



# The Future of Medication Disposal: Federal Policy and New Legislation

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# Disclaimer

Although this work was reviewed by EPA and approved for presentation, it may not necessarily reflect official Agency policy.





# Overview

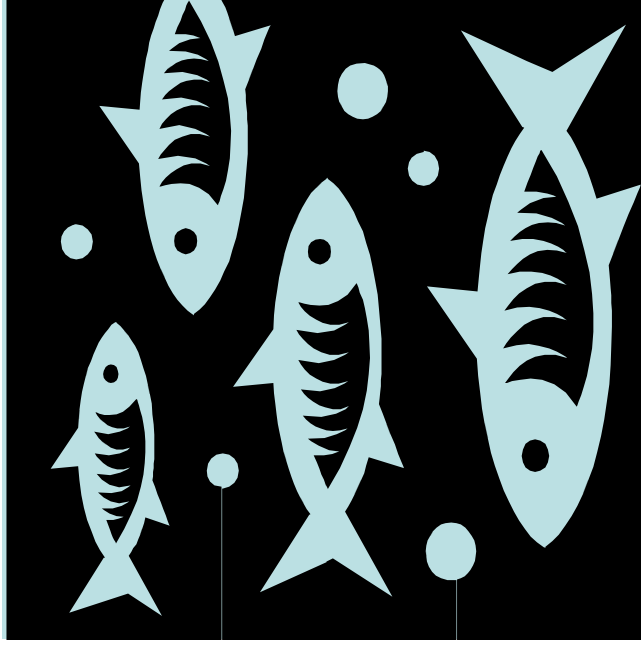
**Background and Demographics— Population and RX  
Drugs**

**Federal Legislation—Secure and Responsible Drug  
Disposal Act of 2010**

**Best Management Practices for Health Care  
Facilities  
USGS Study**

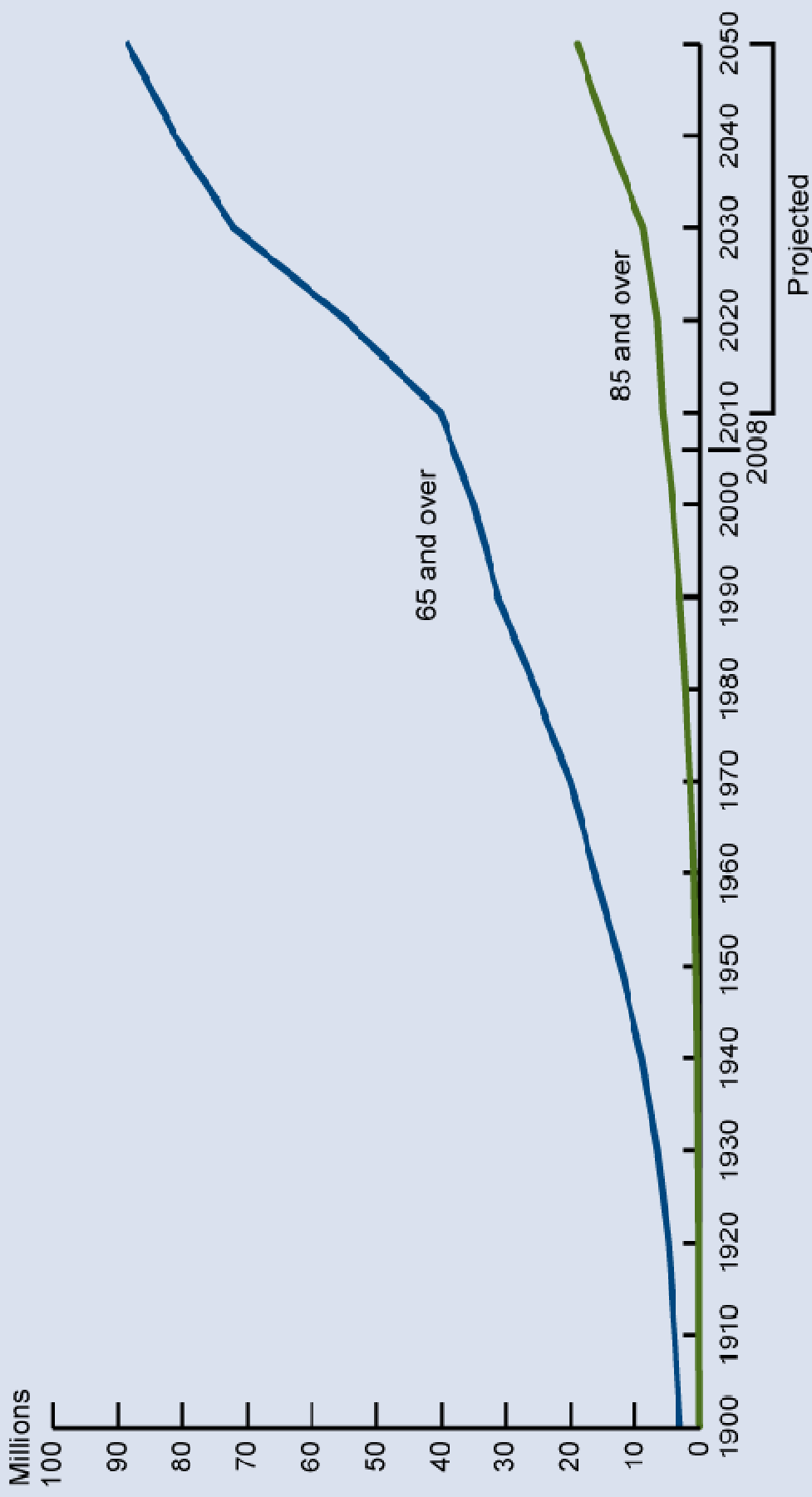
**Pollution Prevention & Product Stewardship**

# What's the Caption?



## Indicator 1 – Number of Older Americans

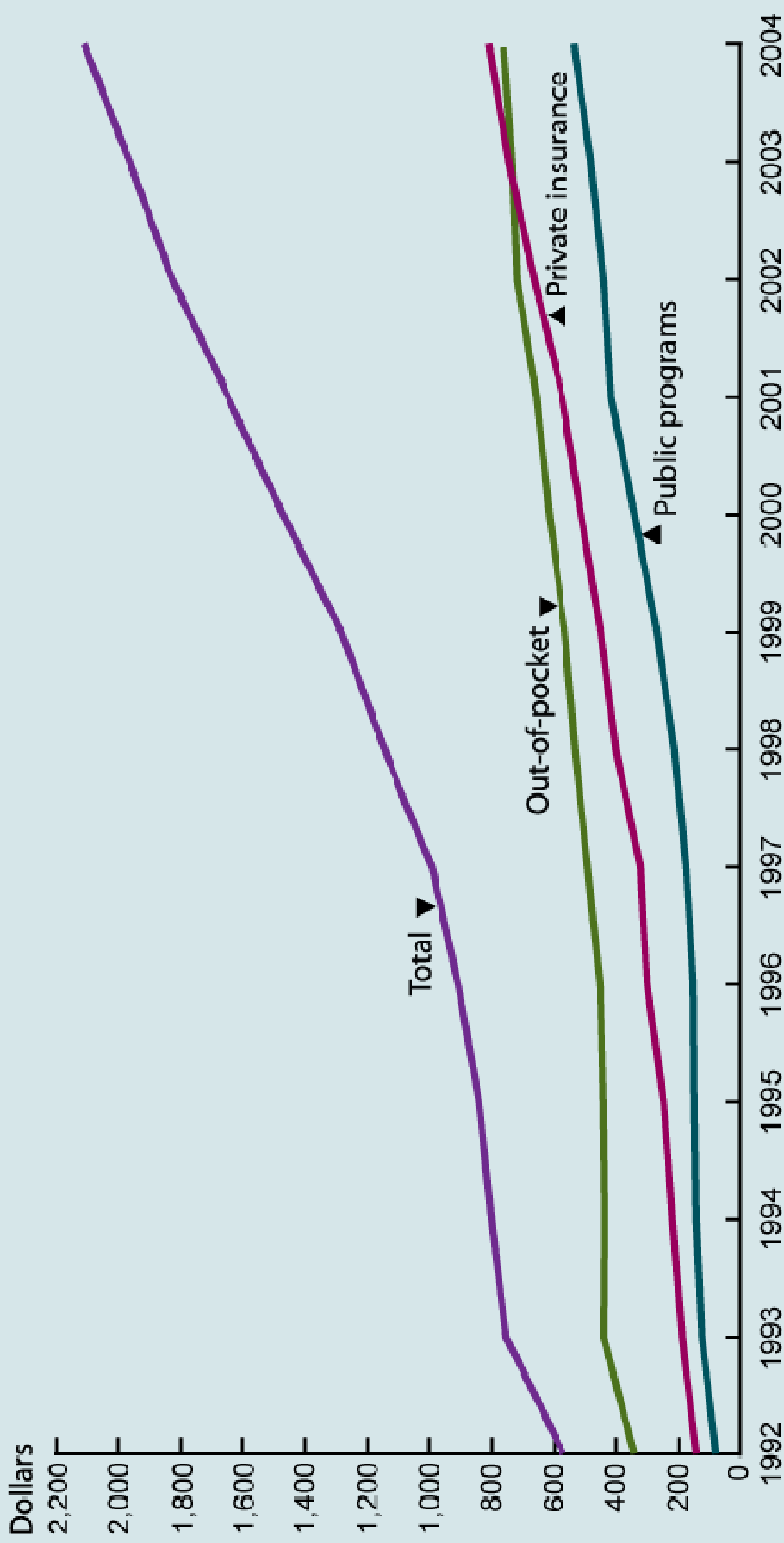
### Population age 65 and over and age 85 and over, selected years, 1900–2008 and projected 2010–2050



NOTE: Data for 2010–2050 are projections of the population.  
Reference population: These data refer to the resident population.  
SOURCE: U.S. Census Bureau, Decennial Census, Population Estimates and Projections.

## Indicator 31 – Prescription Drugs

### Average annual prescription drug costs for noninstitutionalized Medicare enrollees age 65 and over, by sources of payment, 1992–2004



NOTE: Dollars have been inflation-adjusted to 2004 using the Consumer Price Index (Research Series). Reported costs have been adjusted by a factor of 1.205 to account for underreporting of prescription drug use. Public programs include Medicare, Medicaid, Department of Veterans Affairs, and other state and federal programs. Data for 2005 and 2006 were not available in time to include in this report. Reference population: These data refer to Medicare enrollees. SOURCE: Centers for Medicare and Medicaid Services, Medicare Current Beneficiary Survey.

# Indicator 30 – Health Care Expenditures

## Major components of health care costs among Medicare enrollees age 65 and over, 1992 and 2006



NOTE: Data include both out-of-pocket costs and costs covered by insurance. "Other" includes short-term institutions, hospice services, and dental care.  
 Reference population: These data refer to Medicare enrollees.  
 SOURCE: Centers for Medicare and Medicaid Services, Medicare Current Beneficiary Survey.

# Important Developments in Safe Disposal of Medications in the U.S.

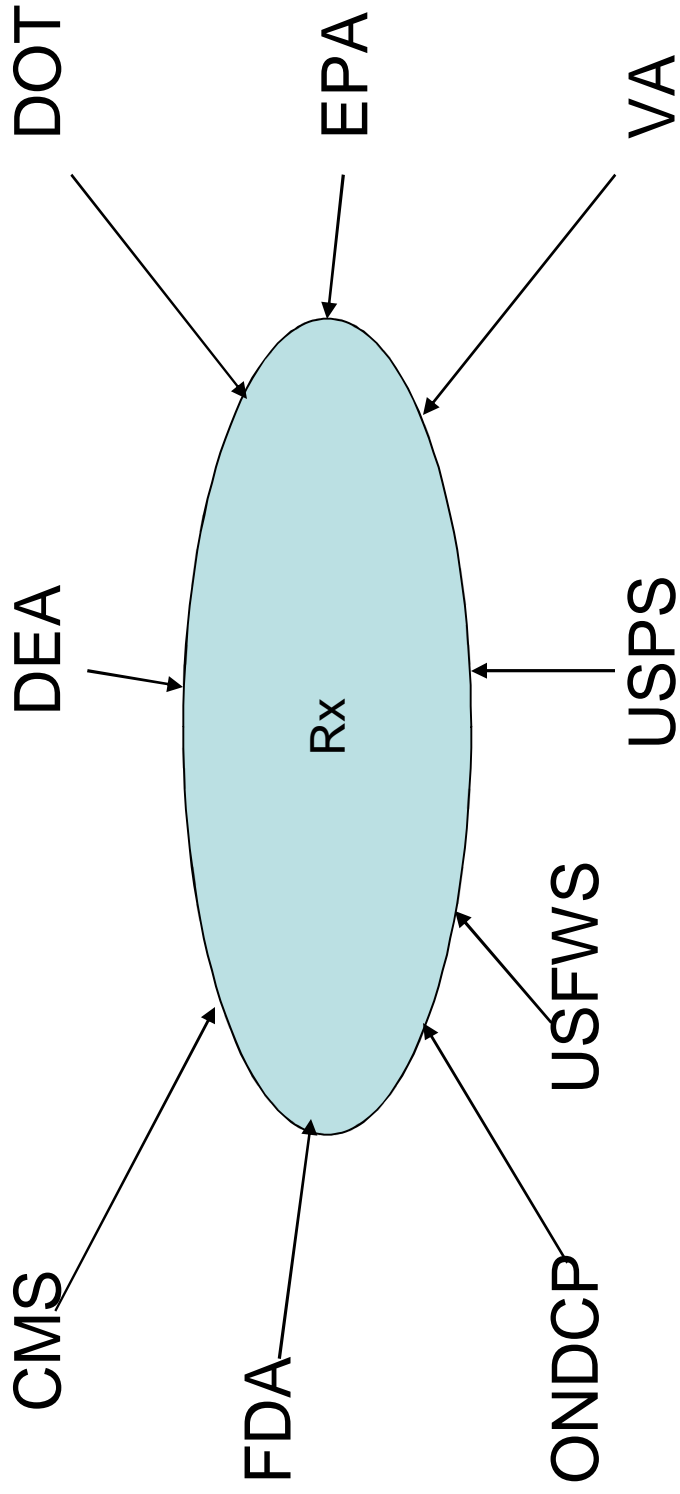
- May, 2004: Maine enacts first state bill
- February 2007: ONDCP Issues Guidance
- Oct. 2009: Revised Guidance issued
- Sept. 2009: Maine Care 15 day Rx initial limit
- Sept.2010: Federal Legislation passes



# Federal Agencies Involved with Drug Disposal

- Centers for Medicare and Medicaid
- Drug Enforcement Administration
- U.S. Department of Transportation
- Food and Drug Administration
- U.S. Environmental Protection Agency
- Office of National Drug Control Policy
- U.S. Postal Service
- U.S. Fish and Wildlife Service
- Veteran's Administration

# Federal Agencies Involved in Rx Disposal



# Local Hazardous Waste Disposal

Federal

Regional

State

Local

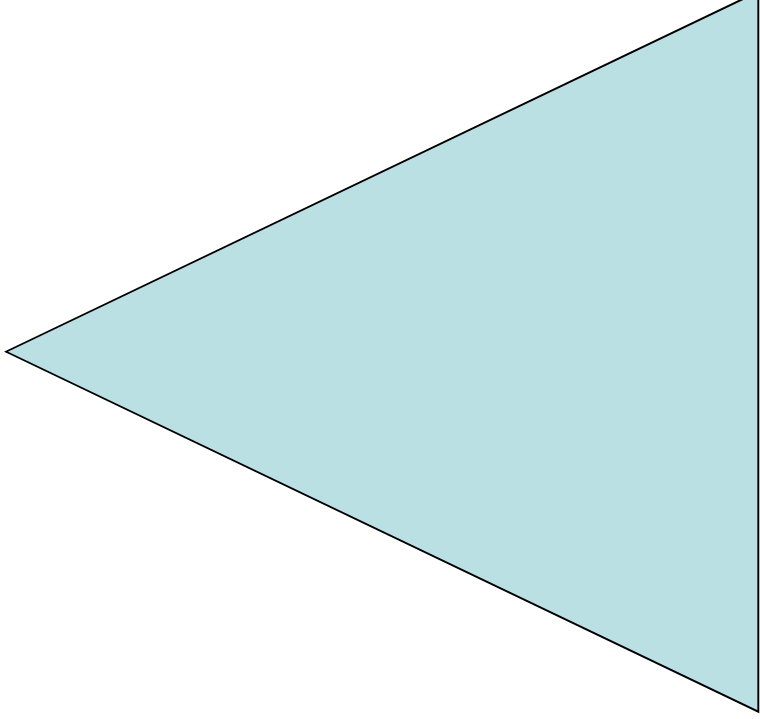
USEPA

EPA Region 1

Maine DEP

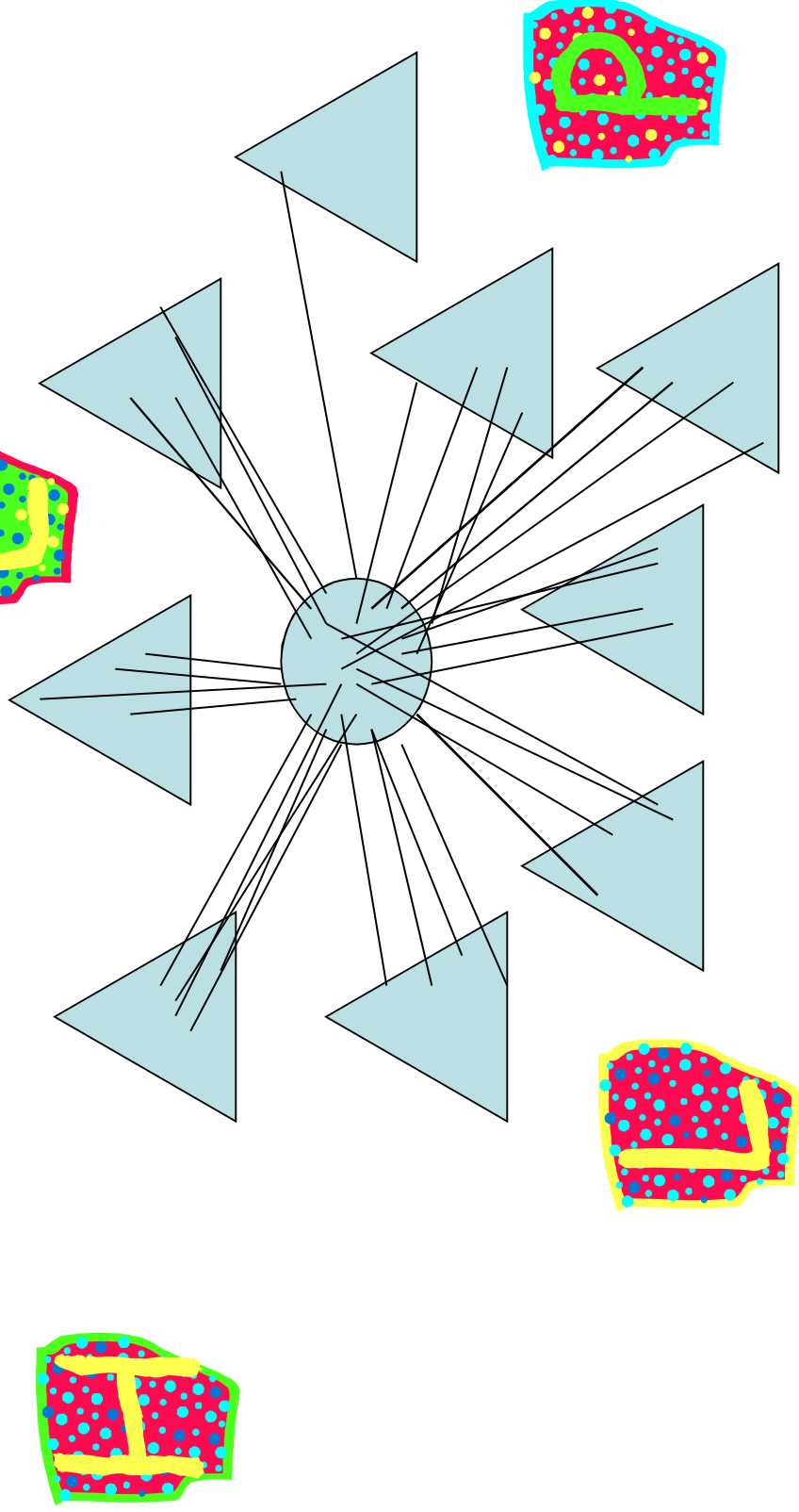
Portland

Riverside Recycling HHW



# Lines of communication

- Connect the dots...



Sponsors: Klobuchar, Cornyn,  
Grassley, Brown --S. 3397

“I introduced this legislation because I believe we have to give families a better option than either leaving dangerous medication in their homes or flushing such medication into the water supply.”

## House Sponsor: Inslee (WA)

“We now have a commonsense solution,...and we need to make sure these programs are put in place for all Rx drugs to keep these powerful substances off the streets & out of our drinking water.”

“I want to note one success of this bill. *Bart Stupak* and others have been really great leaders in designing a program that would be flexible and easy for communities to use.”

# Findings Section

- Nonmedical use of Rx drugs is a growing problem, particularly among teens.
- Take-back programs often can't dispose of the most dangerous Rx drugs

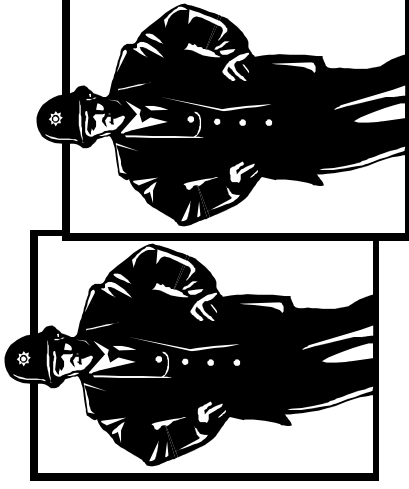
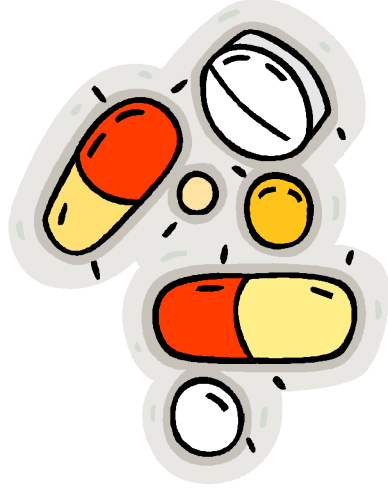
# Authority to Attorney General

- ...Promulgate new regulations
- ...Deliver unused Rx controlled substances to appropriate entities for disposal in a safe & effective manner



## Congress Passes the Secure and Responsible Drug Disposal Act of 2010

- Federal law prohibited take-back programs to accept controlled substances
  - must obtain permission from the DEA and arrange for full time law enforcement officers to receive the controlled substances directly



# Letter from Ronald Weich Assistant AG to Congressman Inslee

“As a matter of course, the Department (DOJ) would consult with the EPA on any environmental issues that may be raised by the legislation...”

# Final 2010 Effluent Guidelines Program Plan



Health Care Industry Study  
September, 2010

# Background

- Proposed 2010 ELG Plan (Dec. 28, 2009 in Federal Register (FR))
- 35 Comments--Health Care Industry Study
- Final 2010 ELG Plan: Expected publish in FR December 28, 2010

# Summary of Comments

- Health Care Industry-- Unused pharmaceuticals:
  - General support of the study;
  - EPA should continue to work with DEA on “mixed messages”;
  - EPA should work with FDA and insurance companies to encourage returns and coordinate message;
  - EPA should develop BMPs;
  - Take-back programs;
  - BMPs, disposal guidelines, flyers, waste rule, etc.;
  - Current disposal practices & barriers to return/reuse etc.;
  - Control authority and POTW control of flushing.

# Status and Results of Studies

## Health Care Industry:

- Outreach to over 700 stakeholders
- Drafted guidance document discusses source reduction, segregation, and proper disposal.
- The guidance document was reviewed by other federal agencies (FDA, CMS, DEA)
- Publish final guidance with publication of Final 2010 304m Plan.

# Draft Guidance BMP

## Best Management Practices (BMP) for Unused Rx at Health Care Facilities

- Was reviewed by federal agencies (FDA, CMS, DEA)
- Please Comment thru **November 8, 2010**.
- Publish final guidance with publication of Final 2010 304m Plan.

# Health Care Industry Study Contact

Meghan Hessenauer:  
[hessenauer.meghan@epa.gov](mailto:hessenauer.meghan@epa.gov)

Submit comments on the guidance document to  
[unusedpharms@epa.gov](mailto:unusedpharms@epa.gov)

For more information, please visit the webpage:  
<http://water.epa.gov/scitech/wastetech/guide/unuseddraft.pdf>



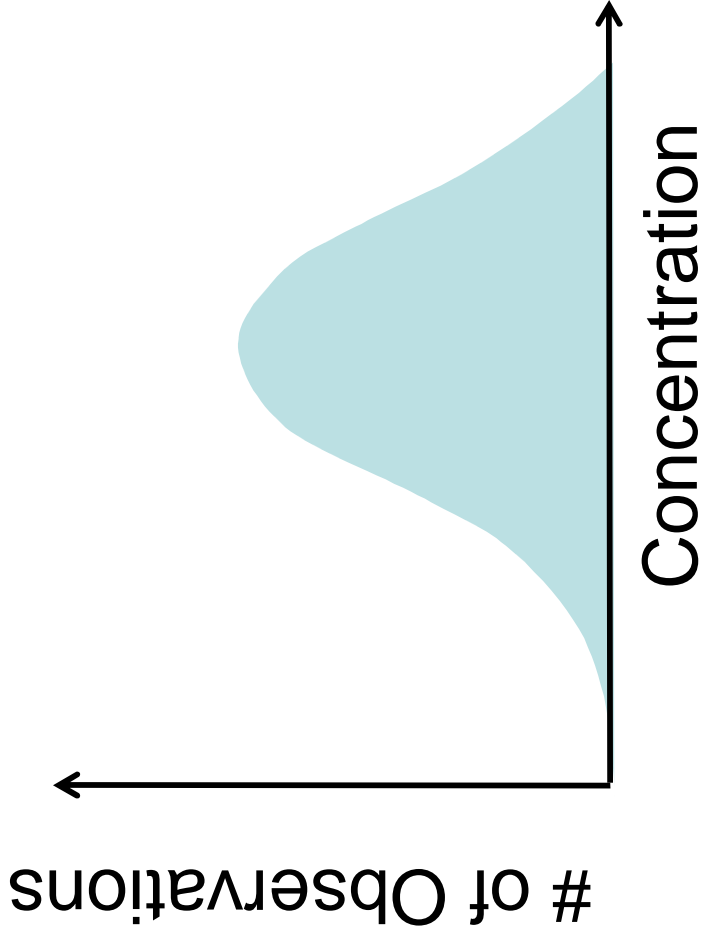
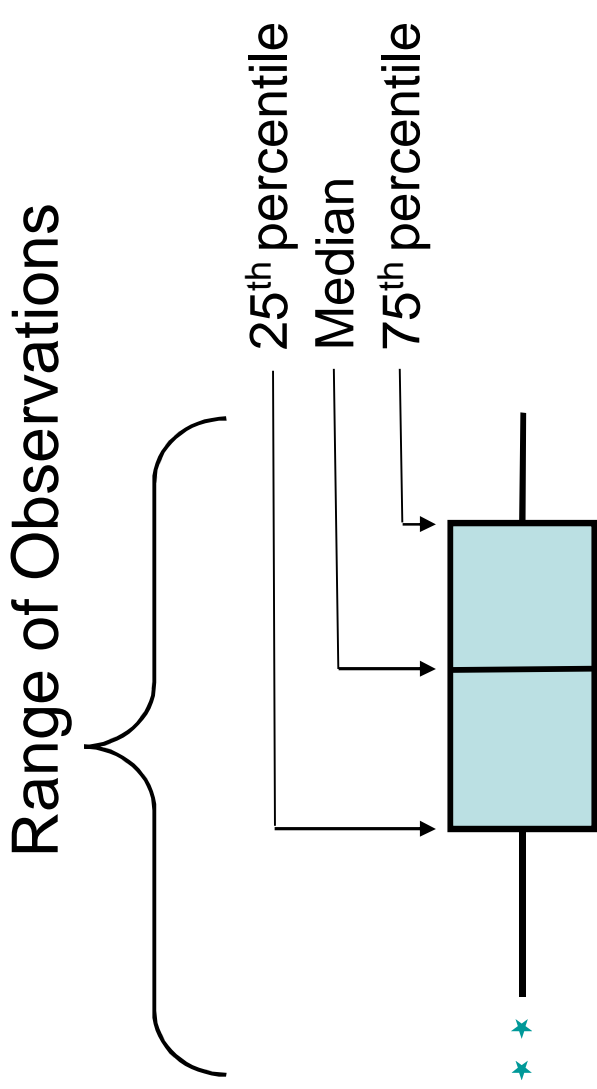
## USGS Study Conducted in Cooperation with the State of New York

- First study in the U.S. to identify pharmaceutical manufacturing facilities as a significant source of pharmaceuticals to the environment.



# The Box Plot

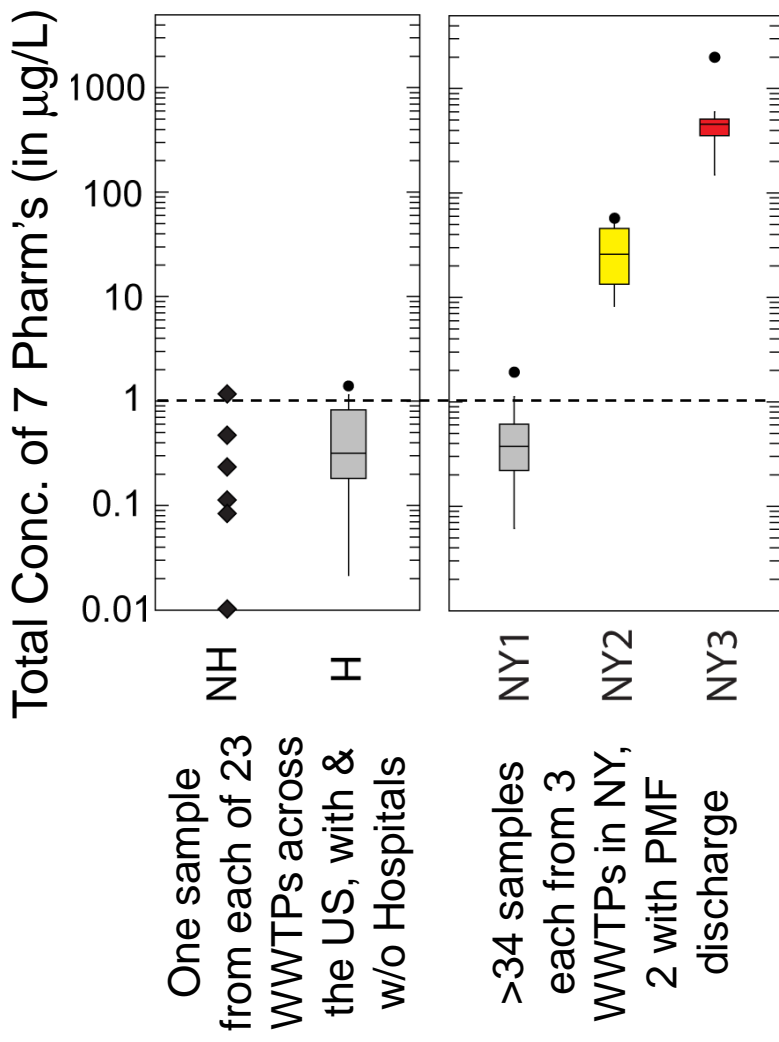
Used to compare distributions.



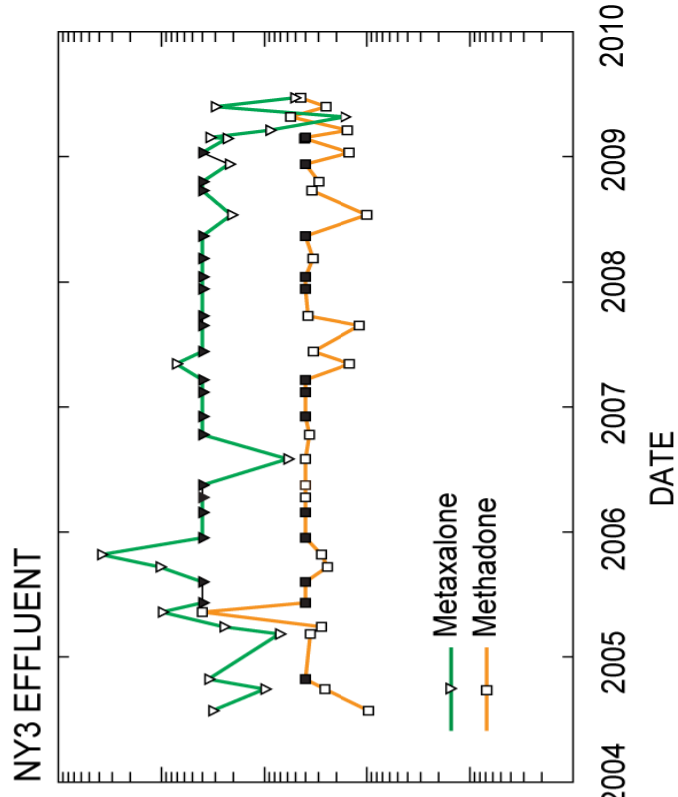
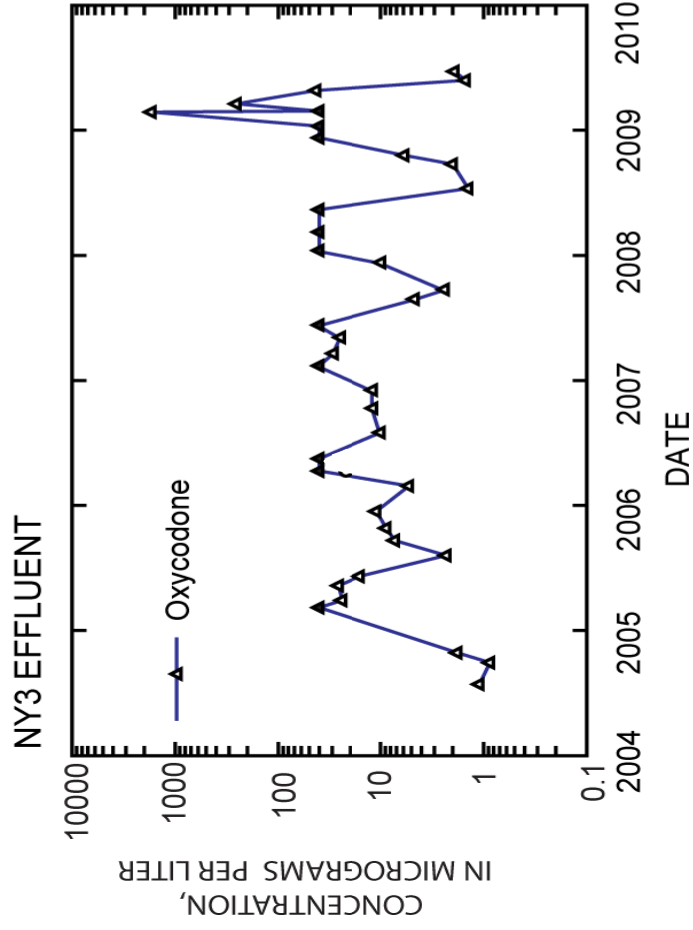
# Pharmaceutical Manufacturing Facilities as a Source of Pharmaceuticals



A Forensic analysis found 7 Opioids and Muscle Relaxants

Butalbital,  
Carisoprodol,  
Diazepam,  
Metaxalone,  
Methadone,  
Oxycodone,  
Phendimetrazine



# Concentrations thru Time at Site NY3 Oxycodone, Metaxalone, Methadone



 Concentration exceeded uppermost calibration point of 40 micrograms per Liter  


# Summary Findings

Outflow from 2 wastewater treatment plants in NY that receive more than 20% of their wastewater from Pharm. facilities had concentrations of pharmaceuticals that were 10 to 1000 times higher than outflows from 24 plants nationwide that do not receive wastewater from Pharm. manufacturers.

## Max. concentrations in outflows from these two NY wastewater treatment plants

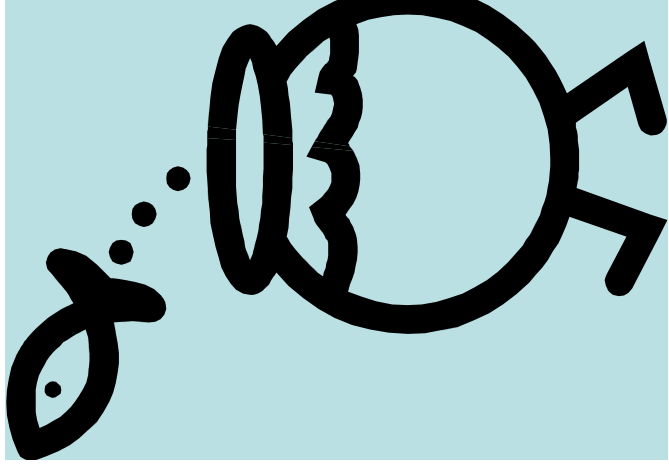
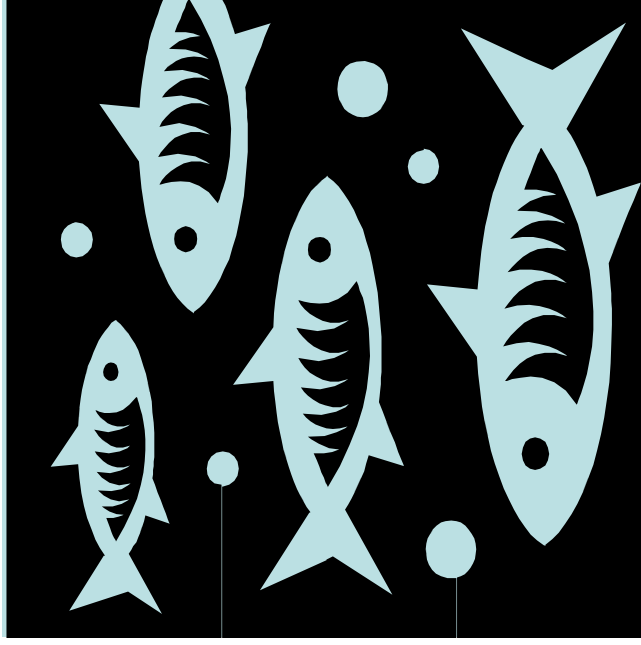
- 3,800 ppb - *metaxalone (muscle relaxant)*
- 1,700 ppb - *oxycodone (opioid for pain relief)*
- >400 ppb - *methadone (opioid for pain relief & withdrawal)*
- 160 ppb - *butalbital (a barbiturate)*
- > 40 ppb - *phendimetrazine (stimulant for obesity)*
- > 40 ppb - *carisoprodol (muscle relaxant)*
- 3.9 ppb - *diazepam (anti-anxiety) (Valium)*

## Study is part of a long-term effort

- To identify and determine the fate & effects of chemicals of emerging environmental concern.
- To provide water-resource managers with objective info to assist in development of effective water management practices.

<http://toxics.usgs.gov/highlights/PMFs.html>

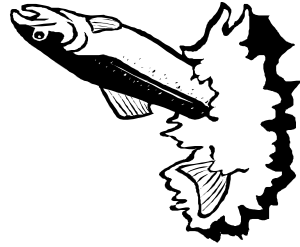
“I want what they’re having!”





# Product Stewardship-- Life Cycle

- WA House Bill 1165
  - Every producer of products must participate in a product stewardship program for unwanted products from resident sources by 2012.
  - Maine also introduced legislation to this effect
  - PharmEcovigilance, green pharmacy and product stewardship---working up stream



# Questions?

Contact Kathy Sykes  
[sykes.kathy@epa.gov](mailto:sykes.kathy@epa.gov) (202) 564-3651

EPA's Aging Website  
[www.epa.gov/aging](http://www.epa.gov/aging)

EPA's Office of Water Website  
<http://water.epa.gov/scitech/swguidance/ppcp/>

EPA's PPCP website  
<http://www.epa.gov/ppcp/>

# Appendices

S. 3397 Secure and Responsible Drug  
Disposal Act

<http://www.govtrack.us/congress/billtext/xpd?bill=s111-3397>

# Guts of the Bill S. 3397

## SEC. 3. DELIVERY OF CONTROLLED SUBSTANCES BY ULTIMATE USERS FOR DISPOSAL.

(a) *Regulatory Authority.*--Section 302 of the Controlled Substances Act (21 U.S.C. 822) is amended by adding at the end 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.

“(2) In developing regulations under this subsection, the Attorney General shall take into consideration the public health and safety, as well as the ease and cost of program implementation and participation by various communities. Such regulations may not require any entity to establish or operate a delivery or disposal program.

# CRS Summary Secure and Responsible Drug Disposal Act of 2010 -

- Amends the Controlled Substances Act to allow an ultimate user of a controlled substance (or, if deceased, any person lawfully entitled to dispose of the ultimate user's property) who has lawfully obtained such substance to deliver that substance to another person, without being registered, for disposal if: (1) the person receiving the controlled substance is authorized to engage in such activity; and (2) the disposal takes place in accordance with regulations issued by the Attorney General to prevent diversion of controlled substances.
- Requires the Attorney General, in developing regulations under this Act, to consider the public health and safety, as well as the ease and cost of program implementation and participation by various communities.
- Permits the Attorney General to authorize long-term care facilities to dispose of controlled substances on behalf of ultimate users who reside, or have resided, at such facilities in a manner that will provide effective controls against diversion and that is consistent with public health and safety.
- Directs the United States Sentencing Commission to review and, if appropriate, amend its guidelines and policy statements to ensure an appropriate penalty increase for persons convicted of a drug offense involving receipt of a controlled substance for disposal.