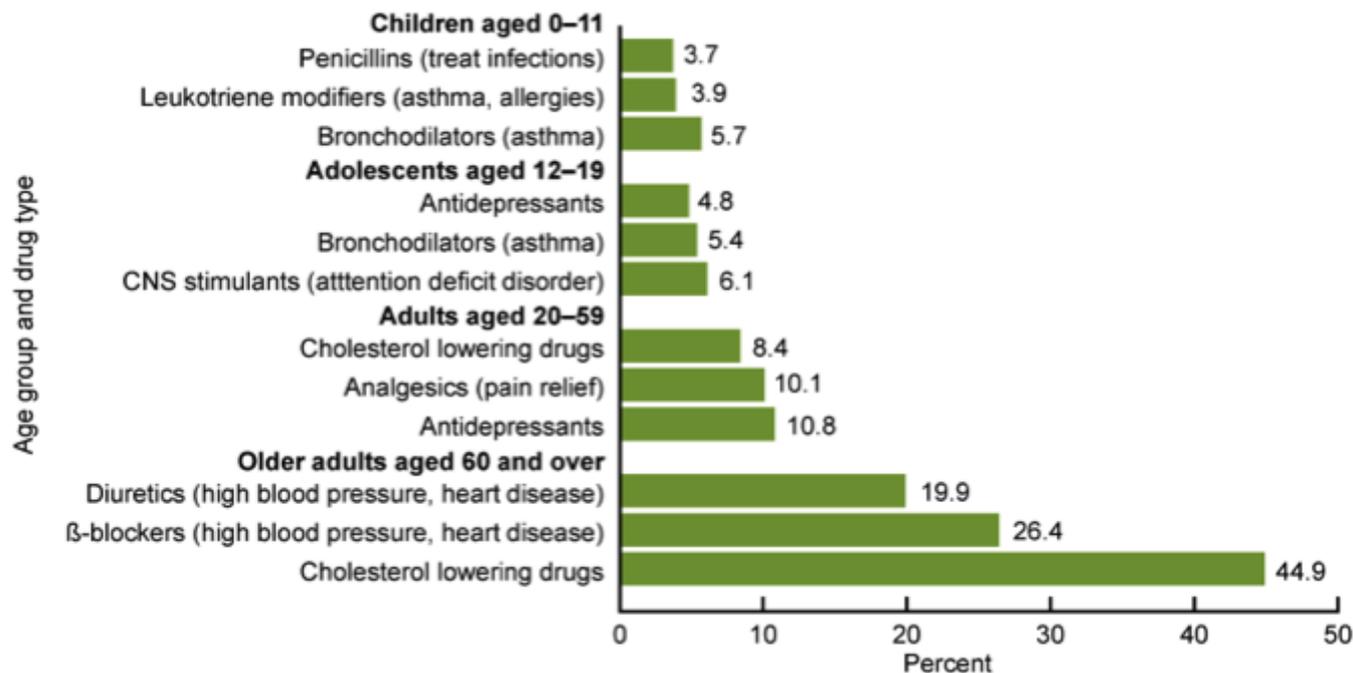
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<http://www.epa.gov/osw/hazard/generation/pharmaceuticals.htm>

# + 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.



# + How big is the problem?



- “The **United States still leads the world** in pharmaceutical production, accounting for 39% of world production”<sup>1</sup>
- “**Americans consume 80%** of opiate painkillers produced in the world.”<sup>2</sup>
- **48% percent of Americans** have taken at least one prescription drug in the past month<sup>3</sup>
- In 2007-2008, **1:5 children** and **9:10 older Americans** reported using at least one prescription drug in the past month<sup>4</sup>
- U.S. hospitals and long-term care facilities annually flush approximately **250 million pounds** of unused pharmaceuticals down the drain<sup>5</sup>
- 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.<sup>6</sup>

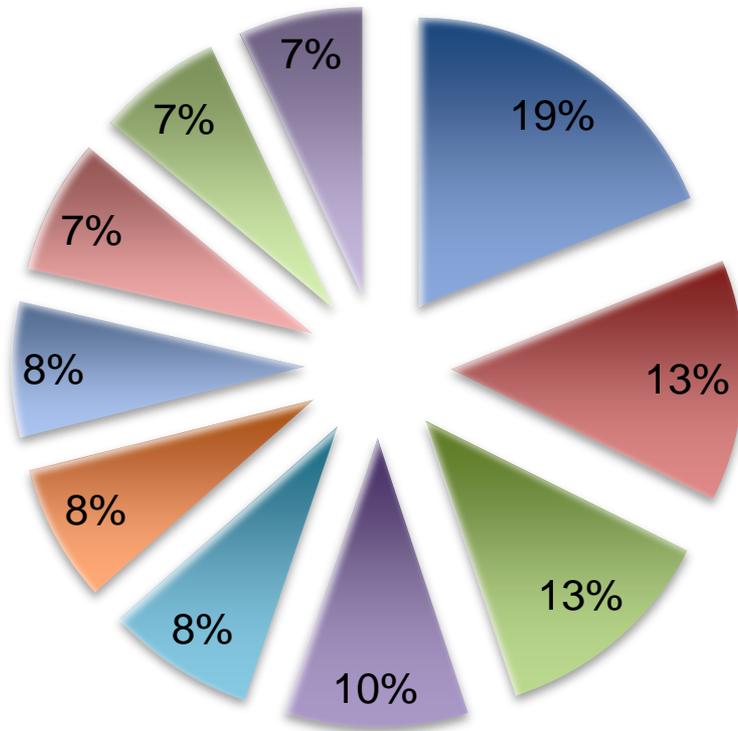
# + What does that mean?



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

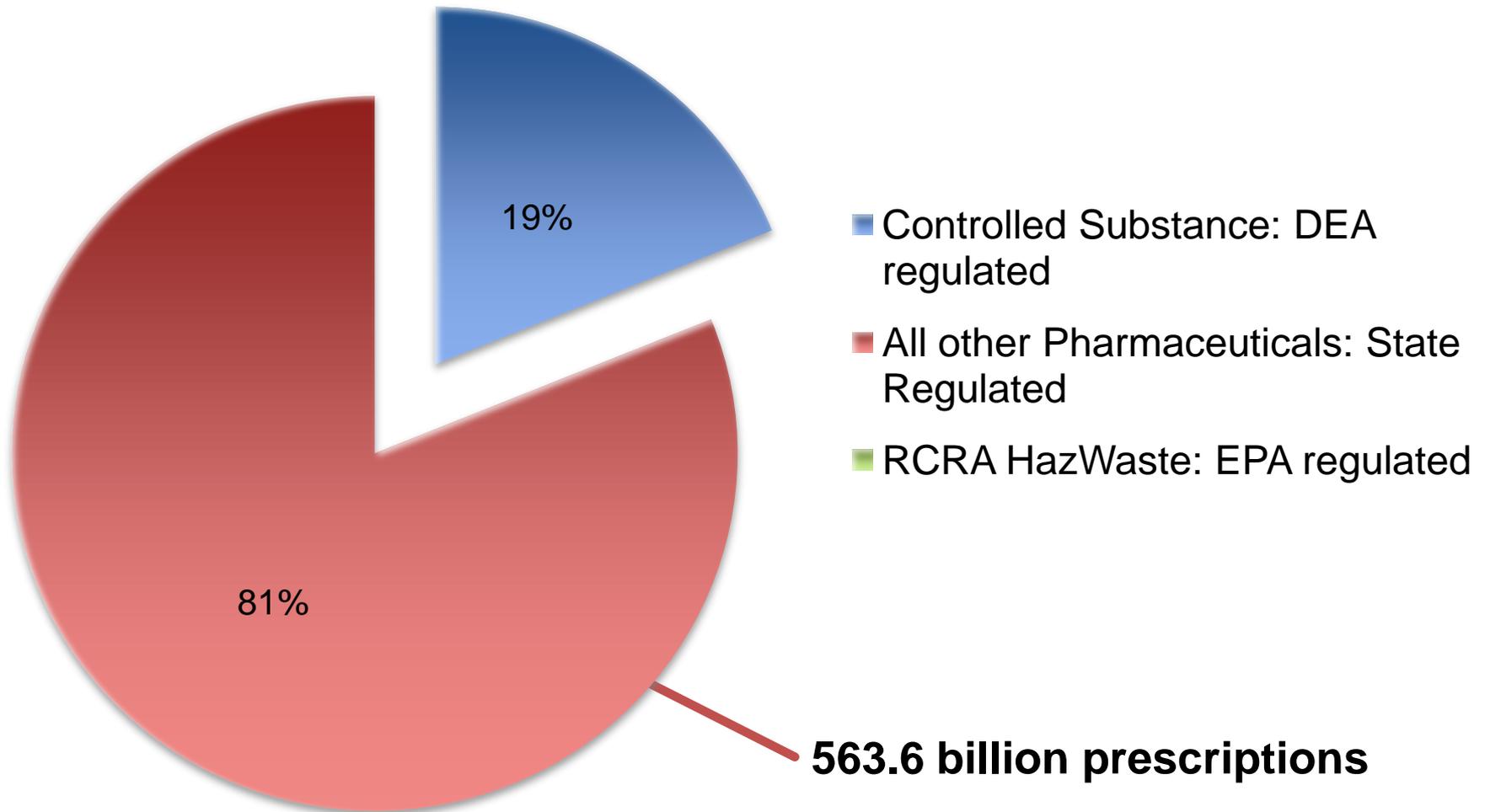
- **Controlled substances:** Federally regulated by DEA per the Controlled Substance Act of 1970
- **RCRA hazardous waste (5%):** Federally regulated by EPA per the Resource Conservation and Recover Act of 1976
- **All other pharmaceutical waste:** No federal regulations
  - **California:** Regulated 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>

# + 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 base on Waste Regulation



+ Misunderstanding leads to mismanagement



# + 2008 Associated Press Investigation



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/](http://hosted.ap.org/specials/interactives/pharmawater_site/)

- “Drugs found in drinking water” – USA Today 3/2008 [http://usatoday30.usatoday.com/news/nation/2008-03-10-drugs-tap-water\\_N.htm](http://usatoday30.usatoday.com/news/nation/2008-03-10-drugs-tap-water_N.htm)
- “Drugs in U.S. Drinking Water” – Medical News Today 3/2008 <http://www.medicalnewstoday.com/articles/100038.php>
- “Dosed without prescription” – National Resource Defense Council 12/2009 [http://docs.nrdc.org/health/files/hea\\_10012001a.pdf](http://docs.nrdc.org/health/files/hea_10012001a.pdf)



# “Prozac Ocean”

- Bai, 2008



- 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 (Bussi eres, 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

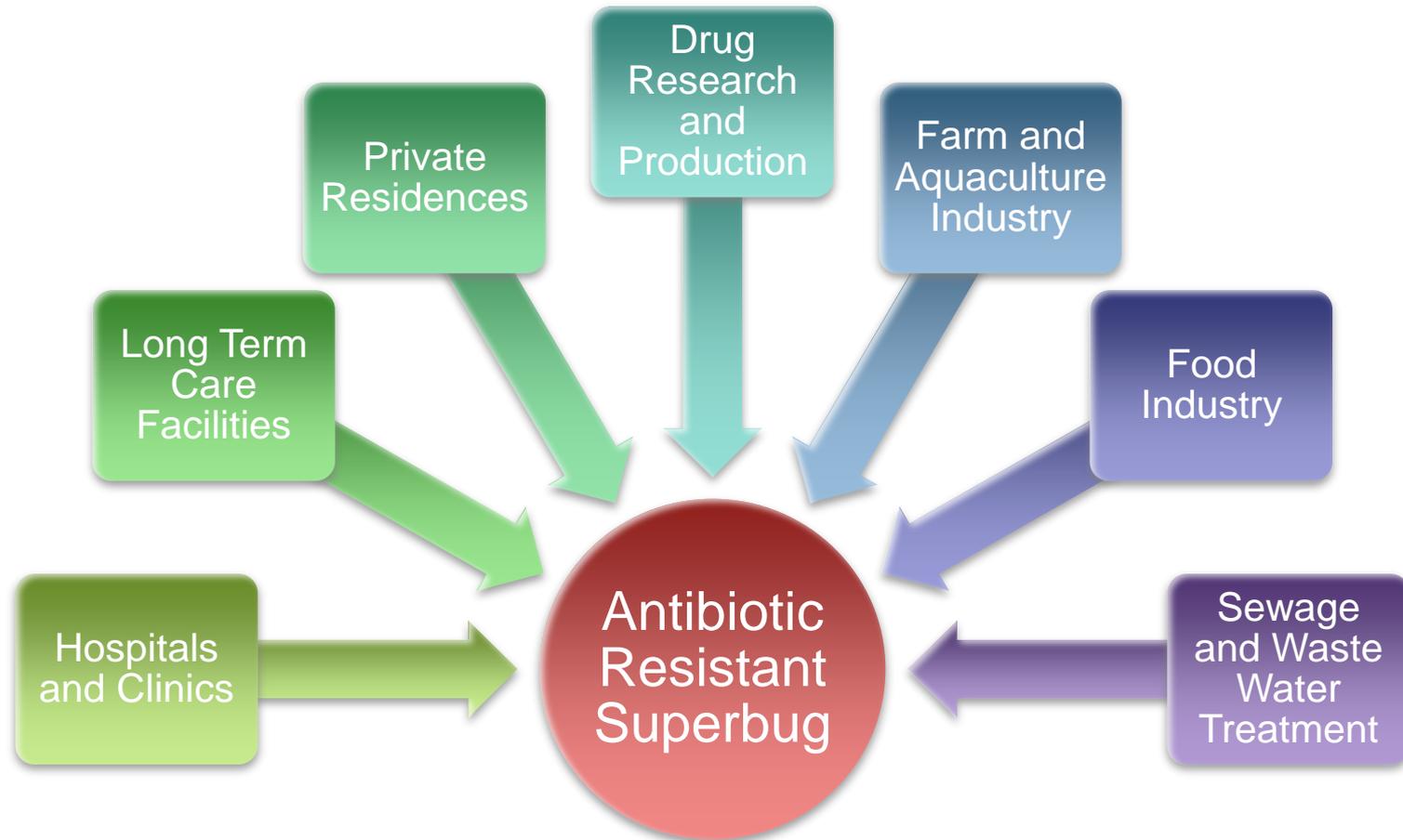


- **Local Impact:** A study of the Tijuana Estuary has shown the presence of antibiotic resistant bacteria caused by “natural” selection from storm water runoff (Cummings, 2008).
- **State Impact:** Drugs have been detected in the drinking water supplies of 24 major metropolitan areas including southern California (AP, 2008)
- **National Impact:** The U.S. Geological Survey (USGS) showed pharmaceutical contamination in national waterways (Barnes et al., 2008).
- **International Impact:** Pharmaceutical contaminates 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





# 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 possess the resistance gene to survive exposure, thereby increasing their prevalence in nature and human exposure.



# Hope for the future?

Resource for health care facilities



- <http://practicegreenhealth.org/>

The screenshot shows the Practice Greenhealth website. At the top, there is a navigation bar with links for Home, About, Membership, Topics, Tools & Resources, Greenhealth Academy, Awards, and Initiatives. Below the navigation bar is a search bar and a 'Submit' button. The main content area features a green header with the text 'Home » Topics » Waste » Waste Categories & Types » Pharmaceutical Waste'. The main heading is 'Pharmaceutical Waste'. A list of links is provided, including Background, Pharmaceutical Management Basics, Pharmaceutical Management Team, Formulary Review, Management Approaches, Hazardous Pharmaceuticals, Common P-Listed Pharmaceuticals, Common U-Listed Pharmaceuticals, and Selected chemotherapy agents by brand name. On the right side, there is a 'Topics' sidebar with a list of categories: Leadership & Infrastructure, Waste, Waste Categories & Types, Solid Waste, Regulated Medical Waste, Hazardous Waste, Pharmaceutical Waste, Universal Waste, and Beneficial Reuse & Donation. The 'Pharmaceutical Waste' category is highlighted in orange.

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Members: Log In Here

Home » Topics » Waste » Waste Categories & Types » Pharmaceutical Waste

## 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](#)

### Topics

- [Leadership & Infrastructure](#)
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- [Solid Waste](#)
- [Regulated Medical Waste](#)
- [Hazardous Waste](#)
- [Pharmaceutical Waste](#)
- [Universal Waste](#)
- [Beneficial Reuse & Donation](#)



# 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
  - YouTube PSA: <http://youtu.be/4thDeCfBehc>
- **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)

+

## Quote for the Day:



*“Collection and analysis should not be allowed to consume resources if action does not follow it”*

(Foege, 1976, p.29)