Pharmaceuticals and Personal Care Products in Water – OW Perspective

2011 Northeast Water Science Forum
Portland, ME
April 28, 2011

John Wathen, C.G.
Disclaimers

1. This presentation is based on the views and opinions of the author and does not necessarily reflect EPA policy.

2. Speaker is a physical and water quality scientist, not a biologist or toxicologist.
Presentation Outline

- Background
- EPA Office of Water Strategy
- Challenges
Contaminants of Emerging Concern in Water*

*Not an exhaustive list.
Context of PPCPs

Among Contaminants of Potential Concern

Bisphenol A? Phthalates?

PBDE? PFOA/PFOS?

EDCs

PBTs

Pesticides

Methoxychlor? Atrazine?

PPCPs

Galaxolide? SSRIs?

Triclosan?
In 2009, global pharmaceutical sales exceeded $773 billion; a 4.8% growth over previous year.

Consumption has increased significantly in the last 20 years.

In 2010, global pharmaceutical markets were expected to grow 4 – 6%, exceeding $825 billion.

Origins and Fate of PPCPs in the Environment

Pharmaceuticals and Personal Care Products

Legend

1. Usage by individuals (1a) and pets (1b): Metabolic excretion (unmetabolized parent drug, parent-drug conjugates, and bioactive metabolites); sweat and vomitus. Excretion exacerbated by disease and slow-dissolving medications
   - Disposal of unused/outdated medication to sewage systems
   - Underground leakage from sewage system infrastructure
   - Disposal of euthanized/medicated animal carcasses serving as food for scavengers (1c)

2. Release of treated/untreated hospital wastes to domestic sewage systems (weighted toward acutely toxic drugs and diagnostic agents, as opposed to long-term medications); also disposal by pharmacies, physicians, humanitarian drug surplus

3. Release to private septic/leach fields
   - Treated effluent from domestic sewage treatment plants discharged to surface waters or re-injected into aquifers (recharge)
   - Overflow of untreated sewage from storm events and system failures directly to surface waters

4. Transfer of sewage solids ("biosolids") to land (e.g., soil amendment/fortification)
   - "Straight-piping" from homes (untreated sewage discharged directly to surface waters)
   - Release from agriculture: spray drift from tree crops (e.g., antibiotics)
   - Dung from medicated domestic animals (e.g., feed) - CAFOs (confined animal feeding operations)

5. Direct release to open waters via washing/bathing/swimming

6. Discharge of regulated/controlled industrial manufacturing waste streams
   - Disposal/release from clandestine drug labs and illicit drug usage

7. Disposal to landfills via domestic refuse, medical wastes, and other hazardous wastes
   - Leaching from defective (poorly engineered) landfills and cemeteries

8. Release to open waters from aquaculture (medicated feed and resulting excreta)
   - Future potential for release from molecular pharming (production of therapeutics in crops)

9. Release of drugs that serve double duty as pest control agents:
   - Examples: 4-aminopyridine, experimental multiple sclerosis drug used as avicide; warfarin, anticoagulant → rat poison; azacholesterol, antilipidemics → avian/rodent reproductive inhibitors; certain antibiotics → used for orchard pathogens; acetaminophen, analgesic → brown tree snake control; caffeine, stimulant → coqui frog control

10. Ultimate environmental transport/fate:
    - Most PPCPs eventually transported from terrestrial domain to aquatic domain
    - Phototransformation (both direct and indirect reactions via UV light)
    - Physicochemical alteration, degradation, and ultimate mineralization
    - Volatilization (mainly certain anesthetics, fragrances)
    - Some uptake by plants
    - Respirable particulates containing sorbed drugs (e.g., medicated-feed dusts)

Christian G. Daughton, U.S. EPA-Las Vegas

PPCPs in Water Supplies

- Residuals have been found in:
  - Surface water
  - Sewage effluent
  - Sewage sludge
  - Groundwater
  - Drinking water
- Types of PPCPs:
  - Beta blockers
  - Analgesics
  - Anticonvulsants/antidepressants
  - Antibiotics
  - Antimicrobials
Also been measured in...

- Soil irrigated with reclaimed water

- Plants from soil applied with biosolids and irrigated with contaminated water
Increased public & Congressional interest…

AP: Drugs found in drinking water

Hormonal chemicals may be imperiling fish

Pervasive in area’s water | Even at the low levels detected, scientists worry about the possible effect on fish growth and reproduction.

By Warren Cornwall and Keith Ogden
Seattle Times staff reporters

As they swim deep beneath Seattle’s Elliott Bay, male English sole carry something in their bodies that’s not supposed to be there: a protein that could be a hormone-mimicking chemical—flushed into the water from sewage-treatment plants, factories, sewers and runoff from rain that had made its way to the bay before going through area

Pain pills a rising cause of death

Prescription drug overdoses are up 56% since 1997

Drugs in water causing troubling problems to fish, wildlife

OxyContin abuse in region soars

Outpacing meth | The illicit use of the painkiller, especially among teens, has driven up its street price, which has made pharmacies robbery targets.

the region say that methamphetamine’s popularity is quickly being outpaced by the powerful prescription painkiller simply known as “Oxy,” among teens, Oxy commands a street value of $80 per pill.

According to the Drug Enforcement Administration (DEA), prescription-drug
Office of Water’s Strategy

EPA/OW is pursuing a four-pronged strategy:

- Strengthening Science
- Improving Public Understanding
- Identifying Partnerships and Promoting Stewardship Opportunities
- Taking Regulatory Action When Appropriate
Completed Activities

- Office of Water website for PPCPs in Water
- Analytical methods
- Exploratory occurrence studies
  - Targeted National Sewage Sludge Survey
  - Nine POTW Study
  - Fish Tissue Pilot Study
- National Academy of Science workshop
- SAB review of draft Methodology for Aquatic Life Criteria for Contaminants of Emerging Concern
- Federal disposal guidelines
- Treatment Technology Compendium
- Third Contaminant Candidate List (CCL3)
Fish Tissue Pilot Study

**Principle Goals**
- To investigate the occurrence of PPCP chemicals in fish tissue from effluent-dominated streams at five locations in various parts of the U.S.

**Study Design**
- Collected fish samples from 5 effluent dominated streams from various locations across the country
- Collected 18 to 24 fish in the vicinity of wastewater treatment plant discharges
- Validated analytical methods available for 24 pharmaceuticals and 12 personal care products
Ongoing Activities

- **Occurrence**
  - National Rivers & Streams Assessment
  - National Coastal Condition Assessment (Great Lakes)

- **Techniques for risk assessment**
  - Methodology for Aquatic Life Criteria for Endocrine Disruption
  - Human Health Risk Assessment Screening

- **Guidance**
Now the question is...

- SO WHAT does this mean?
  - Detection ≠ or = Risk?

  - Some scientific evidence that aquatic life may be impacted

  - No scientific evidence to date that human health has been impacted
Are New Risk Assessment Methods or Approaches Required?

NAS Public Workshop – December 2008

“Characterizing the Potential Human Toxicity of Low Doses of Pharmaceuticals in Drinking Water”

• Panel members provided ideas and opinions for EPA to consider when evaluating potential human health risks from low doses of pharmaceuticals in drinking water
Techniques for Risk Assessment

Key Observations from NAS Workshop

- Levels vary from ppt-ppb based on detection limits
- Potency, presence, and persistence identified as key criteria for prioritization
- EPA’s risk assessment paradigm adequate w/ “tweaking”
  - Chemical Safety Adjustment Factors for kinetic/dynamic differences
  - Departure from chemical by chemical assessment of risk
  - Identify therapeutic classes of drugs posing greatest risk
  - Explore efficient and effective screening tools
- Lack of data on sensitive, non-targeted populations
- Risk communication essential to build public trust
Red Herrings

- Comparing detected concentrations of pharmaceuticals to therapeutic doses or blood levels may not address the relevant effect(s)
- Expressing concentrations of pharmaceuticals as numbers of molecules (conc. X Avogadro’s number) is contrary to current toxicological thinking
- Answer? More research needed
NAS Workshop Follow-up Activities

- Prioritization and screening
  - Working to identify therapeutic classes of drugs posing greatest risk

- Cumulative Risk
  - Investigating approaches to allow departure from chemical-by-chemical assessment of risk

- FDA/EPA Workgroup formed in October 2009
  - Working to develop an approach for assessing groups of pharmaceuticals
Building Partnerships

- Active participant in World Health Organization (WHO) Task Force on PPCPs in Drinking Water

- Participated in Interagency Workgroup on Pharmaceuticals in the Environment (PiE) to coordinate federal research efforts

- Others
  - Pharmaceutical Researchers and Manufacturers of America (PhRMA)
  - Drug Enforcement Administration (DEA)
  - Food & Drug Administration (FDA)
  - US Geological Survey (USGS)
EPA/USGS Drinking Water Project

Drinking Water Phase II - 2010

- Phase II to examine source and finished water pairs at 20-25 utilities across US
- Sampling began Summer 2010
- Results expected - 2011
Opportunities for Stewardship

- Stewardship efforts supported by EPA:
  - Take-back programs
    - Great Lakes Earth Week (2008)
    - California Statewide “No Drugs Down the Drain” campaign (2008)
    - Grants: University of Maine; Area Resources for Community Health Services Foundation (2009) (reports available online)
Here’s something we can all do….

Federal Guidelines:

- Do not flush prescription drugs down the toilet or drain unless the label or accompanying patient information specifically instructs you to do so. For information on drugs that should be flushed visit the FDA’s website.

- To dispose of prescription drugs not labeled to be flushed, you may be able to take advantage of community drug take-back programs or other programs, such as household hazardous waste collection events, that collect drugs at a central location for proper disposal. Call your city or county government’s household trash and recycling service and ask if a drug take-back program is available in your community.

- If a drug take-back or collection program is not available:
  1. Take your prescription drugs out of their original containers.
  2. Mix drugs with an undesirable substance, such as cat litter or used coffee grounds.
  3. Put this mixture into a disposable container with a lid, such as an empty margarine tub, or into a sealable bag.
  4. Conceal or remove any personal information, including Rx number, on the empty containers by covering it with black permanent marker or duct tape, or by scratching it off.
  5. Place the sealed container with the mixture, and the empty drug containers, in the trash.

Use of Existing Regulatory Tools

- Resource Conservation & Recovery Act
  - Universal Waste Rule
    - Proposal to add pharmaceutical waste

- Clean Water Act
  - Health Care Services Guidance
    - Best Management Practices
  - Aquatic Life Criteria
    - Draft methodology for contaminants of emerging concern

- Safe Drinking Water Act
  - Contaminant Candidate List 3 (CCL3)
    - Addition of 9 hormones; 1 antibiotic
CCL 3 – Process Steps

- **Step 1 – Universe**
  - Chemicals that have demonstrated or potential occurrence data for drinking water; or have demonstrated or potential adverse health effects data.

- **Step 2 – Screening to a PCCL**
  - Chemicals with data that have values for health effects and occurrence data elements that reach a level of concern.

- **Step 3 – Classification & Selecting the CCL**
  - Chemicals: Further analyze and characterize the PCCL by using health effects and occurrence attributes and classification models as tools with expert judgment to select the CCL.
  - Solicit expert input and review of the classification models.
Every 5 years, EPA shall publish a determination to regulate/not regulate not fewer than 5 contaminants based upon the findings for the following criteria.

i. The contaminant may have an adverse effect on the health of persons;

ii. The contaminant is known to occur or there is substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and

iii. In the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.
Regulatory Challenges

- Limited occurrence data
  - Limited availability of analytical methods
- Risk assessment techniques
  - Prioritizing groups of pharmaceuticals
  - Limited publicly available data for human pharmaceuticals
    - Toxicological - NOAEL
    - Chronic, low-dose exposure
    - Mixtures
- Different treatment processes remove certain PPCPs
More Challenges

- Research often identifies the need for additional research.

- Messages regarding potential risks are often difficult to convey.
For more information

Visit our websites:
Pharmaceuticals & Personal Care Products in Water
http://water.epa.gov/scitech/swguidance/ppcp/index.cfm

EPA’s Research on Pharmaceuticals
www.epa.gov/ppcp

Octavia Conerly
202-566-1094
conerly.octavia@epa.gov